Appendix 1 to the October 2019 Update: Subject Matter Eligibility
Life Sciences & Data Processing Examples

The following examples should be used in conjunction with the 2019 Revised Patent Subject Matter Eligibility Guidance ("2019 PEG") and the October 2019 Update: Subject Matter Eligibility ("October 2019 Update"). The examples below are hypothetical and only intended to be illustrative of the claim analysis under the 2019 PEG, and of the particular issues noted below in the Issue Spotting Chart. These examples should be interpreted based on the fact patterns set forth below as other fact patterns may have different eligibility outcomes. That is, it is not necessary for a claim under examination to mirror an example claim to be subject matter eligible under the 2019 PEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

Note that the examples herein are numbered consecutively beginning with number 43 because 42 examples were previously issued. Appendix 2 to the October 2019 Update contains a comprehensive index of all 46 of the USPTO's eligibility examples.

Issue Spotting Chart	Treating Kidney Disease	Denveric Acid	Controller For Injection Mold	Livestock Management
Example Number	43	44	45	46
Claim Type				
Process	•			•
Product (Composition of Matter, Manufacture, and/or Machine)		•	•	•
Judicial Exception				
Abstract Idea: Mathematical Concept	•		•	
Abstract Idea: Mental Process	•		•	•
Abstract Idea: Certain Methods of Organizing Human Activity				
Law of Nature	•		•	
Product of Nature		•		
Multiple exceptions in same claim			•	•
No recited exception	•	•		•
Detailed Analysis				
Step 2A Prong One: Generally	•	•	•	•
Step 2A Prong One: Markedly Different Characteristics analysis	•	•		
Step 2A Prong Two: Exception Integrated Into A Practical Application	•	•	•	•
Step 2B: Generally	•	•	•	•
Step 2B: Claim is eligible because it provides an Inventive Concept			•	
Considerations Discussed in Step 2A Prong Two and/or Step 2B				
Improvements to Functioning of a Computer or Other Technology			•	
Particular Treatment or Prophylaxis (Prong Two only)	•			•
Particular Machine		•		
Particular Transformation				
Other Meaningful Limitations		•	•	•
Mere Instructions To Apply An Exception	•	•	•	•
Insignificant Extra-Solution Activity			•	•
Field of Use and Technological Environment			•	•
Well-Understood, Routine, Conventional (WURC) Activity (Step 2B only)			•	
Claim Interpretation Issues				
Contingent limitations				•
Functional language	•	•	•	
Wherein clauses	•	•	•	•

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43. Treating Kidney Disease

This example illustrates the application of Revised Step 2A to treatment claims. The recited disease (Nephritic Autoimmune Syndrome Type 3) and biomarkers (C11 and C13) are hypothetical, but the recited treatments (glucocorticoids, non-steroidal agents, rapamycin, and plasmapheresis) are known treatments in the medical field. Claim 1 is ineligible because it recites a judicial exception (an abstract idea), and the claim as a whole does not integrate the exception into a practical application or provide an inventive concept. Claims 2-4 recite the same judicial exception as claim 1, but are eligible because the claim, including the recited treatment or prophylaxis steps, integrates the exception into a practical application. Claim 5 is eligible because it does not recite a judicial exception. This example also illustrates how process claims reciting nature-based product limitations are analyzed.

Issue spotting

- ✓ Process claims
- ✓ Abstract idea exceptions: mathematical concepts and mental processes
- ✓ Law of nature exception
- ✓ Markedly Different Characteristics analysis, including when to apply it
- ✓ "Integration into a practical application," particularly the "treatment or prophylaxis" consideration
- ✓ Claim interpretation: functional claim language, and wherein clauses

Relevant case law

- *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012)
- *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA Inc.*, 919 F.3d 1347 (Fed. Cir. 2019)
- *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)
- *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016)

BACKGROUND

Nephritic Autoimmune Syndrome Type 3 (NAS-3) is an autoimmune disease that primarily affects the glomeruli, which are tufts of blood vessels in the kidneys that filter waste materials out of the bloodstream. It is known that NAS-3 is associated with the undesired formation of a protein complex (the membrane attack complex) in the person's own glomeruli, thereby causing cell lysis and inflammation, and eventually chronic kidney disease or even kidney failure. More than two-thirds of people suffering from NAS-3 develop kidney failure within five years after their diagnosis.

Treatment of NAS-3 is complicated because the disease progresses rapidly, and some patients do not respond well to glucocorticoids (a class of steroids), which are the conventional first-line treatment. Many patients who are non-responsive to glucocorticoids often respond well to conventional second-line treatments, which include therapy with non-steroidal agents such as rapamycin. Rapamycin is a naturally occurring chemical isolated from bacteria, which has been in use as a therapeutic agent in humans since the early 1970s. Another conventional second-line treatment for some patients is a course of plasmapheresis, which is a filtration process that removes excess autoantibodies from the patient's blood. Because these second-line treatments may have significant side effects such as bone marrow suppression and an increased risk of life-threatening infections, it is desirable to use them only when absolutely necessary, that is, when the patient is not responding to glucocorticoids. Unfortunately, by the time it usually becomes apparent that patients are not responding to glucocorticoids, the disease has often progressed to the point of causing irreversible kidney damage.

Applicant has now discovered and disclosed that the ratio between the levels of two proteins known as C11 and C13 in the blood of a patient with NAS-3 is indicative of patient response to glucocorticoids. In particular, applicant discloses that a high ratio (≥ 3:1) of C11 to C13 is indicative that the patient has a "non-responder phenotype," which the specification defines as meaning that the patient will not respond, or is not responding, to glucocorticoids. Applicant discloses that calculation of this ratio in

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patients diagnosed with NAS-3, and subsequently adjusting treatment in accordance with the calculation, contributes to optimal treatment and better clinical outcomes for patients with NAS-3.

CLAIMS

1. A treatment method comprising:
   (a) calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype;
   (b) administering a treatment to the patient having a non-responder phenotype.

2. The method of claim 1, wherein the treatment is a non-steroidal agent capable of treating NAS-3.

3. The method of claim 1, wherein the treatment is rapamycin.

4. The method of claim 1, wherein the treatment is a course of plasmapheresis.

5. A treatment method comprising administering rapamycin to a patient identified as having Nephritic Autoimmune Syndrome Type 3 (NAS-3).

ANALYSIS

Claim 1 is *ineligible*.

Claim interpretation: Under the broadest reasonable interpretation (BRI), the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Based on the specification's definition of "non-responder phenotype" as meaning that the patient will not respond, or is not responding to glucocorticoids, and the plain meaning of the other terms, the broadest reasonable interpretation of claim 1 is a method of calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with NAS-3 in order to identify the patient as having the non-responder phenotype (*i.e.*, the patient has a calculated ratio of 3:1 or greater and thus is not responding, or will not respond, to glucocorticoids), and administering a treatment to the patient having the non-responder phenotype. No particular treatment is required, *i.e.*, the treatment can be glucocorticoids, other steroids, other therapeutic agents, kidney transplants, plasmapheresis, dialysis, palliative care, etc.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites at least one step or act, including calculating a ratio. Thus, the claim is to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. Limitation (a) in the claim recites several nature-based product limitations including C11, C13, and the blood sample, which raises the question of whether the markedly different characteristics analysis should be used to determine if the nature-based product limitations are product of nature exceptions. For a process claim, the general rule is that the claim is not subject to the markedly different analysis for nature-based products used in the process. MPEP 2106.04(c)(I)(C). While there is an exception to this general rule for process claims that are drafted in such a way that they are no different in substance than a product claim, claim 1 does not invoke this exception because review of this claim indicates that it is focused on a process of determining how much C11 and C13 is present in the blood sample and then treating a patient in accordance with that determination, and is not focused on the products per se. Thus, the general rule expressed in the MPEP applies, meaning that the markedly different characteristics analysis is not

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performed on the recited nature-based product limitations, and the claim is not considered to "recite" any products of nature for purposes of further eligibility analysis. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

Limitation (a) in the claim recites "calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype," which has a BRI that requires performing an arithmetic calculation (division) in order to obtain the ratio of C11 to C13 levels, and then using this ratio to identify whether the patient has the non-responder phenotype (*i.e.*, the patient has a calculated ratio of 3:1 or greater and thus is not responding, or will not respond, to glucocorticoids). This limitation therefore recites a mathematical calculation. The grouping of "mathematical concepts" in the 2019 PEG includes "mathematical calculations" as an exemplar of an abstract idea. 2019 PEG Section I, 84 Fed. Reg. at 52. Thus, limitation (a) falls into the "mathematical concept" grouping of abstract ideas. In addition, this type of simple arithmetic calculation (division) can be practically performed in the human mind, and is in fact performed in the human mind on a daily basis, for instance by school-aged children studying mathematics. Note that even if most humans would use a physical aid (*e.g*., pen and paper, a slide rule, or a calculator) to help them complete the recited calculation, the use of such physical aid does not negate the mental nature of this limitation. Thus, limitation (a) also falls into the "mental process" groupings of abstract ideas. In addition, limitation (a) describes a naturally occurring relationship between the ratio of C11 to C13 and the non-responder phenotype, and thus may also be considered to recite a law of nature. Accordingly, limitation (a) recites a judicial exception (an abstract idea that falls within the mathematical concept and mental process groupings in the 2019 PEG, and a law of nature), and the analysis must therefore proceed to Step 2A Prong Two.

Although limitation (a) falls under several exceptions (*e.g*., a mathematical concept-type abstract idea, a mental process-type abstract idea, and a law of nature), there are no bright lines between the types of exceptions. *See, e.g*., MPEP 2106.04(I). Thus, it is sufficient for the examiner to identify that limitation (a) aligns with at least one judicial exception, and to conduct further analysis based on that identification. *See* October 2019 Update at Section I.B n.7. For purposes of further discussion, this example identifies the recited exception as an abstract idea.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Besides the abstract idea, the claim recites the additional element of "administering a treatment to the patient having a non-responder phenotype" in limitation (b). Although this limitation indicates that a treatment is to be administered, it does not provide any information as to how the patient is to be treated, or what the treatment is, but instead covers any possible treatment that a doctor decides to administer to the patient. In fact, this limitation is recited at such a high level of generality that it does not even require a doctor to take the calculation step's outcome (the patient's phenotype) into account when deciding which treatment to administer, making the limitation's inclusion in this claim at best nominal. Like the claims in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78 (2012), claim 1 here tells the relevant audience (doctors) about the mathematical concepts and at most adds a suggestion that the doctors take those laws into account when treating their patients. Limitation (b) thus fails to meaningfully limit the claim because it does not require any particular application of the recited calculation, and is at best the equivalent of merely adding the words "apply it" to the judicial exception. Accordingly, limitation (b) does not integrate the recited judicial exception into a practical application and the claim is therefore directed to the judicial exception (*Step 2A: YES*).

Step 2B: This part of the eligibility analysis evaluates whether the claim as a whole amounts to significantly more than the recited exception, *i.e.*, whether any additional element, or combination of additional elements, adds an inventive concept to the claim. MPEP 2106.05. As explained with respect to Step 2A Prong Two, the claim recites a single additional element in limitation (b), which does not require any particular application of the recited calculation and is at best the equivalent of merely adding the words "apply it" to the judicial exception. Mere instructions to apply an exception cannot provide an inventive concept (*Step 2B: NO*). The claim is not eligible.

Practice note: A rejection of claim 1 should identify the exception by pointing to limitation (a) in the claim and explaining why it recites an abstract idea and/or a law of nature. The rejection should also explain that the claim as a whole, including the highly generic "treatment" step, does not integrate the exception into a practical application or amount to significantly more than the exception because it is at best the equivalent of merely adding the words "apply it" to the claim. The examiner could also include a citation to MPEP 2106.05(f), which provides a detailed explanation and examples of how courts have evaluated the "mere instructions to apply an exception" consideration.

While the analysis here identifies the recited exception as an abstract idea, it also explains that there are no bright lines between the types of exceptions, and that limitation (a) may also be identified as a law of nature. In the latter case, other than the explanation of why the limitation is a judicial exception, the analysis (and rejection) will be the same as previously described.

Claim 2 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 2 depends from claim 1, and adds a wherein clause specifying that the administered treatment is a non-steroidal agent capable of treating NAS-3. It is important to remember during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight because the claim requires that the treatment be an agent (*e.g.*, a medicament) that is not a steroid and that has the function of being capable of treating NAS-3. No particular agent is required, so long as the agent is not a glucocorticoid or other steroid, and that it has the claimed function of treating NAS-3.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites at least one step or act, including calculating a ratio. Thus, the claim is to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 2 depends from claim 1, and thus recites the same limitation (a). For the reasons discussed above for claim 1, this limitation recites an abstract idea, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG at Section III(A)(2).

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Besides the abstract idea, the claim recites the additional element of "administering a treatment to the patient having a non-responder phenotype," wherein "the treatment is a non-steroidal therapeutic agent capable of treating NAS-3." Although the background of this example explains that non-steroidal therapeutic agents are a conventional second-line treatment for NAS-3, the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55). Thus, the following evaluation does not take into account whether or not the therapeutic agent is well-known. *See* October 2019 Update at Section III.D.

When this particular element is evaluated in the context of the claim as a whole, and under the broadest reasonable interpretation of this claim, it is evident that this limitation encompasses the administration of a "particular treatment or prophylaxis" under the 2019 PEG, *i.e.*, the administration of a therapeutic agent that is capable of treating NAS-3 and that is not a steroid. For instance, this limitation has more than a nominal relationship to the judicial exception because it uses the recited abstract idea in a manner that imposes a meaningful limit on it, *i.e.*, the abstract idea is used to identify the patient as being non-responsive to glucocorticoids, and the patient is then administered a treatment that is particular to that identified phenotype (*i.e.*, a drug that is not a glucocorticoid or other steroid). *See* October 2019 Update at Section III.C, discussing how to evaluate the "particular treatment or prophylaxis" consideration in more detail. In this regard, the claim here is like those in *Endo Pharms. Inc. v. Teva Pharms. USA Inc.*, 919 F.3d 1347 (Fed. Cir. 2019) and *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), both of which also used a judicial exception to identify patients in need of a particular treatment, and then administered the treatment to the identified patients. For instance, the *Endo* claims relied on a law of nature (the relationship between oxymorphone and patients with renal impairment) to identify a patient as requiring a particular treatment (a lower dosage of oxymorphone), and then administered that particular treatment to the patient. Just like the treatment step in *Endo*, the treatment limitation here integrates the recited judicial exception into a practical application, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: Although claim 2 is eligible, it may be unpatentable for other reasons, and thus it is important to practice compact prosecution by examining each claim for compliance with every statutory requirement for patentability in the initial review of the application. For instance, the examiner should evaluate whether the functionally-claimed genus of non-steroidal agents capable of treating NAS-3 is adequately supported by the written description. See MPEP 2163(II)(A)(3)(a).

