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What's New in Patent Prosecution in the US and EPO

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Meet the Speakers

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Agenda

- US and EPO Standards for Enablement and Written Description
- US and EPO Approaches to Subject Matter Eligibility, including for AI Inventions
- Recent Developments at the EPO and in the US relating the On-Sale Bar

Standards for Enablement and Written Description

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US Standards for Enablement and Written Description

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US Standards - Enablement and Written Description

35 U.S.C. § 112(a)(applicable to applications filed on or after September 16, 2012)

(a) IN GENERAL—The specification shall contain

a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms

as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and

shall set forth the **best mode** contemplated by the inventor or joint inventor of carrying out the invention.

These three requirements are separate and distinct from each other

US Standards for Enablement – US Supreme Court

Amgen, Inc. v. Sanofi, 598 U.S. 594 (2023)

- Amgen's two patents relating to antibodies that reduce high cholesterol, claimed only by their binding and inhibiting functions to a specific target protein, which was the main invention
- Functional Claims
  - 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, 1154, P155, R194, D238, A239, 1369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
  - 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.
- Claims define the antibodies not by structure, but by binding function

US Standards for Enablement – US Supreme Court

Amgen, Inc. v. Sanofi, 598 U.S. 594 (2023)

- Court agreed with Sanofi that claims cover "a vast number" (millions) of antibodies, but the patents provided details for only 26
- "If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, **the patent's specification must enable a person skilled in the art to make and use the entire class.** In other words, the specification **must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.**" Id. at 610.
- Court unanimously held Amgen's broad functional claims **invalid** for lack of enablement

US Standards for Enablement

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

- US Synthetic (USS) filed complaint with the ITC, alleging intervenors infringed patents claiming polycrystalline diamond compact (PDC) compositions
- ALJ and ITC rejected intervenor's argument that the claims lacked enablement, but held the invention was patent-ineligible under §101 as an abstract idea, because the relationship of the claimed compositions and their magnetic properties were too "loose and generalized"
- On appeal, intervenor relied heavily on *Amgen v Sanofi* to support their lack of enablement arguments that the ITC's "loose and generalized" determination in the 101 analysis is tantamount to unpredictability, thereby supporting a conclusion of lack of enablement

US Standards for Enablement

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

- FC noted that notwithstanding their concern with the "loose and generalized" determination for § 101 purposes, these "decontextualized words" are not grounds to disturb the Commission's express, separate findings on enablement
- FC noted that *Amgen* applied the same statutory enablement requirement that the Supreme Court has enforced for more than 150 years
- *Amgen* also reinforced that a specification may call for a reasonable amount of experimentation to make and use a patented invention and what is reasonable in any case will depend on the nature of the invention and the underlying art

US Standards for Enablement

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

FC held that ITC made no error in concluding the intervenor failed to prove a lack of enablement under § 112(a), and reversed on 101

Key Takeaways – If faced with a lack of enablement rejection, try to argue that the specification provides at least enough information that any amount of experimentation required would be reasonable based on the specific nature of your invention and the specific prior art in your case

US Standards for Enablement - Post-*Amgen*

Key Takeaways

- More predictability in underlying art = more likely experimentation will be “reasonable”
- Avoid purely functional language in claims – still judged more harshly after *Amgen*
- Draft claims to recite specific details of specific method steps and avoid drafting claims too broadly, as scope of enablement must meet the full scope of the claims
- Specification must include clear guidance on how to make and use – not recipe for trial and error
- For software/AI cases - not sufficient to merely recite method steps in the specification without further details of how to make and use the underlying software or AI model to enable the claims
- Include examples of actual use in all areas of technology, e.g., many different antibodies, many different compositions, and actual use of software/AI model with actual input data and output data

US Standards for Written Description

Impact Engine, Inc. v. Google LLC, 2024 WL 3287126 (Fed. Cir., July 3, 2024)

- Patents describe and claim “systems and methods for creating, editing, sharing and distributing high-quality, media-rich web-based communications”
- Claim 30 recites an online advertisement generation system for autonomously generating and broadcasting a communication, comprising a “compiling engine” that performed certain functions
- DC held claim 30 invalid for lack of written description and lack of enablement (112(a))
  - The specification “does not disclose any information or mechanism that would inform a person of skill in the art how a compiler as construed”—“a program that translates source code into machine or object code”—also performs the claimed functions

US Standards for Written Description

Impact Engine, Inc. v. Google LLC, 2024 WL 3287126 (Fed. Cir., July 3, 2024)

