Trends and Changes in View of the USPTO’s Updated Revised Guidance

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How Did We Get Here? – Patent Subject Matter Eligibility

1790 Patent Act

1952 Patent Act

2014 Alice/Mayo

1998-2019 Revised Street Guidance

162 Years

46 Years

1998 State Street

2012 2010 2014 2016 2018
Prometheus Bilski DDR Enfish Dir Iancu Berkheimer

2014 2016 2016 2019
Alice/Mayo McRO Electric Power Group Revised Guidance

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2019 Revised Guidance

• Effective: January 7, 2019

• Comment Period: January 4, 2019 - March 9, 2019

• Purpose:
  – “The legal uncertainty surrounding Section 101 poses unique challenges for the USPTO, which must ensure that its more than 8500 patent examiners and administrative patent judges apply the Alice/Mayo test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields.”
The Alice/Mayo 101 Analysis Framework

Figure 1

- Step 1: Is the claim to a process, machine, manufacture, or composition of matter?
  - Yes: Can claim be amended to fall within a statutory category?
  - No: Can analysis be streamlined?

- When viewed as a whole, is the eligibility of the claim self-evident?
  - Yes: Directed to a law of nature, a natural phenomenon, or an abstract idea?
  - No: Is the claim directed to a law of nature, a natural phenomenon, or an abstract idea?

- Do the claim recite additional elements that amount to significantly more than the judicial exceptions?
  - Yes: Claim qualifies as eligible subject matter under 35 USC §101.
  - No: Claim is not eligible subject matter under 35 USC §101.
Revised Guidance - Creation of New 101 Analysis Framework

**Figure 2**

- **Streamlined Analysis**
  - **Prong One**: Does the claim recite an abstract idea, law of nature, or natural phenomenon?
    - **Pathway B**
      - The claim is not directed to a judicial exception.
    - **Yes**: Prong Two
      - Does the claim recite additional elements that integrate the judicial exception into a practical application?
        - **No**: Step 2B
        - **Yes**: Claim qualifies as eligible subject matter under 35 U.S.C. 101
  - **No**: Step 2B
Key Decision Points for the 2019 Revised Guidance

**Judicial Exception**
- Identify specific limitation that is considered directed to abstract concept
- Limitations must be mapped to one of three Enumerated Groupings

**Practical Application**
- Does identified limitation integrates judicial exception into a practical application?
- Well-understood, routine, conventional activities can satisfy this test

**Significantly More**
- Do remaining claim elements can establish significantly more” than the exception itself
- Claim limitations not satisfying practical application test can be considered for establishing significantly more
Example 37 – Relocation of Icons on a Graphical User Interface

Example 38 – Simulating an Analog Audio Mixer

Example 39 – Method for Training a Neural Network for Facial Detection

Example 40 – Adaptive Monitoring of Network Traffic Data

Example 41 – Cryptographic Communications

Example 42 – Method of Transmission of Notifications When Medical Records Are Updated
October 17 – Revised Guidance Updates

1 Discussion and Clarification of Revised Guidance

2 Additional Life Sciences and Data Processing Examples 43-46

3 Index of Subject Matter Eligibility Examples
Discussion and Clarification of Revised Guidance
Revised Guidance – Step 2A – Prong One

**Figure 2**

Streamlined Analysis

**REVISED STEP 2A**

PRONG ONE
Does the Claim Recite An Abstract Idea, Law Of Nature, or Natural Phenomenon?

- **NO**
  - PATHWAY B1: The claim is not directed to a judicial exception.

- **YES**
  - PRONG TWO
    - Does the Claim Recite Additional Elements That Integrate The Judicial Exception Into A Practical Application?
      - **NO**
        - **Claim Qualifies As Eligible Subject Matter Under 35 U.S.C. 101**
      - **YES**
        - **Step 2B**
Evaluation of Whether a Claim Recites a Judicial Exception

• Meaning of “Recites”

  – Step 2A – Prong One: Determine whether claim recites a judicial exception

  – Claim “recites” a judicial exception when the judicial exception is “set forth” or “described” in the claim
    o Set Forth – Claims clearly state the judicial exception (e.g., clearly state a mathematical equation)
    o Describe – Claims do not explicitly state the judicial exception but the concept of the judicial exception can be identified (e.g., recitation of the concept of intermediated settlement without recitation of the terms “intermediated” or “settlement”)
Evaluation of Whether a Claim Recites a Judicial Exception