Claim 3 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 3 depends from claim 1, and adds a wherein clause specifying that the administered treatment is rapamycin. It is important to remember during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight because the claim requires that the treatment be rapamycin. The claim does not require any particular dosage, mode of administration, or frequency of administration.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites at least one step or act, including calculating a ratio. Thus, the claim is to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 3 depends from claim 1, and thus recites the same limitation (a). For the reasons

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discussed above for claim 1, this limitation recites an abstract idea, and the analysis must therefore proceed to Step 2A Prong Two. Note that while claim 3 recites an additional nature-based product limitation (the rapamycin in the administration step), analysis of the claim as a whole indicates that the claim remains focused on a process of determining how much C11 and C13 is present in the blood sample and then treating a patient in accordance with that determination, and is not focused on the products per se. Thus, the general rule in MPEP 2106.04(c)(I)(C) still applies, such that the claim is not considered to "recite" any products of nature for purposes of further eligibility analysis.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55.

Besides the abstract idea, the claim recites the additional element of "administering a treatment to the patient having a non-responder phenotype," wherein "the treatment is rapamycin." Although the background of this example explains that rapamycin is a conventional second-line treatment for NAS-3, the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55). Thus, the following evaluation does not take into account whether or not the rapamycin is well-known. *See* October 2019 Update at Section III.D.

When this particular element is evaluated in the context of the claim as a whole, and under the broadest reasonable interpretation of this claim, it is evident that this limitation encompasses the administration of a "particular treatment or prophylaxis" under the 2019 PEG, *i.e.*, the administration of rapamycin. For instance, this limitation has more than a nominal relationship to the judicial exception because it uses the recited abstract idea in a manner that imposes a meaningful limit on it, *i.e.*, the abstract idea is used to identify the patient as being non-responsive to glucocorticoids, and the patient is then administered a treatment that is particular to that identified phenotype (rapamycin is not a glucocorticoid). *See* October 2019 Update at Section III.C, discussing how to evaluate the "particular treatment or prophylaxis" consideration in more detail. As discussed above for claim 2, the claim here is like those in *Endo*, 919 F.3d 1347, and *Vanda*, 887 F.3d 1117, both of which also used a judicial exception to identify patients in need of particular treatment, and then administered the particular treatment to the identified patients. Like the treatment step in *Endo*, the treatment limitation here integrates the recited judicial exception into a practical application, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: The same claim interpretation must be used when evaluating the claim for compliance with all requirements for patentability (*e.g.*, eligibility, definiteness, novelty, non-obviousness, written description, etc.). Although limitation (a) recites an abstract idea, it still imposes a limit on the claim scope and serves as a patentable distinction that cannot be ignored. Thus, for example, a reference disclosing administration of rapamycin to a patient identified as having NAS-3 would not anticipate claim 3 unless the reference also discloses calculation of the ratio of C11 to C13 levels in a blood sample from the patient.

Claim 4 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 4 depends from claim 1, and adds a wherein clause specifying that the administered treatment is a course of plasmapheresis. It is important to remember

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during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight because the claim requires that the treatment be a particular type of procedure, *i.e.*, plasmapheresis. The claim does not require any specifics about the procedure, for instance, how many plasma exchanges are performed, how often they are performed, or how much of the patient's blood volume is processed during each exchange.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites at least one step or act, including calculating a ratio. Thus, the claim is to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 4 depends from claim 1, and thus recites the same limitation (a). For the reasons discussed above for claim 1, this limitation recites an abstract idea, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55.

Besides the abstract idea, the claim recites the additional element of "administering a treatment to the patient having a non-responder phenotype," wherein "the treatment is plasmapheresis." Although the background of this example explains that plasmapheresis is a conventional second-line treatment for NAS-3, the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55). Thus, the following evaluation does not take into account whether or not the plasmapheresis is well-known. *See* October 2019 Update at Section III.D.

Practice note: As illustrated by the analysis of this claim and described in the 2019 PEG, the "treatment" consideration encompasses the integration of any type of judicial exception into a practical application, including, *e.g.*, the abstract idea recited in claim 4. This consideration also encompasses both treatment and prophylaxis limitations, including, *e.g.*, the plasmapheresis limitation recited in claim 4. Examples of "treatment" and "prophylaxis" limitations include (but are not limited to) administration of medication, dialysis, organ transplants, phototherapy, physiotherapy, radiation therapy, surgery, and the like.

When this particular element is evaluated in the context of the claim as a whole, and under the broadest reasonable interpretation of this claim, it is evident that this limitation encompasses the administration of a "particular treatment or prophylaxis" under the 2019 PEG, *i.e.*, the administration of plasmapheresis (a therapeutic procedure). For instance, this limitation has more than a nominal relationship to the judicial exception because it uses the recited abstract idea in a manner that imposes a meaningful limit on it, *i.e.*, the abstract idea is used to identify the patient as being non-responsive to glucocorticoids, and the patient is then administered a treatment that is particular to that identified phenotype (plasmapheresis does not involve administering glucocorticoids). *See* October 2019 Update at Section III.C, discussing how to evaluate the "particular treatment or prophylaxis" consideration in more detail. As discussed above for claim 2, the claim here is like those in *Endo*, 919 F.3d 1347, and *Vanda*, 887 F.3d 1117, both of which also used a judicial exception to identify patients in need of particular treatment, and then administered the particular treatment to the identified patients. Like the treatment step in *Endo*, the treatment limitation here

integrates the recited judicial exception into a practical application, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Claim 5 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Based on the plain meaning of the words in the claim, the broadest reasonable interpretation of claim 5 is a method of administering rapamycin to a patient having NAS-3. The claim does not require any particular dosage, mode of administration, or frequency of administration.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites at least one step or act, including administering rapamycin to a patient. Thus, the claim is to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. The administering step in the claim recites rapamycin, which is a nature-based product limitation, and thus raises the question of whether the markedly different characteristics analysis should be used to determine if the nature-based product limitation is a product of nature exception. For a process claim, the general rule is that the claim is not subject to the markedly different analysis for nature-based products used in the process. MPEP 2106.04(c)(I)(C). While there is an exception to this general rule for process claims that are drafted in such a way that they are no different in substance than a product claim, claim 5 does not invoke this exception because review of this claim indicates that it is focused on a process of administering rapamycin to a patient identified as having NAS-3, and is not focused on the products per se. Thus, the general rule expressed in the MPEP applies, meaning that the markedly different characteristics analysis is not performed on the recited nature-based product limitations, and the claim is not considered to "recite" any products of nature for purposes of further eligibility analysis. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

The recited step of administering rapamycin to a patient having NAS-3 does not set forth or describe any recognized exception. As explained by the courts, a method of treating cancer with chemotherapy is not directed to the cancer cells' inability to survive chemotherapy, and a method of treating headaches with aspirin is not directed to the human body's natural response to aspirin. *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1049 (Fed. Cir. 2016), cited in MPEP 2106.04(b)(I); *see also Mayo*, 566 U.S. at 78 (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Thus, the administration step here is not a judicial exception. Because the claim does not recite a judicial exception, it cannot be directed to one (*Step 2A: NO*). The claim is eligible.

Practice note: Although claim 5 is eligible, it may be unpatentable for other reasons, and thus it is important to practice compact prosecution by examining each claim for compliance with every statutory requirement for patentability in the initial review of the application. For instance, the examiner should evaluate whether claim 5 is patentable over prior art. As explained in the background, administering rapamycin to a patient identified as having NAS-3 is a conventional treatment for NAS-3, and thus the claim is anticipated by a reference disclosing such administration. In addition, if applicant has stated, either in the specification or during prosecution, that administering rapamycin to a patient identified as having NAS-3 is a conventional treatment for NAS-3, the examiner may consider this statement to be applicant-admitted prior art, which may be relied upon for both an anticipation and obviousness determination. See MPEP 2129(I).

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44. Denveric Acid

This example illustrates the application of Revised Step 2A to product claims reciting nature-based product limitations. The Rocky Mountain cassia tree and denveric acid are hypothetical products, but protamine is a known product used in the medical field. Claim 1 is ineligible because the claimed nature-based product lacks markedly different characteristics from what exists in nature, and the claim as a whole does not integrate the exception into a practical application or provide an inventive concept. Claim 2 recites the same judicial exception as claim 1, but is eligible because the claim as a whole integrates the exception into a practical application. Claims 3 and 4 are eligible because the claimed nature-based products have markedly different characteristics from what exists in nature.

Issue spotting

- ✓ Product claims
- ✓ Product of nature exceptions
- ✓ Markedly Different Characteristics analysis, including when and how to apply it
- ✓ "Integration into a practical application," particularly the "particular machine" and the "other meaningful limitations" considerations
- ✓ Claim interpretation: functional claim language, and wherein clauses

Relevant case law

- *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)
- *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)
- *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)
- *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1339 (Fed. Cir. 2014)

BACKGROUND

Diabetes is a disease characterized by abnormal regulation of glucose and insulin. Glucose is a sugar used by the human body's cells to produce energy, and insulin is a naturally-occurring protein that helps regulate how the body uses or stores glucose. Many patients with diabetes take medications called insulin-sensitizing agents that help reduce their requirements for insulin, but these medications may have adverse side effects such as gastrointestinal irritation.

Applicant discovered a protein in the bark of the Rocky Mountain cassia tree that it calls "denveric acid." When administered to a human, denveric acid reduces the human's need for insulin because it: (a) reduces the rate of gluconeogenesis (glucose production) in the patient; and (b) acts as an insulin-sensitizing agent. Denveric acid has a much lower rate of adverse side effects than known insulin-sensitizing agents, but acts much more quickly in the body than these known agents, thus requiring more frequent dosing.

Applicant has now filed an application claiming several products comprising denveric acid, and discloses several containers that can be used to hold denveric acid solutions, for instance bottles, vials, pre-filled syringes, and delivery devices such as infusion pumps. The application explicitly defines the term "container" as a human-made container, and discloses several exemplary embodiments of the container including a bottle, syringe, or vial. In one embodiment, the application discloses a dosage unit that is a delivery device wearable by a patient. The delivery device has a flexible patch-shaped housing, which when placed on a patient's body (*e.g.*, the upper arm or abdomen) will conform to the patient's body contours for comfortable and discreet use. As shown in Fig. 1, the delivery device also comprises a reservoir located inside the housing in which the denveric acid is stored, a needle assembly mounted on one side of the housing, a dosage control button mounted on the opposite side of the housing from the needle assembly, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly. The button and valve can be calibrated to deliver different dosage amounts as desired by patients and their physicians. When delivery of a denveric acid bolus is scheduled, the dosage control button activates the delivery valve to dispense the selected dosage of denveric acid

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to the needle assembly, and triggers a pressure mechanism (not shown) to move the needle assembly toward the patient so that the needles pierce the skin and administer the dosage of denveric acid. The application notes that this wearable delivery device is well-understood, and is routinely used to administer other medications.

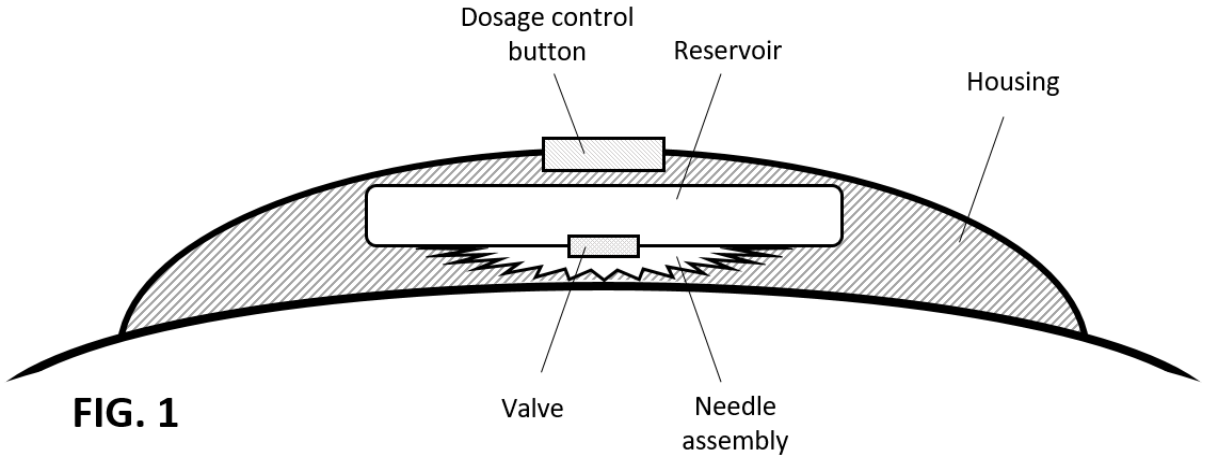

FIG. 1

Applicant also discloses that denveric acid has particular glycemic control characteristics that may not be suitable for all situations. For instance, denveric acid is considered to be a "short-acting" agent, in that the onset of glycemic control is about 30 minutes post-injection, peak action is about 1 hour post-injection, and duration of action is about 1 to 3 hours post-injection. Sometimes a longer period of control is desired, for instance during the nighttime when a patient desires uninterrupted sleep. Applicant discloses that a slower onset of glycemic control is desirable in some situations, and so a patient may need to administer an "intermediate-acting" denveric acid, which applicant defines as having particular glycemic control characteristics, *i.e.*, an onset of glycemic control about 1 to 3 hours post-injection, a peak action about 3 hours post-injection, and a duration of action of about 3 to 6 hours post-injection. Although applicant does not disclose any denveric acid molecules that are intermediate-acting, applicant explains that those of ordinary skill in the art understand how to modify insulin-sensitizing agents (*e.g.*, by modifying one or more amino acids or by making some other structural modification) in order to make them have the recited functionality. Applicant also discloses that a mixture of denveric acid with protamine, another naturally-occurring protein, in a particular amount (0.75 mg to 1.5 mg of protamine per every mg of denveric acid) changes the glycemic control characteristics to be long-acting, *i.e.*, the mixture has an onset of glycemic control about 90 minutes post-injection, peak action about 6 to 8 hours post-injection, and duration of action about 12 to 18 hours post-injection.