- FC affirmed the rejection under 112(a) based on lack of written description
- For written description to be adequate, patent must describe the claimed compiling engine **with all of the specific functions recited in the claim**
  - "integrating the at least one selected media asset with the at least one selected online advertisement template" and
  - "grouping the design layers, design elements, and content containers into the collection of slides so as to generate the communication capable of being rendered in a manner so as to be content specific to the user data, keyword data, and geographic data"
- The patent specification nowhere contains that description
  - Patent shows a "compiler" as a black-box functionality
  - No description of "compiling engine" that provides the claimed functions

US Standards for Written Description

Impact Engine, Inc. v. Google LLC, 2024 WL 3287126 (Fed. Cir., July 3, 2024)

- Even an enabling disclosure may not suffice to meet the written description requirement – a skilled artisan might know how to implement a functionality, as Impact Engine's expert argued, but no evidence here the inventor possessed that functionality
- Claim 30 invalid as a matter of law for lack of written description

Key Takeaways

- Be careful not to rely merely on black-box flow charts to support claims that you may need to amend during prosecution to include more details that may be in the application, but not sufficiently clearly described in the application to show possession of the claimed invention
- Do not rely to much on what you think a skilled person can implement

US Standards for Written Description

In re Xencor Inc., __ F.4th __, 2025 WL 793963 (Fed. Cir., July 3, 2024)

- Application describes modifying antibodies with certain amino acid substitutions to provide longer half-life and reduce number of treatments
- Provides one example of an anti-C5 antibody, 5G1.1
- Application includes Jepson claim and method of treatment claim
  - In a method of treating a patient by administering an anti-C5 antibody…, the improvement comprising…. [specific aa substitutions]
  - A method of treating a patient by administering an anti-C5 antibody comprising [means for binding, and specific aa substitutions]
- Board concluded preambles of claims were limiting and Xencor had failed to show sufficient written description and failed to show anti-C5 antibodies were well-known in the art

US Standards for Written Description

In re Xencor Inc., __ F.4th __, 2025 WL 793963 (Fed. Cir. July 3, 2024)

- Affirmed on rehearing by Board
- Appeal Review Panel held preambles limiting and WD is required for Jepson preambles, but lacking here
- “treating a patient” is not merely a statement of purpose but is necessary to give meaning to the claim, because the claim associates a therapeutic use with the “increased in vivo half-life” of the antibodies
- Xencor argued method claim's preamble of “treating a patient” is not limiting, that preamble of Jepson claim does not require WD or that WD was satisfied for the preambles of both claims

US Standards for Written Description

In re Xencor Inc., __ F.4th __, 2025 WL 793963 (Fed. Cir. July 3, 2024)

- FC affirmed lack of written description, holding:
  1) phrase "treating a patient" in preamble of method claim was limiting
     - The preamble informs the meaning of the claim language
  2) substantial evidence supported determination that application did not satisfy written description requirement for "treating a patient"
     - application "does not define the term 'treating,' and it does not describe or provide any data associated with treating any patient with any disease or condition with any anti-C5 antibody
  3) Jepson claim preamble required written description
     - In Jepson format, the inventor must provide written description sufficient to show possession of the claimed improvement to what was known in the prior art

US Standards for Written Description

In re Xencor Inc., __ F.4th __, 2025 WL 793963 (Fed. Cir. July 3, 2024)

- (4) evidence supported determination that application did not satisfy WD requirement for prior art limitation in Jepson claim preamble
  - applicant must establish that what is claimed to be well-known in the prior art is, in fact, well-known in the prior art
  - Applicant failed to show the anti-C5 antibodies were well-known in the art
  - Applicant's expert not credible

Key Takeaways

- If use Jepson format, be especially careful to describe in detail how the improvement is applied to the prior art
- Use a solid, trustworthy expert

EPO Standards for Enablement and Written Description

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EP Standards for Enablement

Article 83 EPC: The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- Two main standards depending on the type of claim:

- For most types of claims, a successful objection of lack of sufficiency presupposed that there were serious doubts substantiated by verifiable facts
  - Examiner/Opponent carries the burden

- For medical use claims, the application must provide some information in the form of, for example, experimental tests that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease
  - Applicant/Patentee carries the burden

EP Standards for Enablement

The “at least one way” and “whole range claimed” requirements:

- At least one way: An invention is sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention.

- Over the whole range claimed: A skilled person must be able to carry out the invention as defined in the independent claims over the whole scope of the claims without undue burden.

