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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PETER HARTMANN,
CHING TAT LAI,
and LEON R. MITOULAS

Appeal 2012-007518
Application 11/903,363
Technology Center 3700

Before JEFFREY N. FREDMAN, CHRISTOPHER G. PAULRAJ, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134 involving claims to a method of rapidly determining milk production capacity of a nursing mother. The Examiner rejected the claims as failing to comply with the written description requirement, as non-statutory, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part and enter a New Grounds of Rejection.

¹ Appellants identify the Real Party in Interest as Medela Holding AG (*see* App. Br. 1).

Statement of the Case

Background

“Many mothers who deliver prematurely have a delayed initiation of lactation and are more likely to have a low milk supply. . . . Thus, these mothers most often use a breastpump for both the initiation and maintenance of their milk supply” (Spec. 2). “Current expression regimes can place a great demand on mothers who . . . do not have the ability to basically be ‘on-call’ to breastfeed a baby . . . a method that can optimize milk production and minimize the effort for the mothers would greatly enhance their chance of having successful lactation” (Spec. 5).

The Claims

Claims 1, 10, 20, and 27 are on appeal. Independent claims 1 and 27 are representative and read as follows:

1. A method of rapidly determining milk production capacity of a nursing mother, comprising the steps of:
measuring, via a breastpump, the volume of milk produced in at least three pumping sessions where said breastpump is used to express milk from the mother and where a first pumping session is the first milk expression for a day, a second pumping session next occurs after said first pumping session, and a following pumping session is after said second session, wherein said milk volume in said following pumping session is established as an average yield of milk production per pumping session for the mother; and
administering, via said breastpump, an expression protocol for the mother comprising predicted amounts that the interval of expression can be extended without compromising the volume of milk produced, where said volume of milk produced is determined based on an average yield of milk per pumping session.

27. A method comprising:
administering an expression protocol to a mother comprising predicted amounts that the interval of expression can be extended without compromising the volume of milk produced, where said volume of milk produced is determined based on an average yield of milk per pumping session;
wherein said average yield of milk per pumping session is initially established for the mother as a pumping session that follows both a first pumping session and a second pumping session; and
wherein said first pumping session is the first milk expression for a day, and wherein said second pumping session next occurs after said first pumping session.

The Issues

- A. The Examiner rejected claims 1, 10, and 20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 4–5).
- B. The Examiner rejected claim 27 under 35 U.S.C. § 103(a) as obvious over Daly² (Ans. 6–7).
- C. The Examiner rejected claim 27 under 35 U.S.C. § 101 as directed to non-statutory subject matter (Ans. 5–6).
- A. *35 U.S.C. § 112, First Paragraph, New Matter*

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that the phrases “measuring, via a

² Daly et al., *Frequency and degree of milk removal and the short-term control of human milk synthesis*, 81 EXPERIMENTAL PHYSIOLOGY 861–875 (1996) (hereinafter “Daly”).

breastpump” and “administering, via said breastpump, an expression protocol” represent new matter?

Findings of Fact

1. The Specification teaches “a method of determining a strategic expression regime for mothers who are using breastpumps. The method requires expressing milk from the mother at certain intervals during a day, and then measuring the amount of milk expressed at each interval to determine milk volume” (Spec. 6).

2. The Specification teaches that women “recorded their milk production from each breast at each expression. The records included the starting and finishing times of each expression from each breast and the volume of milk (by weighing the bottle before and after an expression) of each expression from each breast (Spec. 11).

3. The Specification teaches that:

The slope of the regression line predicts that there would be an improvement in both mothers’ milk productions if the interval between breast expressions did not exceed 4 hours. According to the regression equation for the actual milk yield for both breasts in Fig. 19, 23% of 24-hour milk production should be achieved at 4 hour intervals. On this basis, it was predicted that 4 hour intervals would result in an increase of 38% in the 24-hour milk yield per breast, and therefore an increase of 72% in total daily milk production for both breasts.

(Spec. 18.)

Principles of Law

“[I]t is the specification itself that must demonstrate possession [of the invention]. And while the description requirement does not demand any

particular form of disclosure . . . or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010).