CLAIMS

1. A dosage unit comprising denveric acid in a container.

2. The dosage unit of claim 1, wherein the container is a wearable delivery device having a flexible patch-shaped housing, a needle assembly mounted on one side of the housing, a reservoir located inside the housing in which the denveric acid is stored, a dosage control button mounted on the opposite side of the housing from the needle assembly, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly.

3. The dosage unit of claim 1, wherein the denveric acid is an intermediate-acting denveric acid.

4. The dosage unit of claim 1, further comprising protamine that is mixed with the denveric acid in the container in an amount of 0.75 mg to 1.5 mg protamine per every mg of denveric acid.

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ANALYSIS

Claim 1 is *ineligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Based on the specification's identification of "denveric acid" as being a particular protein isolated from the Rocky Mountain cassia tree, and the plain meaning of the other terms, the broadest reasonable interpretation of claim 1 is a product comprising denveric acid (which is naturally occurring) in a container. The preamble language ("A dosage unit") does not indicate any structural or manipulative difference in the invention recited in the body of the claim (the denveric acid), and instead merely conveys an intended use of the claimed denveric acid. The claim also recites a container, but does not impose any limits on the container.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Here, the claim recites denveric acid, which is a protein. Because proteins are composed of matter, the denveric acid is a composition of matter, which is a statutory category of invention. In addition, the container is a concrete thing that was produced by a human from raw or prepared materials, *e.g*., a plastic bottle, and thus is a manufacture, which is also a statutory category. As explained in the MPEP, it is not necessary to identify a single category into which a claim falls, so long as it is clear that the claim falls into at least one category. MPEP 2106.03(I). Here, because the denveric acid is a composition of matter, and the container is a manufacture, the claim is to at least one statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. Because claim 1 recites a nature-based product limitation (the denveric acid), the markedly different characteristics analysis is used to determine if the nature-based product limitation is a product of nature exception. MPEP 2106.04(c)(I). Although the claim also recites a non-nature based product limitation (the container), the markedly different characteristics analysis should be applied only to the nature-based product limitation. MPEP 2106.04(c)(I)(A). The markedly different characteristics analysis is performed by comparing the nature-based product limitation in the claim to its naturally occurring counterpart to determine if it has markedly different characteristics from the counterpart. MPEP 2106.04(c)(II). Here, the closest natural counterpart is naturally occurring denveric acid. When the claimed denveric acid is compared to this counterpart, the comparison indicates that there are no differences in structure, function, or other characteristics. Therefore, the claimed denveric acid is a product of nature exception. *Association for Molecular Pathology v. Myriad Genetics Inc.*, 569 U.S. 576, 589-90 (2013) (naturally occurring things are "products of nature" which cannot be patented). Accordingly, the claim recites a judicial exception, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Claim 1 recites an additional element (the container). Although this limitation indicates that the denveric acid is held in the container, it does not provide any information as to how the denveric acid is contained, or what the container is, but instead covers any possible container that a doctor or pharmacist decides to use. Because denveric acid must be placed in a container in order to store and use it, merely reciting a generic "container" thus fails to meaningfully limit the claim because it is at best the equivalent of merely adding the words "apply it" to the judicial exception.

Accordingly, the container does not integrate the recited judicial exception into a practical application and the claim is therefore directed to the judicial exception (*Step 2A: YES*).

Step 2B: This part of the eligibility analysis evaluates whether the claim as a whole amounts to significantly more than the recited exception, *i.e.*, whether any additional element, or combination of additional elements, adds an inventive concept to the claim. MPEP 2106.05. As discussed with respect to Step 2A Prong Two, the claim recites a single additional element of a generic container, which is at best the equivalent of merely adding the words "apply it" to the judicial exception. Mere instructions to apply an exception cannot provide an inventive concept (*Step 2B: NO*). The claim is not eligible.

Practice note: A rejection of claim 1 should identify the exception by pointing to the nature-based product in the claim (the denveric acid) and explaining why it is a product of nature exception. The rejection should also explain that the claim as a whole does not integrate the exception into a practical application or amount to significantly more than the exception because the additional limitation is at best the equivalent of merely adding the words "apply it" to the claim. If the examiner believes that it would be helpful to cite a court decision, the rejection could include an explanation of how the claimed denveric acid is like the cloned mammal of *Roslin*, which was held ineligible because it lacked markedly different characteristics from its naturally occurring counterparts. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1339 (Fed. Cir. 2014). *See also Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (isolated BRCA genes held ineligible). The examiner could also include a citation to MPEP 2106.05(f), which provides a detailed explanation of the "mere instructions to apply an exception" consideration, as well as specific examples of limitations that the courts have evaluated using this consideration.

Claim 2 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 2 depends from claim 1, and specifies that the container is a wearable delivery device having a flexible patch-shaped housing, a needle assembly mounted on one side of the housing, a reservoir located inside the housing in which the denveric acid is stored, a dosage control button mounted on the opposite side of the housing from the needle assembly, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly. It is important to remember during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight, in that the claim requires that the denveric acid be physically located in the reservoir of a wearable delivery device, which also has particular specified components such as the dosage control button, the delivery valve, and the needle assembly.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Claim 2 depends from claim 1, and thus also recites a composition of matter (the denveric acid) and a manufacture or machine (the container, which in this claim is recited as a wearable delivery device consisting of various manufactured components such as the needle assembly and the dosage control button). Like claim 1, the claim is thus to at least one statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 2 depends from claim 1, and thus recites the same nature-based product limitation (the denveric acid). Although claim 2 also recites a non-nature based product limitation (the delivery device), the markedly different characteristics analysis should be applied only to the nature-based product

limitation. MPEP 2106.04(c)(I)(A). As discussed with respect to claim 1, the claimed denveric acid is a product of nature exception because it lacks markedly different characteristics. Accordingly, the claim recites a judicial exception, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2) 84 Fed. Reg. at 54-55.

Claim 2 recites an additional element (the delivery device), which requires that the denveric acid be physically located in the reservoir of a wearable delivery device, which also has a housing, needle assembly, a dosage control button, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly. Although the background of this example explains that the delivery device is well-understood, and is routinely used to administer other medications, the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55). Thus, the following evaluation does not take into account whether or not the delivery device is well-known. *See* October 2019 Update at Section III.D.

An evaluation of the "particular machine" consideration is then performed, using the three factors set forth in MPEP 2106.05(b). Evaluation of the first factor indicates that the delivery device is not recited at a high level of generality, for instance it is clearly a particular container having specific components (*e.g.*, a reservoir, a needle assembly, a valve, etc.) as opposed to a generic container (denveric acid can be stored in any number of containers, such as vials, test tubes, etc.). Evaluation of the second and third factors indicates that the delivery device is also an integral part of the claim, in that the denveric acid is physically stored in the reservoir of the delivery device, and the amount of denveric acid that is injected is controlled by the delivery valve. Thus, the involvement of the delivery device in the claim is more than just a field of use or other insignificant limitation. The delivery device is therefore a particular machine that applies or uses the denveric acid in a meaningful way that integrates this product of nature exception into a practical application, like the claimed Fourdrinier machine in *Eibel Process*. *See* MPEP 2106.05(b), which discusses *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923) and other cases analyzing the "particular machine" consideration. Accordingly, claim 2 is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: This discussion of claim 2 sets forth the full analysis of this claim under the 2019 PEG, which results in eligibility at Step 2A (Pathway B). During examination, however, a claim like this one may not require the full analysis. As explained in MPEP 2106.06, for purposes of efficiency in examination, examiners may use a streamlined eligibility analysis (Pathway A) when the eligibility of the claim is self-evident. Like the artificial hip prosthesis coated with a naturally occurring mineral that is described in the MPEP, claim 2 is also not an attempt to tie up the naturally occurring denveric acid and thus would be suitable for the streamlined analysis. If the claim were a "close call," however, then a full analysis should be performed in order to ensure that the appropriate result is reached. See MPEP 2106.06(a) for more information about the streamlined analysis for claims like this one.

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Claim 3 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 3 depends from claim 1 (which was interpreted as limited to "denveric acid"), and adds a wherein clause specifying that the denveric acid is an "intermediate-acting denveric acid". It is important to remember during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight because the claim requires that the denveric acid have the function of being intermediate-acting, which is understood by those in the art to mean that it acts more slowly than naturally-occurring denveric acid. As described in the specification, "intermediate-acting denveric acid" is a denveric acid molecule that has been modified to have particular glycemic control characteristics, *e.g.*, specific onset timing of about 1 to 3 hours post-injection, peak action timing of about 3 hours post-injection, and duration of action of about 3 to 6 hours post-injection. As also described in the specification, those of ordinary skill in the art understand that the functional language in the claim ("intermediate-acting") imposes some structural difference on the structure (denveric acid) recited in the claim, for instance it may have a modified amino acid sequence or some other structural modification that provides the recited functionality. Accordingly, claim 3 covers a genus of any denveric acid that has the desired functional effect of being intermediate-acting.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Claim 3 depends from claim 1, and thus also recites a composition of matter (the denveric acid) and a manufacture (the container). Like claim 1, the claim is thus to at least one statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Because this claim recites a nature-based product limitation (the denveric acid), the markedly different characteristics analysis is used to determine if the nature-based product limitation is a product of nature exception. MPEP 2106.04(c)(I). Although the claim also recites a non-nature based product limitation (the container), the markedly different characteristics analysis should be applied only to the nature-based product limitation. MPEP 2106.04(c)(I)(A).

The markedly different characteristics analysis is performed by comparing the nature-based product limitation in the claim to its naturally occurring counterpart to determine if it has markedly different characteristics from the counterpart. MPEP 2106.04(c)(II). Here, the closest natural counterpart is naturally occurring denveric acid. When the claimed denveric acid is compared to this counterpart, the comparison indicates that the claimed denveric acid has a changed functional property, in that it is intermediate-acting. In other words, the glycemic control characteristics of the claimed denveric acid are different than those of naturally-occurring denveric acid. In particular, the claimed denveric acid has intermediate-acting glycemic control characteristics (onset of glycemic control is about 1 to 3 hours post-injection, peak action is about 3 hours post-injection, and duration of action is about 3 to 6 hours post-injection) as compared to naturally occurring denveric acid (onset of glycemic control is about 30 minutes post-injection, peak action is about 1 hour post-injection, and duration of action is about 1 to 3 hours post-injection).

This change in glycemic control characteristics is a marked difference in functional characteristics as compared to the natural counterpart, and therefore the claimed denveric acid is not a "product of nature" exception. Because no judicial exception is recited, the claim cannot be directed to an exception (*Step 2A: NO*). The claim is eligible.

Practice note: Although claim 3 is eligible, it may be unpatentable for other reasons, and thus it is important to practice compact prosecution by examining each claim for compliance with every statutory requirement for patentability in the initial review of the application. For instance, the examiner should evaluate whether the claim is indefinite because those of ordinary skill in the art cannot determine the boundaries of this claim in the absence of a structural description of intermediate-acting denveric acid. See MPEP 2173.05(g). The examiner should also consider whether claim 3 lacks written description, which will depend on what is disclosed in the application, and whether there is a known correlation between denveric acid structure and function that could support the functionally-claimed genus of intermediate-acting denveric acid. See MPEP 2163(II)(A)(3)(a).

Claim 4 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 4 depends from claim 1, and adds protamine that is mixed with the denveric acid in an amount of 0.75 mg to 1.5 mg protamine per every mg of denveric acid. Based on the specification's definition of "denveric acid" as being a particular protein isolated from the Rocky Mountain cassia tree, and the plain meaning of the other terms, the broadest reasonable interpretation of claim 4 is a mixture of denveric acid (which is naturally occurring) with protamine (which is naturally occurring), in a specified ratio (0.75 to 1.5 mg protamine per 1 mg denveric acid). As described in the specification, this mixture of denveric acid and protamine has particular glycemic control characteristics, *e.g.*, specific onset timing of about 90 minutes post-injection, peak action timing of about 6 to 8 hours post-injection, and duration of action of about 12 to 16 hours post-injection.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Claim 4 depends from claim 1, and thus also recites a composition of matter (the denveric acid and protamine mixture) and a manufacture (the container). Like claim 1, the claim is thus to at least one statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. The claimed mixture of denveric acid and protamine is a nature-based product limitation, and thus the markedly different characteristics analysis is used to determine if the nature-based product limitation is a product of nature exception. MPEP 2106.04(c)(I). Although the claim also recites a non-nature based product limitation (the container), the markedly different characteristics analysis should be applied only to the nature-based product limitation. MPEP 2106.04(c)(I)(A).

Because the claim is to a nature-based product produced by combining multiple components (the denveric acid and the protamine), the markedly different characteristics analysis should be applied to the resultant nature-based combination, rather than its component parts. MPEP 2106.04(c)(I)(A). Because denveric acid and protamine do not occur together in nature, there is no naturally occurring counterpart mixture for comparison, and so the claimed mixture is compared to its naturally occurring components (denveric acid and protamine). There is no indication that mixing these components changes the structure of the denveric acid or protamine. However, the mixture has a changed functional property, in that the glycemic control characteristics of the mixture are different than the mere "sum" of the glycemic control characteristics of the individual components.