EP Standards for Enablement

Non-Working Embodiments

- If there is a large number of conceivable alternatives and the specification contains sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with reasonable effort, the inclusion of non-working embodiments is of **no** harm.

- If the specification does **not** contain sufficient information for finding appropriate alternatives, there is lack of reproducibility of the claimed invention, the inclusion of non-working embodiments leads to an insufficient disclosure.

EP Enablement and the Concept of Plausibility

Where do the two different standards come from?

- The Enlarged Board decision G 1/03 states:
  - "… If this is not the case and there is lack of reproducibility of the claimed invention, this may become relevant under the requirements of inventive step or sufficiency of disclosure. *If an* **effect is expressed in** *a claim*, there is lack of **sufficient disclosure**. Otherwise, i.e. *if the* **effect is not expressed** in a claim but is *part of the problem to be solved*, there is a problem of **inventive step**."

- Typical example (in the life sciences at least) of a claim where "an effect is expressed in a claim": a method of treatment claim
- Typical example of a claim where "an effect is not expressed in a claim": a compound/composition of matter claim

EP Enablement and the Concept of Plausibility

Origin of the term “Plausibility” in the Case Law

T 1329/04:

- “The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.”

  - To have an invention, the applicants must at least make it plausible to conclude that a technical problem has been solved.

Admissibility of Post-Filing Evidence

The Enlarged Board decision G 2/21 provides guidance with respect to inventive step:

"A patent applicant or proprietor may rely upon a technical effect for inventive step … if the skilled person … would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention."

- What is a technical teaching?
  - patent protection is reserved for inventions involving a "technical teaching", i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means. [EPO Guidelines, G-II.2]

Post-Filing Evidence for Enablement?

- the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC)
- the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved

[G 1/22, Reasons 77]

Decisions confirming that approach: "In accordance with the finding of the Enlarged Board of Appeal in decision G 2/21, Reasons 77, the proof of the effect recited in claims 1 and 6 had to be provided in the application as filed. A deficiency in this respect cannot be remedied by post-published evidence." [G 166/22, Reasons 5]

The strict requirements of Art. 123(2) EPC

- The European patent **application** or European patent may not be amended in such a way that it contains subject-matter which **extends beyond the content of the application as filed**.

- The European **patent** may not be amended in such a way as **to extend the protection it confers**.

- The standard applied by the EPO is that the amended claim must be **directly and unambiguously derivable** from the application as filed.

Ideally verbatim support

Ideally in the claims / claim-like language

Art. 123(2) EPC – Typical Issues

- Selecting features from the drawings is **possible, but problematic**.

- Selecting a feature from a **particular embodiment and adding it to a claim** (an “intermediate generalization”), is **only possible if**:
  1. the feature is not related or inextricably linked to the other features of that embodiment and
  2. the overall disclosure justifies the generalizing isolation of the feature and its introduction into the claim

- **Removing a feature** from an original independent claim is usually **not possible**

- **Selecting features from two or more lists** is usually **not possible**

Summary and Comparison US vs. EP

US Enablement/Written Description Standards

- These are separate requirements and are analyzed separately
- Any experimentation required to enable the full scope of a claimed invention must be reasonable
- The *Wands* factors can still be applied to determine "Reasonableness of Experimentation"
- Post-*Amgen*, enablement attacks are more likely, and more likely to be successful, in particular with purely functional claim language, regardless of technology
- Must show written description of all elements of the claim, including the preamble

EP Enablement/Written Description Standards

- A skilled person must be able to carry out the invention over the whole scope of the claims without undue experimentation
- Whether there is an undue burden is examined on a case-by-case basis
- As an examiner/opponent carries the burden to substantiate serious doubts that an invention does not work, enablement attacks are rarely successful in most areas of technology
- The EPO has a context-sensitive, strict written description requirement; its violation is dangerous

US Approaches to Subject Matter Eligibility

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US Approaches to Subject Matter Eligibility