Analysis

The Examiner finds that the “amended claims require ‘measuring via a breastpump’ and ‘administering via said breastpump, an expression protocol’, which was not described in the specification as originally filed as being a function of the breast pump” (Ans. 5). The Examiner finds that the “specification only mentions breast pump five times, and in each case only in the context that a breast pump is used to express milk from the breast” (Ans. 5).

Appellants contend that:

As one example, the Field of the Application on page 2 of the Specification states that the invention relates to determining an expression regime for mothers who are using a breastpump. Further, original Claim 11 called for “using a pump to express the milk,” and the Specification discusses recording milk production at each expression, including the starting and finishing times of each expression and the volume of milk, by weighing the bottle before and after an expression: that is, the *bottle of a breast pump*.

(App. Br. 4.)

We find that Appellants have the better position. The Specification clearly recites the use of a breastpump (FF 1) as well as teaching the use of an expression protocol where milk was expressed and the amount produced was measured (FF 2–3). While the Specification may not have expressly used the phrase “administering, via said breastpump, an expression

protocol,” we find that the ordinary artisan would have immediately recognized that only two alternative modes inherently existed to implement the protocol, nursing a child or expressing via a breastpump. “Because the amended material is inherently contained in the original application, it cannot constitute new matter.” *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that the phrases “measuring, via a breastpump” and “administering, via said breastpump, an expression protocol” represent new matter.

B. 35 U.S.C. § 103(a) over Daly

The Examiner finds that “Daly teaches a method comprising administering an expression protocol to a mother comprising predicted amounts that the interval of expression can be extended without compromising the volume of milk produced, where said volume of milk produced is determined based on an average yield of milk per pumping session” (Ans. 6).

The Examiner finds that the ordinary artisan would have found it obvious

[T]o calculate the average production volume per pumping as well as a percentage per pumping in order to determine quantitatively the absolute amount per pumping), and wherein said first pumping session is the first milk expression for a day, and wherein said second pumping session next occurs after said first pumping session

(Ans. 6–7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Daly renders claim 27 obvious?

Findings of Fact

4. Daly teaches that the "relationships between the milk production of the breasts at each expression and the interval since the last expression (Fig. 2) show that milk production is inconsistent with a model ($MP = 4 \cdot 17 t_e$) in which the rate of milk synthesis is constant and all available milk is removed at each expression" (Daly 872).

5. Daly teaches that "when milk is expressed at intervals shorter than the intercept time the breasts produce more than the expected amount of milk, while at intervals longer than the intercept time they produce proportionally less than the expected amount" (Daly 872).

6. Daly teaches that "[t]his suggests that if milk was removed at intervals consistently shorter than the intercept time daily milk production would increase and if the intervals were longer milk production would decrease" (Daly 872).

7. Daly teaches milk production of expressing mothers in Study 1, where:

Subjects A, B, C and D recorded the milk production of each breast at each expression, and the time of each expression, over a period of 4–14 days. Milk production refers to the amount of milk expressed from an individual breast at an expression. We standardized the milk production between breasts and between women by calculating, for each breast at each expression, the amount of milk produced (expressed) as a percentage of the total produced from that breast for that day (MP, %). The time of

day of each expression was noted and the interval (t_e) since the previous expression was calculated. A day was defined as a 24 h period starting at 00.00 h and ending at 24.00 h.

(Daly 862.)

8. Daly teaches that “five mothers (subjects H, I, J, K and L), who had delivered at fullterm and were breastfeeding on demand, were recruited. Generally, they breastfed frequently (on average, ten feeds per 24 h), offering one breast at a breastfeed” (Daly 862).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

Analysis

Daly teaches a method for determining an expression protocol for a mother to determine an “intercept time” which represents the optimal interval of times between milk expressions to maximize milk volumes (FF 4–6). Daly teaches that the amounts of milk produced in an initial pumping session and in second and later pumping sessions were measured, where the first pumping session was set at 00.00 h (FF 7).

We agree with the Examiner that “one of ordinary skill would have found it obvious to calculate the average production volume per pumping as well as a percentage per pumping in order to determine quantitatively the absolute amount per pumping” (Ans. 6–7).

Appellants contend that

Daly is silent on the concept of the use of a single measurement as an average yield. Because Daly does not discuss the concept of taking a particular pumping session to be the average yield of milk per pumping session, and putting that average into a protocol to administer to a mother, one of ordinary skill in the art would not have found it obvious

(App. Br. 7).