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In other words, the denveric acid by itself has relatively short-acting glycemic control characteristics (onset of glycemic control is about 30 minutes post-injection, peak action is about 1 hour post-injection, and duration of action is about 1 to 3 hours post-injection), and the protamine by itself has no glycemic control characteristic, but when combined in the claimed ratio, the resultant mixture has intermediate glycemic control characteristics (onset of glycemic control is about 90 minutes post-injection, peak action is about 6 to 8 hours post-injection, and duration of action is about 12 to 18 hours post-injection). The claimed mixture here is thus unlike the bacterial mixture of *Funk Brothers*, which was held ineligible because each species of bacteria in the mixture continued to have "the same effect it always had," *i.e.*, it lacked markedly different characteristics. *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 131 (1948), discussed in *Myriad Genetics*, 569 U.S. at 591 (explaining that the bacterial mixture of *Funk Brothers* "was not patent eligible because the patent holder did not alter the bacteria in any way"). Because the claimed mixture here has a *different* effect (the changed glycemic control characteristics) than its natural counterparts, it has markedly different characteristics, and therefore is not a "product of nature" exception. Because no judicial exception is recited, the claim cannot be directed to an exception (*Step 2A: NO*). The claim is eligible.

Practice note: When evaluating markedly different characteristics, the examiner should ensure that the claimed nature-based product possesses appropriate characteristics because it is the claim that must define the invention to be patented. Cf. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1338 (Fed. Cir. 2014) (unclaimed characteristics could not contribute to eligibility); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1370 (Fed. Cir. 2018) (same). The examiner can identify the characteristics possessed by the claimed product by looking at what is recited in the claim language and encompassed within the broadest reasonable interpretation of the nature-based product. It is not necessary for the claim to explicitly recite a characteristic that is markedly different, so long as the broadest reasonable interpretation of the claim reflects that the claimed product possesses at least one appropriate characteristic that is markedly different. See MPEP 2106.04(c)(II)(B). Thus, although claim 4 does not recite the glycemic control characteristics of the claimed mixture, a person of ordinary skill in the art would recognize that broadest reasonable interpretation of the claimed mixture encompasses only mixtures which have particular glycemic control characteristics that are markedly different.

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45. Controller for Injection Mold

This example illustrates the application of Revised Step 2A to product claims reciting a machine or manufacture (a controller) for controlling the injection molding of a hypothetical chemical (polyurethane polymer X46). Claim 1 is ineligible because it is directed to judicial exceptions (abstract ideas), and the claim as a whole does not integrate the exceptions into a practical application or amount to significantly more than the exceptions. Claim 2 recites the same judicial exceptions as claim 1, but is eligible because it recites other meaningful limitations that use the abstract ideas to improve the previous molding technology, such that the claim integrates the exceptions into a practical application. Claim 3 recites the same judicial exceptions as claims 1 and 2, and lacks any additional elements that integrate the exceptions into a practical application, but nonetheless is eligible in Step 2B because it recites a specific and unconventional tool in the data gathering steps that amounts to significantly more than the exceptions. Claim 4 recites a different judicial exception, and is eligible because it recites other meaningful limitations that use the abstract idea to improve the previous molding technology, such that the claim as a whole integrates the exception into a practical application.

Issue spotting

- ✓ Product claims
- ✓ Abstract idea exceptions, particularly mathematical concepts and mental processes
- ✓ Law of nature exception
- ✓ Multiple exceptions in the same claim
- ✓ "Integration into a practical application," particularly the "improvements to technology" and "other meaningful limitations" considerations
- ✓ Claim that is eligible at Step 2B
- ✓ Claim interpretation: functional claim language, and wherein clauses

Relevant case law

- *Diamond v. Diehr*, 450 U.S. 175 (1981)
- *Gottschalk v. Benson*, 409 U.S. 63 (1972)

BACKGROUND

Injection molding is a manufacturing process that is commonly used to form plastic articles by injecting raw (uncured) material into a mold and then heating it to cure the material and obtain a product that retains its shape. Applicant has determined that its polyurethane polymer X46 is a particularly useful material for producing roller wheels for skateboards because, when properly cured, the polymer X46 has high strength and durability. Raw (uncured) polyurethane comprises small chemical molecules (monomers) including polyisocyanates (I) and polyols (P), and the curing process cross-links these molecules together to form a large polyurethane polymer $I_nP_{x,}$, thereby changing the chemicals from their raw state into a more durable form that will retain a molded shape. In mathematical terms, the curing process involves the reaction of a large number (n) of polyisocyanates (l) with a large number (x) of polyols (P) to form the polyurethane polymer, *i.e.*, $n(I) + x(P) \rightarrow I_nP_x$.

Proper curing depends upon several factors, particularly temperature. When the polymer is cured within a temperature range of 30° to 100° Celsius (C), the conversion rate (cure rate) of the polymer obeys the Arrhenius equation, with optimal curing occurring at 85° C. If the curing temperature is too low, the polymer may not fully cure, or may take an undesirably long time to achieve a sufficient extent of cure, thereby decreasing efficiency of the molding process. If the temperature is too high (*e.g.*, above 100° C), the polymer X46 undergoes an undesired side reaction that reduces ductility, decreases the strength of the polymer, and negatively affects the wear performance of the wheel.

Applicant describes using a standard or conventional injection mold apparatus to produce the skateboard wheels from its polymer X46, *e.g.*, an apparatus comprising a mold defining a cavity for receiving uncured polyurethane, an injection mechanism for feeding the uncured polyurethane into the mold cavity, and a temperature regulation unit. As disclosed in the specification, the temperature

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regulation unit is configured to heat the mold to, and maintain the mold at, a target temperature, and comprises a heater to heat the mold, and a coolant system comprising tubes or pathways where cool liquid such as water or oil can be pumped through in order to quickly lower the temperature of the mold to avoid over-curing (and to cool the mold after the molded polyurethane is ejected, in order to prepare the mold for the next cycle of operation). The injection molding apparatus is controlled in the usual manner, *e.g.*, applicant's specification discloses the structure of various off-the-shelf industrial controllers that can be used to control the injection molding apparatus, all of which are implemented in hardware, or a combination of hardware and software such as a general purpose computer programmed to control the molding apparatus.

Applicant's specification describes how its controller operates the injection molding apparatus, for instance by sending control signals to the injection molding apparatus to inject uncured polyurethane into the mold, to heat the mold to a target temperature to cure the polyurethane, and to open the mold and eject the molded polyurethane from the mold once the extent of cure has reached a target percentage. The controller also receives the temperature of the mold repeatedly from a thermometer or other device, such as an industrial thermometer having a known thermocouple and a USB plug to connect it to the controller. Applicant discloses a means for temperature measuring, which is described in the specification as an industrial thermometer, which can be plugged into the controller, and that has a particular thermocouple formed from alloys ARC and XY (referred to as the "ARCXY" thermocouple) which has better long-term performance, faster response, and durability than other known thermocouples.

The controller uses the repeatedly obtained mold temperatures to monitor and adjust (if necessary) the mold temperature, *e.g.*, by comparing the obtained temperature to a target temperature, so that the controller can signal the injection molding apparatus to maintain the temperature within two degrees of the target temperature by selectively heating or cooling the mold when the measured temperature of the mold is more than two degrees different than the target temperature. By maintaining the mold temperature within this set range (no more than two degrees higher or lower than the target temperature), applicant's controller prevents the occurrence of undesirable side reactions that would otherwise negatively affect the cured polyurethane's strength and wear performance.

The measured temperatures are also used by the controller to calculate the extent of curing completion using each of the temperatures and the Arrhenius equation. The conversion rate (or cure rate) $d\alpha/dt$ of thermal activated processes such as polyurethane molding can be described using equation (1), where α is the degree or extent of conversion (cure), $k(T)$ is the temperature-dependent rate constant, and $f(\alpha)$ is the reaction model for polyurethane polymer X46, which is a common two component addition reaction. In the present application, $k(T)$ is described by the Arrhenius equation (2), in which A_{exp} is the pre-exponential factor describing the collision frequency of the particles involved in the formation of the activated complex, E is the activation energy, T is the temperature in degrees Kelvin (^{o}C + 273.15) and R is the gas constant. When the temperature-dependent rate constant $k(T)$ in equation (1) is substituted with the Arrhenius equation (2), the resultant equation (3) is achieved.

$$\frac{d\alpha}{dt} = k(T)\, f(\alpha) \tag{1}$$

$$k(T) = A_{exp}\left(\frac{-E}{RT}\right) \tag{2}$$

$$\frac{d\alpha}{dt} = A_{exp}\left(\frac{-E}{RT}\right) f(\alpha) \tag{3}$$

The degree of conversion α is a unit-less parameter having values that range from zero to one, with zero representing zero conversion (no curing has occurred), and one representing complete conversion (cure is complete). To assist in monitoring curing completion, the extent of cure can be determined as a percentage by converting the value of α from decimal format into percentage format, *e.g.*, an α of 0.4 can be converted into 40%, an α of 0.5 can be converted into 50%, and the like. The controller then compares

this calculated percentage to a target percentage, so that the controller can determine when to signal the apparatus to open the mold and eject the molded polyurethane, in order to obtain uniformly cured skateboard wheels from polymer X46. Because the claimed controller opens the mold and ejects the molded polyurethane at the precise time when the target percentage of cure is reached, the claimed controller avoids the problems associated with undercure and overcure, which would otherwise negatively affect the cured polyurethane's strength and wear performance.

CLAIMS

1. A controller for an injection molding apparatus having a mold defining a cavity for receiving uncured polyurethane that is heated to form a molded article during a cycle of operation of the apparatus, the controller configured to:

   (a) repeatedly obtain measurements of the temperature of a mold;

   (b) calculate an extent of curing completion of polyurethane in the mold using the obtained temperatures and the Arrhenius equation; and

   (c) determine the extent that the polyurethane is cured as a percentage.

2. The controller of claim 1, which is further configured to:

   (d) send control signals to the injection molding apparatus once the polyurethane has reached a target percentage, the control signals instructing the apparatus to open the mold and eject the molded polyurethane from the mold.

3. A system comprising the controller of claim 1 connected to a means for temperature measuring that repeatedly measures the temperature of the mold.

4. A controller for an injection molding apparatus having a mold defining a cavity for receiving uncured polyurethane that is heated to form a molded article during a cycle of operation of the apparatus, the controller configured to:

   (a) send a control signal to the injection molding apparatus to regulate injection of uncured polyurethane into the mold, and to heat the mold to a target temperature to cure the polyurethane;

   (b) repeatedly obtain temperature measurements of the mold;

   (c) compare the obtained temperatures to a target temperature; and

   (d) maintain temperature of the mold within two degrees of the target temperature by sending a control signal to the apparatus to selectively heat or cool the mold when the obtained temperature of the mold is more than two degrees different than the target temperature.

ANALYSIS

Claim 1 is *ineligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Based on the plain meaning of the words in the claim, the broadest reasonable interpretation of claim 1 is a controller (which is a device such as a general purpose computer in communication with sensors) for an injection molding apparatus, which performs the functions of (a) repeatedly obtaining measurements of the mold temperature, (b) calculating an extent

of curing completion (*i.e.*, calculating the value of α) of polyurethane in the mold using the obtained temperatures and the Arrhenius equation; and (c) determining the extent that the polyurethane is cured as a percentage, *i.e.*, converting the calculated value of α from decimal format into percentage format. The preamble here does not positively add limitations to the claimed controller, or further modify limitations recited in the body of the claim, and thus does not limit the claim. Instead, it indicates an intended use for the claimed controller, *i.e.*, the controller is intended for use in controlling an injection molding apparatus.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a controller, which is a mechanical and/or electrical device such as a general purpose computer in communication with sensors. Thus, the claim is to a manufacture or a machine, which are statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. There are no nature-based product limitations in this claim (polyurethane is not a nature-based product), and thus the markedly different characteristics analysis is not performed. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

Limitation (b) in the claim recites that the controller is configured to "calculate an extent of curing completion of polyurethane in the mold using the obtained temperatures and the Arrhenius equation." As is evident from the background of this example, the claimed calculation is a mathematical calculation of the value of the extent of cure (degree of conversion) variable α, using mathematical formulas including the Arrhenius equation. The grouping of "mathematical concepts" in the 2019 PEG is not limited to formulas or equations, and in fact specifically includes "mathematical calculations" as an exemplar of a mathematical concept. 2019 PEG Section I, 84 Fed. Reg. at 52. Thus, limitation (b) recites a concept that falls into the "mathematical concept" group of abstract ideas. This limitation also falls into the "mental process" group of abstract ideas, because the recited mathematical calculation is simple enough that it can be practically performed in the human mind, *e.g.*, scientists and engineers have been solving the Arrhenius equation in their minds since it was first proposed in 1889. Note that even if most humans would use a physical aid (*e.g.*, pen and paper, a slide rule, or a calculator) to help them complete the recited calculation, the use of such physical aid does not negate the mental nature of this limitation. *See* October Update at Section I(C)(ii) and (iii). Nor does the recitation of a controller in this claim negate the mental nature of this limitation because the claim here merely uses the controller as a tool to perform the otherwise mental process. *Id*. In addition, limitation (b) recites a law of nature because the Arrhenius equation describes the naturally occurring relationship between temperature and reaction rate for many chemical and biological reactions, such as the bloom time of cherry blossoms, the rate of cricket chirps, and the curing of polyurethane claimed in this example.

Although limitation (b) falls under several exceptions (*e.g.*, a mathematical concept-type abstract idea, a mental process-type abstract idea, and a law of nature), there are no bright lines between the types of exceptions. *See, e.g.*, MPEP 2106.04(I). Thus, it is sufficient for the examiner to identify that limitation (b) aligns with at least one judicial exception, and to conduct further analysis based on that identification. *See* October 2019 Update at Section I.B n.7. For purposes of further discussion, this example identifies the recited exception as an abstract idea.

Limitation (c) in the claim recites that the controller is configured to "determine the extent that the polyurethane is cured as a percentage." As is evident from the background of this example, this determination is a simple conversion of the value of α from decimal format into percentage format that is performed by multiplying the value of α by 100, in accordance with the mathematical relationship between a decimal value and its corresponding percentage, *e.g.*, an α of 0.4 is equivalent to 40% of the polyurethane being cured, an α of 0.5 is equivalent to 50% of the polyurethane being cured, and the like.