• Multiple Judicial Exceptions
  – Distinct claim elements can be treated separately
  – Examiners should not parse claims even if multiple groupings may apply
  – Examiners should consider the limitations together to avoid a plurality of separate abstract idea calculations

• Revised Guidance Examples – Multiple Judicial Exceptions
  – Example 43 – Treating Kidney Disease
    (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;
  – Example 45 – Controller for Injection Mold
    (b) calculate an extent of curing completion of polyurethane in the mold using the obtained temperatures and the Arrhenius equation;
Judicial Exceptions – Subject Matter Groupings

MATHEMATICAL CONCEPTS
Mathematical relationships, mathematical formulas or equations, mathematical calculations

CERTAIN METHODS OF ORGANIZING HUMAN ACTIVITY
Fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions)

MENTAL PROCESSES
Concepts performed in the human mind (including an observation, evaluation, judgment, opinion)
Role of Examples and Case Law in Interaction with the USPTO

• One Way Street – Can the USPTO Rely on Examples?
  – 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.

• October Update – Steering Away from Case Law
  – As further explained in the 2019 PEG, the Office has shifted its approach from the case-comparison approach in determining whether a claim recites an abstract idea and instead uses enumerated groupings of abstract ideas. The enumerated groupings are firmly rooted in Supreme Court precedent as well as Federal Circuit decisions interpreting that precedent. By grouping the abstract ideas, the 2019 PEG shifts examiners’ focus from relying on individual cases to generally applying the wide body of case law spanning all technologies and claim types. In sum, the 2019 PEG synthesizes the holdings of various court decisions to facilitate examination.
Guidance on Mathematical Concepts – October Update

• Mathematical Concepts:
  – Mathematical relationships:
    o “A mathematical relationship is a relationship between variables or numbers. A mathematical relationship may be expressed in words or using mathematical symbols.”
  – Mathematical formulas or equations:
    o “A claim that recites a numerical formula or equation will be considered as falling within the “mathematical concepts” grouping. In addition, there are instances where a formula or equation is written in text format that should also be considered as falling within this grouping.”
  – Mathematical calculations:
    o “A claim that recites a mathematical calculation will be considered as falling within the “mathematical concepts” grouping. There is no particular word or set of words that indicates a claim recites a mathematical calculation.”
    o “For example, a step of “determining” a variable or number using mathematical methods or “performing” a mathematical operation may also be considered mathematical calculations when the broadest reasonable interpretation of the claim in light of the specification encompasses a mathematical calculation.”
Guidance on Mathematical Concepts

• Examiners should consider whether the claim recites a mathematical concept or merely includes limitations that are based on or involve a mathematical concept.
  – Claims do not recite a mathematical concept if it is only based on or involves mathematical concepts.

• Revised Guidance Examples – Recitation of Mathematical Concepts
  – Example 41 – Cryptographic Communications
    encoding each of the message block word signals MA to produce a ciphertext word signal CA, whereby CA=MAe (mod n);
      where CA is a number representative of an encoded form of message word MA;
      where MA corresponds to a number representative of a message and 0 ≤ MA ≤ n-1;
      where n is a composite number of the form n=p*q;
      where p and q are prime numbers;
      where e is a number relatively prime to (p-1)*(q-1);
  – Example 45 – Controller for Injection 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
Guidance on Mathematical Concepts – No Judicial Exception

• Example 39 – Method for Training a Neural Network for Facial Detection
  A computer-implemented method of training a neural network for facial detection comprising:
  - collecting a set of digital facial images from a database;
  - applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images;
  - creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;
  - training the neural network in a first stage using the first training set;
  - set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and
  - training the neural network in a second stage using the second training set.

• “[T]he claim does not recite any mathematical relationships, formulas, or calculations. While some of the limitations may be based on mathematical concepts, the mathematical concepts are not recited in the claims.”
Guidance on Certain Methods of Organizing Human Activity

• The term “certain” qualifies the “certain methods of organizing human activity” grouping as a reminder of several important points.