35 U.S.C. 101 - Inventions patentable

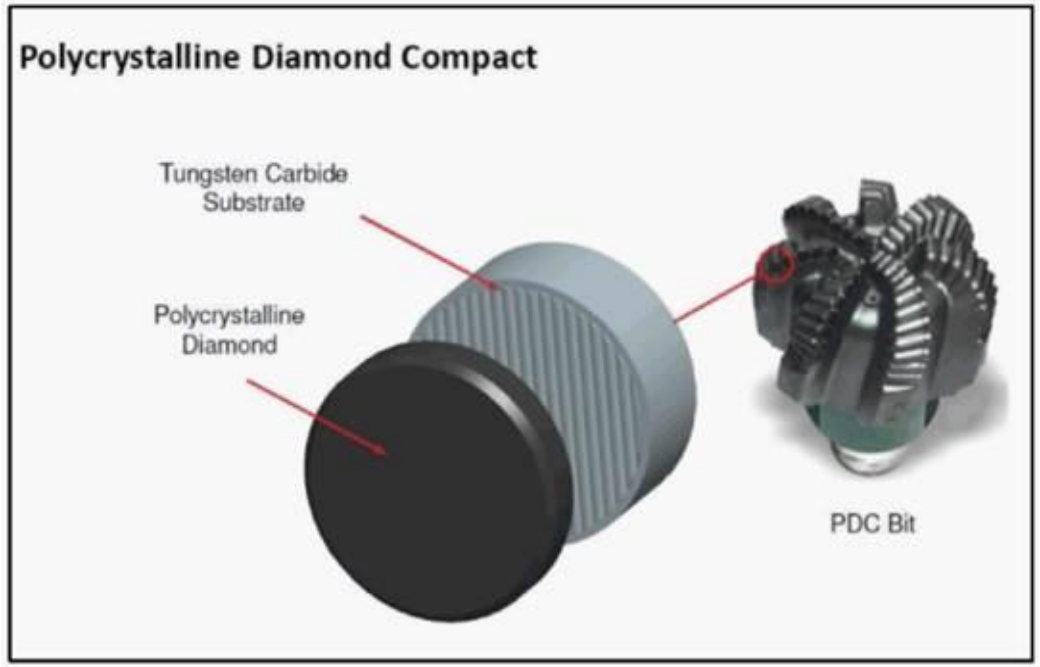
- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title

- A claimed invention must be eligible for patenting:
  a) first, a claimed invention must fall within one of the four statutory categories of invention set forth in **35 U.S.C. 101**, i.e., process, machine, manufacture, or composition of matter; and
  b) second, a claimed invention must be directed to patent-eligible subject matter and not a judicial exception (abstract ideas, laws of nature, and natural phenomena (including products of nature)) *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208, 216, 110 USPQ2d 1976, 1980 (2014)

US Approaches to Subject Matter Eligibility

***US Synthetic Corp. v. International Trade Commission*, 128 F.4th 1272 (Fed. Cir., February 13, 2025)**

- US Synthetic (USS) filed complaint with the ITC, alleging intervenors infringed patents claiming polycrystalline diamond compact (PDC) compositions



US Approaches to Subject Matter Eligibility

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

1. A polycrystalline diamond compact, comprising:
   - a polycrystalline diamond table, at least an unleached portion of the polycrystalline diamond table including:
   - a plurality of diamond grains bonded together and … exhibiting an average grain size of about 50 μm or less; and
   - a catalyst including cobalt, …
     - wherein the unleached portion of the polycrystalline diamond table exhibits a coercivity of about 115 Oe to about 250 Oe;
       - wherein the unleached portion of the polycrystalline diamond table exhibits a specific permeability less than about 0.10; and
       - a substrate bonded to the polycrystalline diamond table along an interfacial surface, the interfacial surface exhibiting a substantially planar topography, wherein a lateral dimension of the polycrystalline diamond table is about 0.8 cm to about 1.9 cm.

US Approaches to Subject Matter Eligibility

***US Synthetic Corp. v. International Trade Commission,* 128 F.4th 1272 (Fed. Cir., February 13, 2025)**

- Respondents argued claims were directed to natural phenomenon
- ALJ and ITC found patents patent-ineligible under §101, but as abstract ideas, because the relationship of the claimed compositions and their magnetic properties were too "loose and generalized," but rejected intervenor's argument that the claims lacked enablement
- ITC at *Alice* step one, determined that "the claims are directed to the abstract idea of PDCs that achieve ... desired magnetic ... results, which the specifications posit may be derived from enhanced diamond-to-diamond bonding"
- The magnetic properties are mere "side effects"

US Approaches to Subject Matter Eligibility

***US Synthetic Corp. v. International Trade Commission,* 128 F.4th 1272 (Fed. Cir., February 13, 2025)**

- FC held:
  1. claims were not directed to an abstract idea;
  2. specification sufficiently disclosed relationship between magnetic properties of PDC composition and its structure
- ***Alice* Step 1** - consider the claims "in their entirety to ascertain whether their character as a whole is directed to excluded subject matter"
  - If the claims are not directed to an abstract idea at *Alice* Step 1, the inquiry ends; if the claims are directed to an abstract idea, we continue with *Alice* Step 2