This conversion between decimal and percentage representations is analogous to the conversion between binary-coded decimal and pure binary numerals at issue in *Benson*, which the Supreme Court described as a "mathematical problem[] of converting one form of numerical representation to another." *Gottschalk v. Benson*, 409 U.S. 63, 65 (1972). This limitation thus describes a "mathematical relationship," which is specifically identified in the 2019 PEG as an exemplar in the "mathematical concepts" grouping of abstract ideas. 2019 PEG Section I, 84 Fed. Reg. at 52. In addition, because the BRI of limitation (c) requires the performance of an arithmetic operation (multiplying the value of α by 100), this limitation also describes a "mathematical calculation," which is also specifically identified in the 2019 PEG as an exemplar in the "mathematical concepts" grouping of abstract ideas. *Id.* Moreover, the recited conversion is also simple enough that it can be practically performed in the human mind, and so it also falls into the "mental process" group of abstract ideas. Thus, limitation (c) recites a concept that falls into the "mathematical concept" and "mental process" groups of abstract ideas.

As explained in the MPEP and the October 2019 Update, in situations like this where a series of steps recite judicial exceptions, examiners should combine all recited judicial exceptions and treat the claim as containing a single judicial exception for purposes of further eligibility analysis. *See* MPEP 2106.04 and 2106.05(II), and October 2019 Update at Section I.B. Thus, for purposes of further discussion, this example considers limitations (b) and (c) as a single abstract idea.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55.

Besides the abstract ideas, the claim recites the additional element of the controller being configured to repeatedly obtain measurements of the mold temperature in limitation (a). An evaluation of whether limitation (a) is insignificant extra-solution activity is then performed. Note that because the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55), this evaluation does not take into account whether or not limitation (a) is well-known. *See* October 2019 Update at Section III.D. When so evaluated, this additional element represents mere data gathering (obtaining the temperature values) that is necessary for use of the recited judicial exception (the temperature values are used in limitation (b)'s mathematical concept) and is recited at a high level of generality. Limitation (a) in the claim is thus insignificant extra-solution activity. The controller is also an additional element which is configured to carry out limitations (a), (b) and (c), *i.e.*, it is the tool that is used to obtain the temperature measurements and perform the mathematical calculations and numeric conversions. But the controller is recited so generically (no details whatsoever are provided other than that it is a "controller") that it represents no more than mere instructions to apply the judicial exceptions on a computer. It can also be viewed as nothing more than an attempt to generally link the use of the judicial exceptions to the technological environment of a controller. It should be noted that because the courts have made it clear that mere physicality or tangibility of an additional element or elements is not a relevant consideration in the eligibility analysis, the physical nature of the controller does not affect this analysis. *See* MPEP 2106.05(I) for more information on this point, including explanations from judicial decisions including *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 224-26 (2014). Even when viewed in combination, these additional elements do not integrate the recited judicial exception into a practical application and the claim is directed to the judicial exception (*Step 2A: YES*).

Step 2B: This part of the eligibility analysis evaluates whether the claim as a whole amounts to significantly more than the recited exception, *i.e.*, whether any additional element, or combination of additional elements, adds an inventive concept to the claim. MPEP 2106.05. As explained with respect to Step 2A Prong Two, there are two additional elements. The first is the controller, which is configured

to perform limitations (a) through (c). As explained previously, the controller is at best the equivalent of merely adding the words "apply it" to the judicial exception. Mere instructions to apply an exception cannot provide an inventive concept. The second additional element is limitation (a), which as explained previously is extra-solution activity, which for purposes of Step 2A Prong Two was considered insignificant. Under the 2019 PEG, however, a conclusion that an additional element is insignificant extra-solution activity in Step 2A should be re-evaluated in Step 2B. 2019 PEG Section III(B), 84 Fed. Reg. at 56. At Step 2B, the evaluation of the insignificant extra-solution activity consideration takes into account whether or not the extra-solution activity is well-known. *See* MPEP 2106.05(g). Here, the recitation of a controller being configured to repeatedly obtain measurements of the mold temperatures is mere data gathering that is recited at a high level of generality, and, as disclosed in the specification, is also well-known. This limitation therefore remains insignificant extra-solution activity even upon reconsideration. Thus, limitation (a) does not amount to significantly more. Even when considered in combination, these additional elements represent mere instructions to apply an exception and insignificant extra-solution activity, which do not provide an inventive concept (*Step 2B: NO*). The claim is not eligible.

Practice note: A rejection of claim 1 should identify the exception by pointing to limitations (b) and (c) in the claim and explaining why they describe abstract ideas. The rejection should also explain that the controller and limitation (a) are additional elements that do not integrate the exception into a practical application or amount to significantly more than the exception because the recitation of the controller is a mere instruction to apply the exceptions on a computer, and limitation (a) is mere data gathering that is recited at a high level of generality.

Limitation (a) is also well-understood, routine, conventional activity when expressed at this high level of generality, as noted in the specification itself (which is described above as disclosing the use of well-known controllers and thermocouples to perform this data gathering). Accordingly, a conclusion that limitation (a) is well-understood, routine, conventional activity is supported under *Berkheimer* Option 1. If the examiner chooses to rely on this additional consideration in support of the rejection, the rejection should also note that support for the conclusion that limitation (a) is well-understood, routine, conventional activity is found in the specification.

While the analysis here identifies the recited exception in limitation (b) as an abstract idea, it also explains that there are no bright lines between the types of exceptions, and that limitation (b) may also be identified as reciting a law of nature. The analysis also explains that limitations (b) and (c) fall under both the "mathematical concept" and "mental process" groups of abstract ideas. But regardless of whether these limitations are identified as mathematical concepts, mental processes, and/or laws of nature, the analysis (and rejection) will be the same as previously described, other than the explanation of why the limitations are judicial exceptions.

Claim 2 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 2 depends from claim 1, and adds the additional limitation (d) regarding control signals that are sent to the injection molding apparatus once the polyurethane has reached a target percentage, so that the apparatus opens the mold and ejects the molded polyurethane from the mold.

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Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a controller, which is a mechanical and/or electrical device such as a general purpose computer in communication with sensors. Thus, the claim is to a manufacture or a machine, which are statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 2 depends from claim 1, and thus recites the same limitations (b) and (c) as claim 1. For the reasons discussed above for claim 1, these limitations recite abstract ideas, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2) 84 Fed. Reg. at 54-55. The additional elements in this claim include the controller and limitations (a) and (d).

The recited controller is configured to perform limitations (a) through (c), *i.e.*, it is the tool that is used to signal the injection molding apparatus to repeatedly obtain measurements of the mold temperature and perform the mathematical calculations and numeric conversions based on the measurements. For the same reasons stated previously with respect to claim 1, the controller and limitation (a) do not integrate the recited judicial exception into a practical application.

Limitation (d) is also an additional element, which specifies that the controller is configured to send control signals instructing the apparatus to open the mold and eject the molded polyurethane from the mold once the polyurethane has reached a target percentage. Limitation (d) does not merely link the judicial exceptions to a technical field, but instead adds a meaningful limitation in that it employs the information provided by the judicial exceptions (the calculated percentage of the extent of cure) to control the operation of the injection molding apparatus. As explained in the specification, because the claimed controller opens the mold and ejects the molded polyurethane at the time when the target percentage of cure is reached, the claimed controller avoids the technical problems associated with undercure and overcure, which would otherwise negatively affect the cured polyurethane's strength and wear performance. Further, a person of ordinary skill in the art would recognize that limitation (d), in combination with the other claim limitations, reflects the technical advantages described in the specification. The claim as a whole thus improves upon previous controllers used in this technical field of injection molding. Further, using the information obtained via the judicial exception to take corrective action and control the injection molding apparatus in a particular way is an "other meaningful limitation" that integrates the judicial exception into the overall control scheme and accordingly practically applies the exception, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: As illustrated in the analysis of claim 2, the "improvements" consideration requires evaluation of the specification and the claim to ensure that a technical explanation of the asserted improvement is present in the specification, and that the claim reflects the asserted improvement. Examiners are not expected to make a qualitative judgment on the merits of the asserted improvement except when a person of ordinary skill in the art, consulting the claims and specification, would clearly understand the invention does not improve technology as applicant asserts. Note that under the 2019 PEG, examiners should perform their analysis of "improvements" at Step 2A Prong Two without reference to what is well-understood, routine, conventional activity. For more information on the "improvements" analysis, see FAQ G-2, MPEP 2106.05(a), and the Advanced Module training (see slides 22-25).

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Claim 3 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 3 depends from claim 1, and adds an additional limitation wherein the controller further comprises a means for temperature measuring that repeatedly measures the temperature of the mold. The "means for temperature measuring …" limitation is interpreted under 35 U.S.C. 112(f) because the claim limitation satisfies the three-prong analysis set forth in MPEP 2181. Because the means for temperature measuring limitation passes the three-prong test (thus invoking 112(f)), its BRI is limited to the structure, material or act (and equivalents thereof) disclosed and clearly linked in the specification to performance of the claimed function. *See* MPEP 2181. In this case, the corresponding structure is the ARCXY thermocouple, and equivalents thereof.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a controller, which is a mechanical and/or electrical device such as a general purpose computer in communication with sensors. Thus, the claim is to a manufacture or a machine, which are statutory categories of invention (*Step 1: YES*).

Practice note: The same claim interpretation must be used when evaluating the claim for compliance with all requirements for patentability (*e.g.*, eligibility, definiteness, novelty, non-obviousness, written description, etc.). Because the wherein clause was determined to provide a patentable distinction here in the eligibility analysis, it will also provide a patentable distinction elsewhere. Furthermore, the interpretation of the "means for temperature measuring" under 35 U.S.C. 112(f) is also the same for all requirements of patentability. Thus, for example, applicable prior art will need to show that the controller comprises an ARCXY thermocouple or an equivalent thereof. See MPEP 2111.04 for more information on wherein clauses, and MPEP 2182 and 2183 for more information on applying prior art to claim elements that are drafted in 112(f) format.

Because claim 3 includes a limitation that is interpreted under 35 U.S.C. 112(f), examiners should establish the 112(f) interpretation and provide an explanation in the Office action using the appropriate form paragraphs. *See, e.g.*, the 2018 training module on "Addressing 35 U.S.C. § 112(F) or "Means-plus-Function" Limitations in an Office Action using New Form Paragraphs," which is available to the public at this link: https://www.uspto.gov/video/cbt/addressing35-usc112f/index.htm.

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 3 depends from claim 1, and thus recites the same limitations (b) and (c) as claim 1. For the reasons discussed above for claim 1, these limitations recite abstract ideas, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2) 84 Fed. Reg. at 54-55. The additional elements in this claim include the controller, the ARCXY thermocouple (and equivalents thereof), and limitation (a), where it is the ARCXY thermocouple (and equivalents thereof) that repeatedly measures the temperature of the mold.

The recited controller is configured to perform limitations (a) through (c), *i.e.*, it is the tool that is used to signal the injection molding apparatus to repeatedly obtain measurements of the temperature and perform the mathematical calculations and numeric conversions based on the measurements. But, as

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described with respect to claim 1, the controller does not integrate the recited judicial exception into a practical application.

Limitation (a) obtains the temperature measurements that are performed by the ARCXY thermocouple (and equivalents thereof). This additional element represents mere data gathering (obtaining and measuring the temperature values) that is necessary for use of the recited judicial exception (the temperature values are used in limitation (b)'s mental calculation of the extent of curing completion). Although the thermocouple (or its equivalents) adds more detail to this limitation than is recited in claim 1, the additional detail (*e.g.*, that the thermocouple is made from ARC and XY alloys) does not alter the performance of the limitation. Moreover, as discussed above for claim 1, the evaluation of whether this limitation is insignificant extra-solution activity in Step 2A Prong One does not take into account whether or not the limitation is well-known. Limitation (a) in the claim is thus insignificant extra-solution activity. Further, this determination precludes the ARCXY thermocouple from being considered to be a "particular machine," because its involvement in the claim is only as insignificant extra-solution activity. *See* MPEP 2106.05(b), particularly the third factor.

The combination of these additional elements also fails to integrate the recited judicial exceptions into a practical application of the exceptions. Whether viewed individually or in combination, the controller still represents mere instructions to apply the judicial exceptions on a computer, and limitation (a) as performed by the controller in conjunction with the ARCXY thermocouple (and equivalents thereof) is insignificant extra-solution activity. Thus, these additional elements do not integrate the recited judicial exception into a practical application and the claim is directed to the judicial exception (*Step 2A: YES*).

Step 2B: This part of the eligibility analysis evaluates whether the claim as a whole amounts to significantly more than the recited exception, *i.e.*, whether any additional element, or combination of additional elements, adds an inventive concept to the claim. MPEP 2106.05. As explained previously, the controller is at best the equivalent of merely adding the words "apply it" to the judicial exception. Mere instructions to apply an exception cannot provide an inventive concept. The other additional element is limitation (a) as performed by the ARCXY thermocouple (and equivalents thereof), which for purposes of Step 2A Prong Two was considered insignificant. Under the 2019 PEG, however, a conclusion that an additional element is insignificant extra-solution activity in Step 2A should be re-evaluated in Step 2B. 2019 PEG Section III(B), 84 Fed. Reg. at 56. As discussed above for claim 1, at Step 2B the evaluation of the insignificant extra-solution activity consideration takes into account whether or not the extra-solution activity is well-known. *See* MPEP 2106.05(g).