We are not persuaded. Claim 27 does not require the use of a single measurement, rather reciting that the “volume of milk produced is determined based on an average yield of milk per pumping session.” Thus, claim 27 is reasonably interpreted as open to measurements of the amounts expressed from each individual breast as taught by Daly (FF 7). Daly then teaches standardizing the amounts using percentages, but we agree with the Examiner that the ordinary artisan would have recognized that averaging the amounts expressed to obtain a total amount represents a known alternative mathematical approach for addressing two data points at a single time point.

Appellants contend that

[I]t appears that impermissible hindsight reconstruction was used in an effort to reject Applicants’ claims. The only reason to achieve the function of using “said average yield of milk per pumping session . . . as a pumping session that follows both a first pumping session and a second pumping session” is Applicants’ claims themselves

(App. Br. 7).

We are not persuaded. While we are fully aware that hindsight bias often plagues determinations of obviousness, *Graham v. John Deere Co.*,

383 U.S. 1, 36 (1966), we are also mindful that the Supreme Court has clearly stated that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. In the instant case, the use of averages to analyze data such as milk production is a known alternative data analysis approach, as noted above. Indeed, Daly evidences that averages are known, teaching that “they breastfed frequently (on average, ten feeds per 24 h)” (Daly 862; FF 8; emphasis added). Because the use of averages is a known technique (FF 8), relied upon to analyze data, we agree with the Examiner that it would have been obvious to modify Daly’s analysis to rely upon average yields of milk rather than percentage yields of milk as known alternative, predictable mathematical techniques for data analysis which yield predictable results.

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Daly renders claim 27 obvious.

C. 35 U.S.C. § 101

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that claim 27 is directed to non-statutory subject matter?

Findings of Fact

9. The Specification teaches that the “concept of the autocrine inhibition of milk production, as a result of the accumulation of an inhibitory factor in the milk of a full breast, seems to conveniently explain the

observation of increased milk production associated with more frequent breastfeeding and/or breast expression” (Spec. 3–4).

10. The Specification teaches that “the underlying rate of milk production from the third to seventh pumping represented the intrinsic synthetic (production) capacity of the breast” (Spec. 11).

Principles of Law

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012), the Supreme Court set forth a “framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014). As reiterated by the Supreme Court in *Alice Corp.*:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the claim” into a patent-eligible application. We have described step two of this analysis as a search for an “inventive concept” --*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”

Id. (citations omitted.)

Analysis

The Examiner finds that “claim 27 is held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101” (Ans. 5). The Examiner explains that the “rationale for this finding is

explained below: Claim 27 recites: mental activities: ‘administering an expression protocol . . .’ (claim 27, lines 2-5), and mathematical concepts: ‘said average yield of milk per pumping session . . .’ (claim 27, lines 6-8)” (Ans. 5–6).

Appellants contend that “Claim 27 is directed to eligible subject matter as the claim does not recite and preempt a natural phenomenon, a mathematical equation, or mental process, but instead recites a *particular application* - administering an expression protocol for a mother” (App. Br. 5). Appellants contend that claim 27 “includes the limitation of administering a protocol to a mother to express milk. In this step, the mother’s body is effected upon (i.e., undergoes a ‘transformation’) as milk is expressed from the mother in accordance with the improved method of the protocol administered. Thus, the claim includes a transformation” (App. Br. 6).

We find that the Examiner has the better position. We apply the analytical framework of the recently revised USPTO utility guidelines, which are consistent with *Mayo* and *Alice*.³

³ The recently revised USPTO utility guidelines state that “[a]fter determining what applicant has invented by reviewing the entire application disclosure and construing the claims in accordance with their broadest reasonable interpretation (MPEP 2103), determine whether the claim as a whole is directed to a judicial exception.” 79 Fed. Reg. 74622 (Dec. 16, 2014). The guidelines further explain that a “claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (*i.e.*, set forth or described) in the claim.” *Id.* The guidelines direct Examiners to “[d]etermine whether any element, or combination of elements, in the claim is sufficient to ensure that

Claim 27 sets forth a “law of nature” or “abstract idea,” namely, the relationship between the volume of milk expressed by a woman in a pumping session and the time interval between pumping sessions, in order to identify optimal time intervals for pumping sessions to maximize intervals and milk production (*see* claim 27). While it takes a human action (measuring and calculating the amount of milk expressed in several pumping sessions) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the way in which mammary tissue produces milk, an entirely natural process. As the Specification itself explains, “the underlying rate of milk production from the third to seventh pumping represented the intrinsic synthetic (production) capacity of the breast” (Spec. 11; FF 10). It is this intrinsic production capacity which is being addressed in claim 27 and therefore, claim 27, which describes that relation, simply sets forth a natural law.