• Not all methods of organizing human activity are abstract ideas (e.g., “a defined set of steps for combining particular ingredients to create a drug formulation” is not a “certain method of organizing human activity”).

• The grouping is limited to activity that falls within the enumerated sub-groupings of:
  – Fundamental economic principles or practices:
    o Subject matter related to hedging, insurance, and mitigating risk.
    o Examples 35 and 36
  – Commercial or legal interactions:
    o Subject matter relating to agreements in the form of contracts, legal obligations, advertising, marketing or sales activities or behaviors, and business relations.
    o Examples 6 and 7
  – Managing personal behavior or relationships or interactions between people:
    o Subject matter related to social activities, teaching, and following rules or instructions.
    o Examples 6, 7 and 42

• The grouping are not generally to be expanded beyond these.
Guidance on Mental Processes

- Mental processes grouping is defined as concepts performed in the human mind, and examples of mental processes include observations, evaluations, judgments, and opinions.

- Claims do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations.

- Claims can recite a mental process even if they are claimed as being performed on a computer.

- The use of a physical aid (i.e., the pen and paper) to help perform a mental step (e.g., a mathematical calculation) does not negate the mental nature of this limitation.
• Example 37 – Relation of Icons on a Graphical User Interface (Claim 2)
  A method of rearranging icons on a graphical user interface (GUI) of a computer system, the method comprising:

  receiving, via the GUI, a user selection to organize each icon based on a specific criteria, wherein the specific criteria is an amount of use of each icon;

  determining the amount of use of each icon using a processor that tracks how much memory has been allocated to each application associated with each icon over a predetermined period of time; and

  automatically moving the most used icons to a position on the GUI closest to the start icon of the computer system based on the determined amount of use.

• USPTO Analysis: For instance, the claim does not recite a mental process because the claim, under its broadest reasonable interpretation, does not cover performance in the mind but for the recitation of generic computer components. For example, the “determining step” now requires action by a processor that cannot be practically applied in the mind. In particular, the claimed step of determining the amount of use of each icon by tracking how much memory has been allocated to each application associated with each icon over a predetermined period of time is not practically performed in the human mind, at least because it requires a processor accessing computer memory indicative of application usage.
• Example 38 – Simulating an Analog Audio Mixer
  A method for providing a digital computer simulation of an analog audio mixer
  comprising:
  initializing a model of an analog circuit in the digital computer, said model including
  a location, initial value, and a manufacturing tolerance range for each of the circuit
  elements within the analog circuit;
  generating a normally distributed first random value for each circuit element, using
  a pseudo random number generator, based on a respective initial value and
  manufacturing tolerance range; and
  simulating a first digital representation of the analog circuit based on the first
  random value and the location of each circuit element within the analog circuit.

• USPTO Analysis: “With respect to mental processes, the claim does not recite a mental
  process because the steps are not practically performed in the human mind.”
Guidance on Mental Processes – Revised Guidance Examples

• Example 39 – Method for Training a Neural Network for Facial Detection
  A computer-implemented method of training a neural network for facial detection comprising:
  
  collecting a set of digital facial images from a database;
  applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images;
  creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;
  training the neural network in a first stage using the first training set;
  set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and
  training the neural network in a second stage using the second training set.

• USPTO Analysis: “[T]he claim does not recite a mental process because the steps are not practically performed in the human mind.”
Revised Guidance – Step 2A – Prong Two

Figure 2

Streamlined Analysis

REVISED STEP 2A

PRONG ONE
Does The Claim Recite An Abstract Idea, Law Of Nature, or Natural Phenomenon?

YES

PATHWAY B:
The claim is not directed to a judicial exception.

NO

PRONG TWO
Does The Claim Recite Additional Elements That Integrate The Judicial Exception Into A Practical Application?

YES

Claim Qualifies As Eligible Subject Matter Under 35 U.S.C. 101

NO

Step 2B
Step 2A – Prong 2 - Integration into Practical Application

Improvements in the Functioning of a Computer or Improvement to Other Technology

• “[A] n important consideration to evaluate when determining whether the claim as a whole integrates a judicial exception into a practical application is whether the claimed invention improves the functioning of a computer or other technology. The courts have not provided an explicit test for this consideration.”