Here, the recited activity of repeatedly measuring the temperature of the mold is still mere data gathering that is recited at a high level of generality. As disclosed in the specification, performing this activity by using a thermocouple to repeatedly measure the mold temperature is well-known. Thus, if the BRI of limitation (a) encompassed using a typical thermocouple (or other standard hardware such as an industrial thermometer) to measure the temperature, then there would be nothing in the claim that could elevate this limitation from insignificant extra-solution data gathering into a meaningful limitation that would render the claim eligible. But the BRI here does not encompass using just any thermocouple or thermometer. Instead, because the means for temperature measuring limitation invokes 112(f), limitation (a) only encompasses repeatedly measuring the mold temperature using an ARCXY thermocouple (or its equivalents). And using an ARCXY thermocouple to measure mold temperatures is not well-known. The only reference the examiner has found that discloses this type of thermocouple is a journal article written by several scientists employed by the National Aeronautics and Space Administration, which describes the use of an ARCXY thermocouple to measure temperatures repeatedly in conjunction with spacecraft and landing vehicles used for atmospheric studies on other planets where particularly robust equipment is required. Accordingly, the examiner determines that while ARCXY thermocouples are known, mere knowledge of this type of thermocouple in the aeronautical industry does not make its use in an injection molding apparatus routine or conventional. Thus, limitation (a) as performed by the controller in conjunction with the ARCXY thermocouple was

not well-known, and this limitation is therefore no longer considered to be insignificant because the ARXCY thermocouple's better long-term performance and durability would be beneficial in implementing the injection molding apparatus, and its faster response time means that it can measure the temperature more often than other thermocouples. As a result of using this unconventional thermocouple to perform limitation (a), the claim as a whole thus amounts to significantly more than the exception itself (*Step 2B: YES*). The claim is eligible.

Claim 4 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Based on the plain meaning of the words in the claim, the broadest reasonable interpretation of claim 4 is a controller (which is a device such as a general purpose computer in communication with sensors) for an injection molding apparatus, which is configured to perform the functions of (a) sending a control signal to the injection molding apparatus to regulate injection of uncured polyurethane and to heat the mold to a target temperature to cure the polyurethane, (b) repeatedly obtaining measurements of the mold temperature, (c) comparing the obtained temperatures to the target temperature, and (d) maintaining temperature of the mold within two degrees of the target temperature by sending a control signal to the apparatus to selectively heat or cool the mold when the obtained temperature of the mold is more than two degrees different than the target temperature. The preamble here does not positively add limitations to the claimed controller, or further modify limitations recited in the body of the claim, and thus does not limit the claim. Instead, it indicates an intended use for the claimed controller, *i.e.*, the controller is intended for use in controlling an injection molding apparatus.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a controller, which is a mechanical and/or electrical device such as a general purpose computer in communication with sensors. Thus, the claim is to a manufacture or a machine, which are statutory categories of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. There are no nature-based product limitations in this claim (polyurethane is not a nature-based product), and thus the markedly different characteristics analysis is not performed. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

Limitation (c) in the claim recites that the controller is configured to "compare the obtained temperatures to a target temperature." The claimed comparison is an observation or evaluation between the obtained temperatures and the target temperature, *e.g.*, an observation of whether the obtained temperature matches the target temperature, or whether it varies from the target temperature. This type of observation or evaluation is an act that can be practically performed in the human mind, similar to the mental thought processes that occur when a person looks at a temperature read-out of an oral baby thermometer and determines whether the baby has a fever by mentally evaluating whether a measured temperature of 101 degrees Fahrenheit is higher than the baby's target temperature of 98.6 degrees. Such mental observations or evaluations fall within the "mental processes" grouping of abstract idea set forth in the 2019 PEG. 2019 PEG Section I, 84 Fed. Reg. at 52. Note that the recitation of a controller in this claim does not negate the mental nature of this limitation because the claim here merely uses the controller as a tool to perform the otherwise mental process. *See* October Update at Section I(C)(ii). Thus, limitation (c) recites a concept that falls into the "mental process" group of abstract ideas.

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Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Besides the abstract idea, the claim recites the additional element of the controller being configured to perform limitations (a) through (d).

The controller is configured to carry out limitations (a) through (d), *i.e.*, it is the tool that is used to signal the injection molding apparatus to inject uncured polyurethane and heat the mold, and to repeatedly obtain the temperature measurements and perform the comparison of the obtained temperatures with the target temperature. But the controller is recited so generically (no details whatsoever are provided other than that it is a "controller") that it represents no more than mere instructions to apply the judicial exceptions on a computer. It can also be viewed as nothing more than an attempt to generally link the use of the judicial exception to the technological environment of a controller. The controller thus does not integrate the judicial exception into a practical application. It should be noted that because the courts have made it clear that mere physicality or tangibility of an additional element or elements is not a relevant consideration in the eligibility analysis, the physical nature of the controller does not affect this analysis. *See* MPEP 2106.05(I) for more information on this point, including explanations from judicial decisions including *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 224-26 (2014).

Limitation (a) represents the environment in which the judicial exception is used, in that the controller sending control signals to fill and heat the mold provides context for how the other claimed steps fit into an overall curing process, *e.g.*, there is not much point to repeatedly obtaining measurements of the temperature of the mold (and then to comparing the temperatures and signaling the apparatus to adjust the temperature based on that comparison) until the mold is filled and heated. This element is thus a mere indication of the field of use or technological environment in which the judicial exception is performed, like the step of administering a drug providing 6-thioguanine to patients with an immune-mediated gastrointestinal disorder in *Mayo,* which the Supreme Court treated as merely indicating the field of use in which the recited correlations were identified. *See* MPEP 2106.05(h), discussing the administration step in *Mayo Collaborative Servs. v. Prometheus Labs. Inc.,* 566 U.S. 66, 78 (2012) as well as other examples of field of use limitations. This element is also insignificant extra-solution activity because it merely gathers data for use in calculating the extent of curing completion. *See, e.g.*, *OIP Techs., Inc. v. Amazon.com, Inc.,* 788 F.3d 1359, 1363 (Fed. Cir. 2015), in which the Federal Circuit considered a step of presenting offers to potential customers in order to generate statistics about how the potential customers responded to the offers to be insignificant extra-solution activity because it merely gathered data for use in calculating an optimized price. *See also* MPEP 2106.05(g), which discusses the limitations in *OIP Techs.* as well as other examples of mere data gathering. Thus, limitation (a) does not integrate the judicial exceptions, but instead represents a field of use or mere data gathering (filling and heating the mold so that the temperature values can be obtained) that is necessary for use of the recited judicial exception (the temperature values are used in limitation (c)'s mental comparison of the obtained temperatures to a target temperature).

Limitation (b) requires that the controller is configured to repeatedly obtain measurements of the mold temperature. This additional element represents mere data gathering (obtaining the temperature values) that is necessary for use of the recited judicial exception (the temperature values are used in limitation (c)'s mental comparison of the obtained temperatures to a target temperature) and is recited at a high level of generality. Limitation (b) in the claim is thus insignificant extra-solution activity.

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Limitation (d) specifies that the controller is configured to send a control signal instructing the apparatus to selectively heat or cool the mold when the measured temperature is more than two degrees different than the target temperature. In other words, if the comparison indicates that the mold temperature is too low, the controller sends a signal instructing the apparatus to heat the mold, and if the comparison indicates that the mold temperature is too high, the controller sends a signal instructing the apparatus to cool the mold. Limitation (d) does not merely link the judicial exceptions to a technical field, but instead adds a meaningful limitation in that it employs the information provided by the judicial exception (the comparison of the mold temperature with the target temperature) to control the operation of the injection molding apparatus. As explained in the specification, maintaining the temperature within this set range (no more than two degrees higher or lower than the target temperature) will prevent the occurrence of undesirable side reactions that would otherwise negatively affect the cured polyurethane's strength and wear performance. By preventing the occurrence of these side reactions, the claimed controller avoids the technical problems associated with undercure and overcure, which would otherwise negatively affect the cured polyurethane's strength and wear performance. Further, a person of ordinary skill in the art would recognize that limitation (d), in combination with the other claim limitations, reflects the technical advantages described in the specification. The claim as a whole thus improves upon previous controllers used in this technical field of injection molding. Further, using the information obtained via the judicial exception to take corrective action and control the injection molding apparatus in a particular way is an "other meaningful limitation" that integrates the judicial exception into the overall control scheme and accordingly practically applies the exception, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: As illustrated in the analysis of claim 4, the "improvements" consideration requires evaluation of the specification and the claim to ensure that a technical explanation of the asserted improvement is present in the specification, and that the claim reflects the asserted improvement. Examiners are not expected to make a qualitative judgment on the merits of the asserted improvement except when a person of ordinary skill in the art, consulting the claims and specification, would clearly understand the invention does not improve technology as applicant asserts. Note that under the 2019 PEG, examiners should perform their analysis of "improvements" at Step 2A Prong Two without reference to what is well-understood, routine, conventional activity. For more information on the "improvements" analysis, see FAQ G-2, MPEP 2106.05(a), and the Advanced Module training (see slides 22-25).

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46. Livestock Management

This example illustrates the application of Revised Step 2A to claims for obtaining and analyzing identification and behavioral data of livestock animals, such as dairy cattle. Grass tetany (also called grass staggers) is a real nutritional deficiency that affects ruminant animals such as cattle and sheep. Claim 1 is ineligible because it recites a judicial exception (an abstract idea), and the claim as a whole does not integrate the exception into a practical application or amount to significantly more than the exceptions. Claim 2 recites the same judicial exception as claim 1, but is eligible because it recites other meaningful limitations, which, when evaluated in combination, integrate the exceptions into a practical application. Claim 3 recites a different judicial exception (also an abstract idea), and is eligible because it recites other meaningful limitations, which in combination integrate the exception into a practical application. Claim 4 is eligible because it does not recite any judicial exceptions.

Issue spotting

- ✓ Product and process claims
- ✓ Abstract idea exceptions, particularly mental processes
- ✓ Multiple exceptions in the same claim
- ✓ "Integration into a practical application," particularly the "other meaningful limitations" consideration
- ✓ Claim interpretation: Wherein clauses and contingent limitations

Relevant case law

- *Diamond v. Diehr*, 450 U.S. 175 (1981)
- *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016)
- *Electric Power Group, LLC v. Alstom, S.A.*, 830 F.3d 1350 (Fed. Cir. 2016)

BACKGROUND

Monitoring the behavior of livestock animals such as dairy cattle in response to environment and physiological conditions can provide vital clues as to their general health. Traditionally, farmers have monitored livestock animal behavior by physically and visually inspecting the animals at regular intervals, however these traditional practices are labor intensive and require the farmer to remain in close proximity to the herd. Further, by the time that an animal's behavior is immediately identifiable as aberrant by such physical or visual inspection, the animal is often in significant distress and it may be difficult or impossible to quickly return the animal to optimal health. For instance, grass tetany is a serious and sometimes fatal nutritional deficiency associated with low magnesium levels and/or poor magnesium absorption. It often manifests in late winter and early spring, particularly in pasturage that contains high levels of potassium. Early signs of grass tetany may be non-specific, *e.g.*, the affected cow may leave the herd, stop eating, or be more restless or excitable than normal. As the disorder progresses, the symptoms become more noticeable and specific to grass tetany, *e.g.*, a combination of muscle twitching, convulsions, frequent urination, lying down and standing up repeatedly, and/or excessive chewing. When detected early, the affected cow often recovers when provided with a therapeutically effective amount of supplemental salt and minerals, or in some cases, more invasive treatment such as intravenous magnesium solutions. However, this deficiency is often not detected until an advanced stage because the early signs are non-specific, and also require the farmer to visually inspect and evaluate the behavior of each animal in the herd on a continual basis. To that end, applicant has invented a system and method for automatically detecting and tracking the behavior of livestock animals, in particular dairy cattle, that enables the early detection of disease, infection, nutritional deficiencies, parturition, stress, and other conditions of interest.

The system comprises a central computer, a sensor for each animal in the herd, and at least one reader for obtaining information from the sensors. The computer has typical components including a memory and a processor coupled to the memory, and may also include other standard components such as a display, keyboard, network communicator, touch screen, and the like. The processor is programmed with executable instructions including a livestock interface for obtaining animal-specific information,

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and a monitoring component for comparing, analyzing, and displaying the obtained information. The sensors may take the form of an ear tag, leg band, collar, or other form suitable to permit animal monitoring while not interfering with the animal's daily activities, and incorporate one or more conventional sensors such as accelerometers, global positioning satellite (GPS) sensors, temperature sensors, and the like, along with a communication component such as a radio frequency identification (RFID) tag or "smart label". The smart label can contain various types of animal-specific information, including animal identification data, body position data, body temperature data, feeding behavior data (*e.g*., the animal chewed for only 30 minutes in the last three hours, and consumed only two pounds of grass), and movement pattern data (*e.g*., in the last eight hours, the animal spent two hours lying down and six hours walking around the pasture). The reader may be, *e.g*., a radio frequency reader for collecting the animal-specific information from an animal sensor having a radio frequency transponder when the animal sensor is within proximity to the radio frequency reader, and may be mounted in a variety of locations, for instance inside a milking or feeding barn, in a feeding stall, in a pasture, on a fence or gate, and the like. As the information is collected, it is stored in a herd database so that the farmer has a record of each animal's past and present behavior. The herd database may also contain information about a plurality of possible behavioral patterns that are either normal or indicative of disease, infection, nutritional deficiencies, parturition, stress, and other conditions of interest, and may further contain data indicative of a cow or heifer's age, pregnancy status, vaccination history, and the like. The system may also include control mechanisms that are coupled to the readers and the central computers, *e.g*., to automatically control a gate or a feeding device.

Applicant's system and method enables a farmer to automatically monitor health and activity in dairy livestock animals, by collecting animal-specific information from a particular animal, comparing and analyzing the collected information with respect to the herd database in order to identify whether the animal is exhibiting an aberrant behavioral pattern as compared to past behavior of the animal, and then outputting the results of the analysis on a display to enable the farmer to effectively monitor the herd remotely, *e.g*., by checking the display at night from the farm office or the farm house. For instance, when the herd is on their way into the milking barn at night, animal-specific information from each animal's sensor is read by the readers and processed by the livestock interface and the monitoring component to evaluate each animal's behavioral patterns as compared to its past behavioral patterns (and if desired, a set of possible behavioral patterns that are known to occur in a given animal species).