The issue then becomes “do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify

the claim amounts to significantly more than the judicial exception.” *Id.* at 74624. The guidelines explain that “[l]imitations that were found not to be enough to qualify as ‘significantly more’ when recited in a claim with a judicial exception include . . . Simply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, *e.g.*, a claim to an abstract idea requiring no more than a generic computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry.” *Id.*

as patent-eligible processes that *apply* natural laws?” *Mayo*, 132 S. Ct. at 1297. That is, “we must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 134 S. Ct. at 2357.

The single step in claim 27 is “administering an expression protocol,” which step refers to informing a woman of the optimal time intervals that she should use for pumping milk in order to optimize the volume of milk produced. Daly evidences that methods for determining optimal time intervals for pumping of milk were already known in the art (FF 4–7), and the process at issue amounts to nothing more than an instruction to the physician to explain the applicable natural law regarding time intervals for optimal milk expression to nursing mothers. *See Mayo*, 132 S. Ct. at 1298 (“To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons . . . the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”)

The “wherein” clauses in claim 27 simply function to limit the analysis to third and later pumping sessions, which are the precise sessions identified by the Specification as providing “the intrinsic synthetic (production) capacity of the breast” (Spec. 11; FF 10) as versus the fuller or enlarged capacity present in the first or second sessions (FF 9). Therefore,

these wherein clauses reinforce our conclusion that claim 27 applies to calculation of the intrinsic milk production of a breast (FF 10), an unpatentable natural correlation.

Appellants contend that “the mother’s body is indeed effected upon (i.e., undergoes a ‘transformation’) as milk is expressed from the mother in accordance with the improved method of the protocol administered. The expression of milk is optimized, from what the mother may have otherwise been experiencing” (Reply Br. 3).

We are not persuaded. To the extent that Appellants rely upon the “machine-or-transformation test” to support the patentability of the claims, “machine-or-transformation” is not the sole test for deciding whether an invention is a patent-eligible “process.” *Bilski v. Kappos*, 561 U.S. 593, 604 (2010). Moreover, insofar as the rate of synthesis of milk by the mother remains an intrinsic physiological property (FF 10), claim 27 does not require any specific action by the mother, other than receiving an “expression protocol” that provides optimal time intervals for pumping or nursing naturally produced milk.

Our analysis is consistent with Federal Circuit decisions decided after *Mayo*, including *SmartGene* and *PerkinElmer*. In *SmartGene*, the Court held that a computerized method for guiding a patient to identify a therapeutic regimen using a computer database and ranking was ineligible under 101 because “eligibility under section 101 requires that the claim involve ‘enough’ else—applying the idea in the realm of tangible physical objects (for product claims) or physical actions (for process claims)—that is

beyond ‘well-understood, routine, conventional activity.’” *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App’x. 950, 955 (Fed. Cir. 2014).

The claims in *PerkinElmer* were drawn to methods of determining whether a pregnant woman is at increased risk of having a fetus with Down’s syndrome which include steps of measuring ultrasound screening markers and using the frequency of those markers to provide a risk estimate. *PerkinElmer, Inc. v. Intema, Ltd.*, 496 F. App’x. 65, 67 (Fed. Cir. 2012).

The Court held that the “measuring” and “determining” steps were insufficient to make the claims patent-eligible, finding that the

[S]tatistical information mentioned in [the determining] step is insufficient to make the claim patent-eligible because it is well-understood, conventional information. . . . And the unspecified and unclaimed statistical calculation for determining the risk is also known and conventional. . . . (“Any of the known statistical techniques may be used. Preferably the multivariate Gaussian model is used, which is appropriate where the observed distributions are reasonably Gaussian. Such multivariate Gaussian analysis is in itself known. . . .”).