• Test for Practical Application
  • Evaluate the specification to determine if the disclosure provides sufficient details such that one of ordinary skill in the art would recognize the claimed invention as providing an improvement.
  • Second, if the specification sets forth an improvement in technology, the claim must be evaluated to ensure that the claim itself reflects the disclosed improvement.

• “The “improvements” analysis in Step 2A determines whether the claim pertains to an improvement to the functioning of a computer or to another technology without reference to what is well-understood, routine, conventional activity.”

• “Improvement in the judicial exception itself (e.g., a recited fundamental economic concept) is not an improvement in technology.”
Step 2A – Prong 2 - Integration into Practical Application

Improvements in the Functioning of a Computer or Improvement to Other Technology

• Test for Practical Application
• Evaluating the Specification
  • The specification need not explicitly set forth the improvement, but it must describe the invention such that the improvement would be apparent to one of ordinary skill in the art.
  • Conversely, if the specification explicitly sets forth an improvement but in a conclusory manner (i.e., a bare assertion of an improvement without the detail necessary to be apparent to a person of ordinary skill in the art), the examiner should not determine the claim improves technology.
• Claim Reflects the Disclosed Improvement.
  • The claim includes the components or steps of the invention that provide the improvement described in the specification.
  • The claim itself does not need to explicitly recite the improvement described in the specification (e.g., “thereby increasing the bandwidth of the channel”).
Step 2A – Prong 2 - Integration into Practical Application

Applying or Using a Judicial Exception to Effect a Particular Treatment or Prophylaxis for a Disease or Medical Condition

• “[A] a claim can integrate a judicial exception into a practical application by applying or using the judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition.”

• Test for Practical Application
  • The Particularity Or Generality Of The Treatment Or Prophylaxis
    • The treatment or prophylaxis limitation must be “particular,” i.e., specifically identified so that it does not encompass all applications of the judicial exception(s).
  • Whether The Limitation(s) Have More Than A Nominal Or Insignificant Relationship To The Exception(s)
    • The treatment or prophylaxis limitation must have more than a nominal or insignificant relationship to the exception(s).
  • Whether The Limitation(s) Are Merely Extra-Solution Activity Or A Field Of Use
    • The treatment or prophylaxis limitation must impose meaningful limits on the judicial exception, and cannot be extra-solution activity or a field-of-use.
Examination of Application – USPTO’s Duty to Establish a Prima Facie Case

• Step 2A – Prong One
  – The rejection should identify the judicial exception (i.e., abstract idea enumerated in Section I of the 2019 PEG, laws of nature, or a natural phenomenon) by referring to what is recited (i.e., set forth or described) in the claim and explaining why it is considered to be an exception (Step 2A Prong One).
  – There is no requirement for the examiner to provide further support, such as publications or an affidavit or declaration under 37 CFR 1.104(d)(2), for the conclusion that a claim recites a judicial exception.

• Step 2A – Prong Two
  – The rejection should identify any additional elements recited in the claim beyond the judicial exception and evaluate the integration of the judicial exception into a practical application by explaining that 1) there are no additional elements in the claim; or 2) the claim as a whole, looking at the additional elements individually and in combination, does not integrate the judicial exception into a practical application using the considerations set forth in the 2019 PEG (Step 2A Prong Two).

• Step 2B – Significantly More
  – The examiner should explain why the additional elements, taken individually and in combination, do not result in the claim, as a whole, amounting to significantly more than the exception (Step 2B).
Life Sciences and Data Processing Examples – Examples 43 - 46
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).
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.
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.
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.
<table>
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<th>Tips</th>
<th>Drafting Tips</th>
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<td></td>
<td>Continue to review new disclosures with a critical eye (this advice has been</td>
<td>Interview every 101 rejection as many Examiners are indicating that they will</td>
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<td>consistent since Bilski)</td>
<td>withdraw the 101 rejection without the need for further written argument</td>
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<td>Continue to use technical problem/technical solution approach</td>
<td>Be prepared to walk through the entire Revised Guidance analysis</td>
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<td>Look to include additional language/discussion helping support the “practical</td>
<td>For the time being, include arguments for why the claims recite patent eligible</td>
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<td>application”</td>
<td>subject matter under BOTH the revised guidelines and the case law</td>
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<td>The “practical application” should dovetail nicely with the “technical solution”</td>
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