The system may also send signals to control other farm equipment automatically, based on behavioral triggers. For instance, if the analysis results indicate that a particular animal is exhibiting an aberrant behavioral pattern indicative of excess stress, then the system can send a control signal to a sorting gate that is automatically operable to swing in response to a signal from the system so that the stressed animal is separated from the rest of the herd, *e.g.*, into a holding pen, where the farmer or veterinarian can then examine the stressed animal, and treat it if needed. These sorting gates are known, and may have any suitable form, for example a frame and gates that are constructed out of metal tubing and equipped with mechanical, hydraulic, or pneumatic switches that are electronically controlled. Similarly, a reader mounted in a feeding stall can collect information from the animal that enters that particular stall, so that the animal can be identified and its behavioral patterns analyzed. If the analysis results indicate that this particular animal is exhibiting an aberrant behavioral pattern indicative of a particular disease or nutritional deficiency, or even that this particular animal requires more or less food than other animals in the herd, then the system can send a control signal to a feed dispenser to dispense an individualized amount of feed and optional supplements. For instance, if the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany, the control signal may signal the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed.

CLAIMS

1. A system for monitoring health and activity in dairy livestock animals comprising:

   a memory;

   a display; and

   a processor coupled to the memory programmed with executable instructions, the instructions including

      a livestock interface for obtaining animal-specific information, wherein the animal-specific information comprises animal identification data and at least one of body position data, body temperature data, feeding behavior data, and movement pattern data; and

      a monitoring component for

         (a) comparing the obtained animal-specific information with animal information from a herd database to verify an animal's identity, and

         (b) analyzing the obtained animal-specific information to identify whether the animal is exhibiting an aberrant behavioral pattern as compared to past behavior of the animal, and

         (c) displaying the analysis results for the animal on the display.

2. The system of claim 1, wherein the system further comprises

   a feed dispenser that is connected to a feed and supplement supply and is operable to dispense individualized amounts of feed and optional supplements, and

   wherein the monitoring component is further configured for

      (d) automatically sending a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the analysis results for the animal indicate that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany.

3. A method for monitoring health and activity in dairy livestock animals comprising:

   (a) causing a herd of livestock animals to enter a sorting gate that is automatically operable, wherein each animal in the herd is equipped with an animal sensor having a radio frequency transponder,

   (b) for a particular animal in the herd, obtaining, by a radio frequency reader mounted on or near the sorting gate, animal-specific information from the animal sensor when the animal sensor is within proximity to the radio frequency reader, the animal-specific information comprising animal identification data and at least one of body position data, body temperature data, feeding behavior data, and movement pattern data,

   (c) analyzing, by a processor, the obtained animal-specific information from step (ii) with respect to animal information stored in a herd database to identify the animal and to determine whether the animal is exhibiting an aberrant behavioral pattern as compared to the past behavior of the animal,

   (d) automatically operating the sorting gate, by the processor sending a control signal to the sorting gate to route the animal into a holding pen when the analysis results from step (iii) for the animal indicate that the animal is exhibiting an aberrant behavioral pattern, and by the processor sending a control signal to the sorting gate to permit the animal to freely pass through the sorting gate when

the analysis results for the animal indicate that the animal is not exhibiting an aberrant behavioral pattern, and

(e) repeating steps (b) through (d) for each animal in the herd.

4. A system for monitoring health and activity in a herd of dairy livestock animals comprising:

a memory;

a processor coupled to the memory programmed with executable instructions, the instructions including a livestock interface for obtaining animal-specific information for a plurality of animals in the herd, wherein the animal-specific information comprises animal identification data and at least one of body position data, body temperature data, feeding behavior data, and movement pattern data; and

a herd monitor including (a) a radio frequency reader for collecting the animal-specific information from a plurality of animal sensors attached to the animals in the herd when the animal sensors are within proximity to the radio frequency reader, each animal sensor having a radio frequency transponder, and (b) a transmitter for transmitting the collected animal-specific information to the livestock interface.

ANALYSIS

Claim 1 is *ineligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. The preamble here does not positively add limitations to the claimed system, or further modify limitations recited in the body of the claim, and thus does not limit the claim. Instead, it indicates an intended use for the claimed system, *i.e.*, the system is intended for use in monitoring the health and activity of dairy livestock animals.

Based on the specification, the terms "memory," "display," and "processor" are recognized as representing known classes of structures that can perform the functions set forth in the claim, *e.g.*, the display is claimed as a generic device that performs the generic function of displaying data. The term "animal-specific information" is understood to be information about a particular animal in the herd, and to comprise animal identification data as well as at least one of body position data, body temperature data, feeding behavior data, and movement pattern data. Based on the plain meaning of the words in the claim, the broadest reasonable interpretation of claim 1 is a system having a memory, display, and processor, wherein the processor is coupled to the memory and programmed with executable instructions in the form of at least two software modules: a livestock interface and a monitoring component. The claim does not impose any limits on how the animal-specific information is obtained by the livestock interface, and thus this step covers any and all possible ways in which this can be done, for instance by a farmer typing the information into the system, or by the system obtaining the information from an animal sensor such as an RFID tag, microchip, or transponder device. The claim also does not impose any limits on how the comparison or analysis is accomplished, and thus it can be performed in any way known to those of ordinary skill in the art.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a system comprising a combination of concrete devices (a memory, processor, and display), and therefore is a machine, which is a statutory category of invention (*Step 1: YES*).

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Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. There are no nature-based product limitations in this claim, and thus the markedly different characteristics analysis is not performed. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

Limitations (a) and (b) recite that the monitoring component is for "comparing the obtained animal-specific information with animal information from a herd database to verify the animal's identity," and "analyzing the obtained animal-specific information to identify whether the animal is exhibiting an aberrant behavioral pattern as compared to past behavior of the animal." As is evident from the background of this example, the claimed comparison is an observation or evaluation based on the obtained information and the information stored in the herd database, *e.g*., an observation that Bessie the heifer ate only 15 pounds of hay today as opposed to her usual intake of 20 to 25 pounds of hay, and that her hay intake is normally consistent from day-to-day. The claimed analysis is an evaluation based on the comparison, *e.g*., an evaluation that Bessie is exhibiting aberrant feeding behavior as compared to her past behavior because her food intake is much lower than normal. These observations or evaluations are acts that can be practically performed in the human mind, similar to the mental thought processes that occur when a pool maintenance worker looks at the water level in the pool in the morning and notices that the water level is much lower than normal, and then determines that because this has never happened before even in similar weather conditions, there might be a leak in the pool because the lowered water level cannot be accounted for by overnight evaporation. Such mental observations or evaluations fall within the "mental processes" grouping of abstract idea set forth in the 2019 PEG. 2019 PEG Section I, 84 Fed. Reg. at 52. The recitation of a processor in this claim does not negate the mental nature of these limitations because the claim here merely uses the processor as a tool to perform the otherwise mental processes. *See* October Update at Section I(C)(ii). Thus, limitations (a) and (b) recite concepts that fall into the "mental process" grouping of abstract ideas.

As explained in the MPEP and the October 2019 Update, in situations like this where a series of steps recite judicial exceptions, examiners should combine all recited judicial exceptions and treat the claim as containing a single abstract idea for purposes of further eligibility. *See* MPEP 2106.04 and 2106.05(II). Thus, for purposes of further discussion, this example considers limitations (a) and (b) as a single abstract idea.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Besides the abstract idea, the claim recites the additional elements of the memory, the display, the processor, the livestock interface, and limitation (c).

The memory, display and processor are recited so generically (no details whatsoever are provided other than that they are a memory, display and processor) that they represent no more than mere instructions to apply the judicial exception on a computer. These limitations can also be viewed as nothing more than an attempt to generally link the use of the judicial exception to the technological environment of a computer. It should be noted that because the courts have made it clear that mere physicality or tangibility of an additional element or elements is not a relevant consideration in the eligibility analysis, the physical nature of these computer components does not affect this analysis. *See* MPEP 2106.05(I) for more information on this point, including explanations from judicial decisions including *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 224-26 (2014).

An evaluation of whether the livestock interface is "insignificant extra-solution activity" is then performed. Note that because the Step 2A Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity (2019 PEG Section III(A)(2), 84 Fed. Reg. at 55), this evaluation does not take into account whether or not the livestock interface is well-known. *See* October 2019 Update at Section III.D. When so evaluated, the livestock interface represents mere data gathering (obtaining the animal-specific information) that is necessary for use of the recited judicial exception (the obtained information is used in the abstract mental process of comparing and analyzing) and is recited at a high level of generality. The livestock interface is thus insignificant extra-solution activity. Limitation (c), which is carried out by the processor and the display, is also an additional element, *i.e.*, the monitoring component in the processor performs the necessary software tasks so that the result of the abstract mental process is displayed on the display. This limitation represents extra-solution activity because it is a mere nominal or tangential addition to the claim. *See* MPEP 2106.05(g), discussing limitations that the Federal Circuit has considered to be insignificant extra-solution activity, for instance the step of printing a menu that was generated through an abstract process in *Apple, Inc. v. Ameranth, Inc*., 842 F.3d 1229, 1241-42 (Fed. Cir. 2016) and the mere generic presentation of collected and analyzed data in *Electric Power Group, LLC v. Alstom S.A.,* 830 F.3d 1350, 1354 (Fed. Cir. 2016).

Even when viewed in combination, the additional elements in this claim do no more than automate the mental processes that the farmer used to perform (*e.g*., the mental inspection and evaluation of the livestock animals' behavior), using the computer components as a tool. While this type of automation improves the daily life of farmers (by minimizing or eliminating the need for mentally evaluating the behavior of livestock animals), there is no change to the computers and other technology that are recited in the claim as automating the abstract ideas, and thus this claim cannot improve computer functionality or other technology. *See, e.g*., *Trading Technologies Int'l v. IBG, Inc.*, 921 F.3d 1084, 1093 (Fed. Cir. 2019) (using a computer to provide a trader with more information to facilitate market trades improved the business process of market trading, but not the computer) and the cases discussed in MPEP 2106.05(a)(I), particularly *FairWarning IP, LLC v. Iatric Sys.,* 839 F.3d 1089, 1095 (Fed. Cir. 2016) (accelerating a process of analyzing audit log data is not an improvement when the increased speed comes solely from the capabilities of a general-purpose computer) and *Credit Acceptance Corp. v. Westlake Services*, 859 F.3d 1044, 1055 (Fed. Cir. 2017) (using a generic computer to automate a process of applying to finance a purchase is not an improvement to the computer's functionality). Accordingly, the claim as a whole does not integrate the recited judicial exception into a practical application and the claim is directed to the judicial exception (*Step 2A: YES*).

Step 2B: This part of the eligibility analysis evaluates whether the claim as a whole amounts to significantly more than the recited exception, *i.e.*, whether any additional element, or combination of additional elements, adds an inventive concept to the claim. MPEP 2106.05. As explained with respect to Step 2A Prong Two, the memory, display and processor are at best the equivalent of merely adding the words "apply it" to the judicial exception. Mere instructions to apply an exception cannot provide an inventive concept. The other additional elements are the livestock interface and limitation (c), both of which are extra-solution activity, which for purposes of Step 2A Prong Two was considered insignificant. Under the 2019 PEG, however, a conclusion that an additional element is insignificant extra-solution activity in Step 2A should be re-evaluated in Step 2B. 2019 PEG Section III(B), 84 Fed. Reg. at 56. At Step 2B, the evaluation of the insignificant extra-solution activity consideration takes into account whether or not the extra-solution activity is well-known. *See* MPEP 2106.05(g). Here, the recitation of the livestock interface obtaining data is mere data gathering that is recited at a high level of generality, and, as disclosed in the specification, is also well-known. Similarly, limitation (c) is just a nominal or tangential addition to the claim, and displaying data is also well-known. These limitations therefore remain insignificant extra-solution activity even upon reconsideration, and do not amount to significantly more. Even when considered in combination, these additional elements represent mere

instructions to apply an exception and insignificant extra-solution activity, which cannot provide an inventive concept (*Step 2B: NO*). The claim is not eligible.

Practice note: A rejection of claim 1 should identify the exception by pointing to limitations (a) and (b) in the claim and explaining why they describe abstract ideas. The rejection should also explain that the memory, the display, the processor, the livestock interface, and limitation (c) are all additional elements, but that they do not integrate the exception into a practical application or amount to significantly more than the exception because they are mere instructions to apply the exceptions on a computer, and insignificant extra-solution activity.

The examiner may also cite a court decision that supports the identification of limitations (a) and (b) as abstract ideas within the "mental process" grouping in the 2019 PEG. For this claim, suitable citations could include *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372-73 (Fed. Cir. 2011) (comparing intangible data about credit cards is a mental process), *University of Utah Research Foundation v. Ambry Genetics Corp.*, 774 F.3d 755, 763-64 (Fed. Cir. 2014) (comparing information regarding a sample or test subject to a control or target data is a mental process), and *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1351-52 (Fed. Cir. 2016) (a generically-recited analysis step is a mental process).

Claim 2 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. Claim 2 depends from claim 1, and adds a wherein clause specifying that the system further comprises a feed dispenser, and that the monitoring component is further configured for performing limitation (d) regarding a control signal that is sent to the feed dispenser. It is important to remember during claim interpretation that no limitations can be disregarded and the mere fact that the limitation appears in a "wherein" clause does not automatically mean that it is not given weight. In this case, when the wherein clause is considered in view of the specification, it is clear that the wherein clause has patentable weight, in that the claim requires the presence of the feed dispenser, and that the monitoring component is further configured for performing limitation (d). Also, because claim 2 is a system claim, its BRI requires the structure for performing the function of limitation (d) to be present, even though that function (sending a control signal) only needs to occur if a condition precedent is met (*i.e.*, when the analysis results for the animal indicate that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany). *See* MPEP 2111.04 (II) for more information about contingent limitations and how they are interpreted in system claims.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Claim 2 depends from claim 1, and thus also recites a machine, which is a statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. Claim 2 depends from claim 1, and thus recites the same limitations (a) and (b). For the reasons discussed above for claim 1, these limitations recite abstract ideas that are considered a single abstract idea for purposes of further eligibility analysis, and the analysis must therefore proceed to Step 2A Prong Two.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine

whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Besides the abstract idea, the claim recites the additional elements of the memory, the display, the processor, the livestock interface, limitations (c) and (d), and the feed dispenser.