Id. at 71.

Just as the “ranking” in *SmartGene* and the “determining” step in *PerkinElmer* were known calculations, the “average yield of milk per pumping session” in claim 27 also relies upon known a correlation, which has been found insufficient by the Federal Circuit to convert an otherwise patent-ineligible claim into a patent eligible claim.

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that claim 27 is directed to non-statutory subject matter.

New Ground of Rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection.

Claims 1–10, 12, and 20–24 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Consistent with *Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1383–4 (Fed. Cir. 2014), we apply the reasoning detailed above affirming the Examiner’s rejection of claim 27 under 35 U.S.C. § 101 to further reject claims 1–10, 12, and 20–24.

Claim 1 differs from claim 27 in reciting the use of a breastpump in the “measuring” and “administering” stages. The Examiner withdrew the 35 U.S.C. § 101 rejection over the remaining claims based upon an amendment filed March 24, 2011 which added “via a breastpump” to each of the independent claims other than the newly added claim 27. The Examiner explained the distinction between these claims and claim 27 by finding that “claim 27 only recites mental process steps that do not that are not [sic] connected to a machine and do not transform an article or material” (Final Rej. 5, filed June 8, 2011).

As a threshold matter, the machine-or-transformation test does not trump the section 101 exclusions created by case law. *Mayo*, 132 S.Ct. at 1303 (“[W]e have neither said nor implied that the [machine-or-transformation] test trumps the ‘law of nature’ exclusion.”). Thus, even if the test were satisfied, these claims would remain unpatentable.

PerkinElmer, 496 F. App’x. at 72.

In this case, the inclusion of a breastpump into independent claims 1, 10, and 20 does not make patent eligible a “law of nature” or “abstract idea,”

namely, the intrinsic relationship between the volume of milk produced by a woman in a time period and expressed in a pumping session and the optimal time interval between pumping sessions. The use of a breastpump does not impart a meaningful limitation to the claimed invention, as it is merely a well-known prior art device used to express milk (the alternative being nursing by the baby). In this regard, the steps of “measuring” and “administering,” via a breastpump, recited in claim 1 are not unlike the “determining” step in the claims at issue in *Mayo*. There, the Court held that “the ‘determining’ step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use,” and “[t]hus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.” *Mayo*, 132 S. Ct. at 1298. The Court emphasized that “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.” *Id.*

Our determination is also supported by other recent Federal Circuit decisions. In *PerkinElmer*, the ineligible method required measurement of ultrasound images obtained using ultrasound imaging machines, similar to the instant claims requirement for measurement of milk volumes obtained using breastpumps, and the Court held that the “‘measuring’ steps are insufficient to make the claims patent-eligible.” *PerkinElmer*, 496 F. App’x. at 71.

This conclusion is consistent with the *In re BRCA1*, where the Federal Circuit held that “[n]othing is added by identifying the techniques to be used

in making the comparison because those comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences.” *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755, 764 (Fed. Cir. 2014).

The “measuring” step at most transforms data derived from the expressed volume of milk regarding the intrinsic milk production rate (FF 9) into data regarding the optimal time intervals for pumping milk to maximize milk production. As discussed above, the “administering an expression protocol” step refers to informing a woman of the optimal time intervals that she should use for pumping milk in order to optimize the volume of milk produced. Daly evidences that methods for determining optimal time intervals for pumping of milk were already known in the art (FF 4–7), and the process at issue amounts to nothing more than an instruction to the physician to explain the applicable natural law regarding time intervals for optimal milk expression to nursing mothers.

Therefore, looking to the claims as a whole, the steps in combination do not make the ineligible mental step and natural law patent-eligible.

SUMMARY

In summary, we reverse the rejection of claims 1, 10, and 20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

We affirm the rejection of claim 27 under 35 U.S.C. § 103(a) as obvious over Daly.

We affirm the rejection of claim 27 under 35 U.S.C. § 101 as directed to non-statutory subject matter.

A new ground of rejection of claims 1–10, 12, and 20–24 under 35 U.S.C. § 101 is set forth.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellant, **WITHIN TWO MONTHS FROM THE DATE OF THE DECISION**, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

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

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