The memory, display and processor are no more than mere instructions to apply the judicial exceptions on a computer, and the livestock interface and limitation (c) are insignificant extra-solution activity, for the same reasons as stated previously with respect to claim 1. As discussed above for claim 1, even in combination, these additional elements do not change the computers or other technology recited in the claim. Instead, these additional elements automate the mental processes that the farmer used to perform, using the computer components as a tool. Thus, these additional elements do not improve computer functionality.

Limitation (d) specifies that the monitoring component automatically sends a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with the feed when the analysis results for the animal indicate that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany. Thus, limitation (d) does not merely link the judicial exceptions to a technical field, but instead adds a meaningful limitation in that it can employ the information provided by the judicial exception (the mental analysis of whether the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany) to operate the feed dispenser. As explained in the specification, automatically identifying aberrant behavioral patterns and operating farm equipment based on such identification avoids the need for the farmer to evaluate the behavior of each animal in the herd on a continual basis, and then manually take appropriate action for each animal exhibiting aberrant behaviors. Limitation (d) in combination with the feed dispenser enables the control of appropriate farm equipment based on the automatic detection of grass tetany, which goes beyond merely automating the abstract idea. Using the information obtained via the judicial exception to take corrective action such that the monitoring component is operable to control the feed dispenser in a particular way is an "other meaningful limitation" that integrates the judicial exception into the overall livestock management scheme and accordingly practically applies the exception, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Practice note: Because none of the limitations in claim 2 encompass actually dispensing the therapeutic salt and minerals, there is no limitation in the claim that could invoke the "particular treatment or prophylaxis" consideration. That consideration requires the claim to affirmatively recite an action that effects a particular treatment or prophylaxis for a disease or medical condition. *Cf. Ino Therapeutics LLC v. Praxair Distribution Inc.*, No. 2018-1019, 2019 WL 4023576, at *4 (Fed. Cir. Aug. 27, 2019) (non-precedential) slip op. at 9 and 15 (limitation at issue "does not recite giving any affirmative treatment" and thus did not integrate judicial exception into a practical application). Without such action, there is no treatment or prophylaxis. Nonetheless, as illustrated by the analysis of this claim, the combination of limitation (d) and the feed dispenser invokes the "other meaningful limitation" consideration, and thus makes the claim eligible by integrating the abstract ideas into a practical application.

Claim 3 is *eligible*.

<u>*Claim interpretation*</u>: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. The preamble here does not positively add limitations to the claimed method, or further modify limitations recited in the body of the claim, and thus does not limit

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the claim. Instead, it indicates an intended use for the claimed method, *i.e*., the method is intended for use in monitoring the health and activity of dairy livestock animals.

Based on the specification, the terms "sorting gate," "radio frequency reader" and "processor" are recognized as representing known classes of structures that can perform the functions set forth in the claim, *e.g*., the processor is programmed to compare and analyze data.

Regarding step (a), the claim does not impose any limits on how the livestock animals are caused to enter the sorting gate, *e.g.*, they could be driven by a farmer, they could be walking through the gate on their own initiative on the way to the milking barn or another pasture, etc. Regarding steps (b) and (c), the claim does not impose any limits on how the radio frequency reader obtains the animal-specific information, or on how the analysis of the information is accomplished, and thus it can be performed in any way known to those of ordinary skill in the art. The term "herd" is understood to require the presence of at least three, and more typically many more, livestock animals, and the term "animal-specific information" is understood to be information about a particular animal in the herd, and to comprise animal identification data as well as at least one of body position data, body temperature data, feeding behavior data, and movement pattern data.

Regarding step (d), the claim does not impose any limits on how the sorting gate is operated, for example the gate could be equipped with mechanical, hydraulic, or pneumatic switches that are electronically controlled. This step is a contingent limitation, which requires a first action (operating the gate to route the animal into a holding pen) if a first condition occurs (the analysis results for the animal indicate that the animal is exhibiting an aberrant behavioral pattern), and a second action (operating the gate to permit the animal to freely pass through the sorting gate) if a second condition occurs (the analysis results for the animal indicate that the animal is not exhibiting an aberrant behavioral pattern). The claimed invention may be practiced without the first condition occurring, for instance if no animals exhibit an aberrant behavioral pattern, then no animals will be routed into the holding pen. The claimed invention may also be practiced without the second condition occurring, for instance if all animals exhibit an aberrant behavioral pattern, then all of the animals will be routed into the holding pen and none will pass freely through the sorting gate. However, it is not possible to practice the claimed invention without either the first or the second condition occurring. The claim thus encompasses three separate embodiments: a first embodiment in which only the first condition and first action occur (all animals exhibit aberrant behavioral patterns and are thus routed to the holding pen); a second embodiment in which only the second condition and second action occur (all animals exhibit normal behavioral patterns and are thus permitted to freely pass through the sorting gate); and a third embodiment in which both conditions and both actions occur (some animals exhibit aberrant behavioral patterns and are thus routed to the holding pen, and other animals exhibit normal behavioral patterns and are thus permitted to freely pass through the sorting gate). The broadest reasonable interpretation of the claim encompasses all three of these embodiments. *See* MPEP 2111.04(II) for more information about contingent limitations and how they are interpreted in process claims.

Practice note: The same claim interpretation must be used when evaluating the claim for compliance with all requirements for patentability (*e.g*., eligibility, definiteness, novelty, non-obviousness, written description, etc.). Although limitation (c) recites an abstract idea, this limitation still imposes a limit on the claim scope and serves as a patentable distinction that cannot be ignored. In addition, as explained in the analysis for claim 3, the presence of the contingent limitation in step (d) causes this claim to encompass at least three alternative embodiments with respect to how the sorting gate is operated. A prior art reference need only teach one of these embodiments in order to anticipate the claim, assuming that such reference also teaches each of limitations (a)-(c) and (e). See MPEP 2111.04(II) for more information about how to analyze contingent claim limitations.

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Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. Claim 3 recites a step or act of analyzing animal-specific information, and thus is a process (a series of steps or acts). A process is a statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. Limitation (c) recites a step of "analyzing, by a processor, the obtained animal-specific information with respect to animal information stored in a herd database to identify the animal and to determine whether the animal is exhibiting an aberrant behavioral pattern as compared to the past behavior of the animal."

As is evident from the background of this example, the claimed analysis identifies the animal, *e.g*., observes that the obtained information came from sensor number 22 and thus the animal in question is Daisy. This evaluation also compares the obtained information with the information stored in the herd database for that animal to determine if the animal is exhibiting aberrant behavior as compared to past behavior, *e.g*., Daisy is exhibiting extreme restlessness and muscle twitching, and has been repeatedly lying down and standing up at an increasing frequency as compared to her usual behavior, and thus her behavior is aberrant and fits the early stages of grass tetany (among other possible behavioral patterns). These observations or evaluations are acts that can be practically performed in the human mind, similar to the mental thought processes that occur when a babysitter who is watching identical twin children looks at a temperature read-out of an oral thermometer and determines whether one child has a fever by mentally evaluating whether a measured temperature of 101 degrees Fahrenheit is higher than the child's target temperature of 98.6 degrees, and then verifies the identity of the child by checking the tag sewn into the child's shirt (*e.g*., to identify whether that this is the twin who is prone to ear infections) in order to determine whether the elevated temperature is aberrant for this child.

Such mental evaluations fall within the "mental processes" grouping of abstract idea set forth in the 2019 PEG. 2019 PEG Section I, 84 Fed. Reg. at 52. The recitation of a processor in this claim does not negate the mental nature of these limitations because the claim here merely uses the processor as a tool to perform the otherwise mental processes. *See* October Update at Section I(C)(ii). Thus, limitation (c) recites a concept that fall into the "mental process" grouping of abstract ideas.

Step 2A Prong Two: This part of the eligibility analysis evaluates whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. This evaluation is performed by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception, and (b) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application. 2019 PEG Section III(A)(2), 84 Fed. Reg. at 54-55. Besides the abstract ideas, the claim recites the additional elements of steps (a), (b), (d) and (e), and the processor that performs step (c).

Steps (a) and (e) are nothing more than an attempt to generally link the use of the judicial exception to the particular field of livestock management, by indicating that the claimed method is applied to a herd of livestock. It thus represents only a mere token acquiescence to limiting the reach of the claim to this field, like *Bilski*'s identification of the participants in a process for hedging risk as commodity providers and commodity consumers, which the Supreme Court indicated did no more than describe how the abstract idea of hedging risk could be used in the commodities and energy markets. *See* MPEP 2106.05(h), discussing the limitation in *Bilski v. Kappos*, 561 U.S. 593, 595 (2010), as well as other examples of field of use limitations. Step (b) represents mere data gathering (obtaining the animal-specific information) that is necessary for use of the recited judicial exception (the obtained information is used in the abstract mental analysis) and is recited at a high level of generality. Further, steps (b) and (c) are also recited at a high level of generality and represent no more than mere instructions to apply the judicial exception using generic computer components (the radio frequency reader and processor).

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Even in combination, these additional elements do not change the computers or other technology recited in the claim. Instead, these additional elements automate the mental processes that the farmer used to perform, using the computer components as a tool. *See, e.g.*, *Trading Technologies Int'l, Inc. v. IBG LLC*, 921 F.3d 1084, 1093 (Fed. Cir. 2019) (using a computer to provide a trader with more information to facilitate market trades improved the business process of market trading, but not the computer) and the cases discussed in MPEP 2106.05(a)(I). While this type of automation improves the daily life of farmers, it does not improve computer functionality.

Step (d) specifies that the processor automatically operates the sorting gate to route the animals in the herd based on the behavior of the animals. As explained previously, the BRI of this limitation encompasses three embodiments: a first embodiment in which step (d) routes animals exhibiting aberrant behavioral patterns into a holding pen; a second embodiment in which step (d) permits animals that are exhibiting normal behavior to freely pass through the gate; and a third embodiment in which step (d) requires that both actions take place (some animals are routed to the holding pen, and other animals are permitted to freely pass through the gate). In all of these embodiments, step (d) does not merely link the judicial exception to a technical field, but instead adds a meaningful limitation in that it employs the information provided by the judicial exception (the mental analysis of whether the animal is exhibiting an aberrant behavioral pattern) to operate the gate control mechanism and route the animals, thus avoiding the need for the farmer to visually evaluate the behavior of each animal in the herd on a continual basis. Additionally, the first and third embodiments (which automatically separate animals exhibiting aberrant behavior from the herd by routing them into a holding pen) also avoid the need for the farmer to manually separate each animal exhibiting aberrant behavior from the herd, and thus permit the farmer to devote more time to the care and treatment (if needed) of the separated animals. Thus, under any of the three embodiments, step (d) goes beyond merely automating the abstract ideas and instead actually uses the information obtained via the judicial exception to take corrective action by operating the gate and routing the animals in a particular way. This is an "other meaningful limitation" that integrates the judicial exception into the overall livestock management scheme and accordingly practically applies the exception, such that the claim is not directed to the judicial exception (*Step 2A: NO*). The claim is eligible.

Claim 4 is *eligible*.

Claim interpretation: Under the broadest reasonable interpretation, the terms of the claim are presumed to have their plain meaning consistent with the specification as it would be interpreted by one of ordinary skill in the art. *See* MPEP 2111. The preamble here does not positively add limitations to the claimed system, or further modify limitations recited in the body of the claim, and thus does not limit the claim. Instead, it indicates an intended use for the claimed system, *i.e.*, the system is intended for use in monitoring the health and activity of dairy livestock animals. Based on the specification, the terms "memory," "processor" and "herd monitor" are recognized as representing known classes of structures that can perform the functions set forth in the claim, *e.g.*, the herd monitor has a radio frequency reader for collecting information and a transmitter for sending information, and the processor is programmed to compare and analyze data. The term "animal-specific information" is understood to be information about a particular animal in the herd, and to comprise animal identification data as well as at least one of body position data, body temperature data, feeding behavior data, and movement pattern data. Based on the plain meaning of the words in the claim, the broadest reasonable interpretation of claim 4 is a system having a memory, display, and a herd monitor, wherein the processor is coupled to the memory and programmed with executable instructions in the form of a livestock interface that communicates with the herd monitor.

Step 1: This part of the eligibility analysis evaluates whether the claim falls within any statutory category. MPEP 2106.03. The claim recites a system comprising a combination of concrete devices (a memory,

processor, and radio frequency reader), and therefore is a machine, which is a statutory category of invention (*Step 1: YES*).

Step 2A Prong One: This part of the eligibility analysis evaluates whether the claim recites a judicial exception. As explained in MPEP 2106.04(II) and the October 2019 Update, a claim "recites" a judicial exception when the judicial exception is "set forth" or "described" in the claim. There are no nature-based product limitations in this claim, and thus the markedly different characteristics analysis is not performed. However, the claim still must be reviewed to determine if it recites any other type of judicial exception.

There is no exception recited in the claim. The claim does not recite any abstract ideas, such as a mathematical concept, mental process, or a method of organizing human activity such as a fundamental economic concept or managing interactions between people. The system's operation, like all computers, is based on mathematical theory, but that underlying operation does not trigger an eligibility analysis because it is not set forth or described in the claim. Similarly, while the claim involves the observation of natural phenomena or laws of nature (the behavior of the livestock animals), such limited involvement does not rise to the level of this claim actually reciting a natural phenomenon or law of nature. *See* MPEP 2106.04(II) and October Update at Section I(A) for more information about what "recite" means.

Because the claim does not recite a judicial exception, it cannot be directed to one (*Step 2A: NO*). The claim is eligible.

Practice note: Although claim 4 is eligible, it may be unpatentable for other reasons, and thus it is important to practice compact prosecution by examining each claim for compliance with every statutory requirement for patentability in the initial review of the application. For instance, the examiner should evaluate whether the claim is patentable over prior art, particularly in view of the application's explanation that the components in the system are typical or standard (*e.g.*, off-the-shelf) computer and sensor components, and they are being used in the claim for their intended purposes.