US Approaches to Subject Matter Eligibility

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

- ***Alice* Step 2** - consider "the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application."
- Applying *Alice* Step 1, we conclude that the asserted claims are not directed to an abstract idea
  - claims are directed to a specific, non-abstract composition of matter—a PDC—that is defined by its constituent elements (i.e., diamond, cobalt catalyst, substrate), particular dimensional information, and quantified material magnetic properties
  - the material properties correlate to the diamond table's structure and thereby further inform a skilled artisan about the claimed PDC.
  - We reach this conclusion by reading the claims as a whole and in light of the specification

US Approaches to Subject Matter Eligibility

***US Synthetic Corp. v. International Trade Commission*, 128 F.4th 1272 (Fed. Cir., February 13, 2025)**

- At the core of the Commission's erroneous step 1 analysis is a view that the patent's disclosed relationship between the claimed magnetic properties and the structure of the PDC "is so loose and generalized that the claimed limitations appear to be little more than side effects"
- ITC relied on the specification's use of "may" to support its position that the disclosed correlation between the structural and magnetic properties is too weak and equivocal
- The patent demonstrates that the described correlations are concrete and meaningful, rather than something that is merely speculative

US Approaches to Subject Matter Eligibility

US Synthetic Corp. v. International Trade Commission, 128 F.4th 1272 (Fed. Cir., February 13, 2025)

- The working examples show that the claimed magnetic properties are indicative of a diamond table with “significantly less cobalt” and “a lower mean free path between diamond grains” compared to prior art diamond tables.
- The claimed PDC is not an abstract result of generic computer functionality, but instead is a physical composition of matter defined by its constituent elements, dimensional information, and inherent material properties

Key Takeaways

- Make sure to include significant details and any actual data you have to support correlations between physical structures/compositions with any beneficial material properties
- Avoid the use of “may” and instead use more concrete language

US Approaches to Subject Matter Eligibility

***Ex Parte Yudong Cao, Appeal 2024-002159, Application No. 16/591,239* (USPTO PTAB, February 13, 2025) [Zapata Computing, real party]**

- The claimed invention relates to hybrid quantum-classical computer for solving linear systems
- Claims to a method for preparing a quantum state that approaches a solution to a linear system of equations…, comprising,
  - (a) on a classical computer, generating an objective function …; and
  - (b) training a set of circuit parameters…, comprising:
    - (1) on a quantum computer, controlling…,
    - (2) on the quantum computer, obtaining a measured sample…,
    - (3) on the classical computer… and
    - (4) on the classical computer….
- PTAB reversed Examiner's rejection under Section 101

US Approaches to Subject Matter Eligibility

***Ex Parte Yudong Cao, Appeal 2024-002159, Application No. 16/591,239* (USPTO PTAB, February 13, 2025)[Zapata Computing, real party]**

- PTAB followed *Alice* two-step analysis
  - Claim is "directed to" **a judicial exception** – abstract idea
  - The "directed to" inquiry applies a stage-one filter to claims, considered in the light of the specification, based on whether their character as a whole is directed to excluded subject matter (*Enfish v. Microsoft*, 822 F.3d 1327, 1335 (Fed. Cir. 2016)
- Under Step 2A, Prong 2, we determine whether additional elements integrate the abstract idea into a practical application, e.g., an improvement to a technology or technical field

US Approaches to Subject Matter Eligibility

***Ex Parte Yudong Cao, Appeal 2024-002159, Application No. 16/591,239* (USPTO PTAB, February 13, 2025)[Zapata Computing, real party]**

- Examiner combined Step 2A, Prong 1, Step 2, Prong 2, and Step 2B analysis, but fails to provide adequate analysis under Step 2A, Prong 2 to support the rejection
- The additional elements of controlling a plurality of qubits on a quantum computer are the focus of the invention, not just data gathering, and integrate the abstract idea of mathematical relationships into a practical application of enabling noisy quantum computers to solve linear systems
- A clear technology improvement
- Specification describes prior art deficiency of being unable to use quantum computers to solve linear systems, and the present improvement

US Approaches to Subject Matter Eligibility

***Ex Parte Yudong Cao, Appeal 2024-002159, Application No. 16/591,239* (USPTO PTAB, February 13, 2025) [Zapata Computing, real party]**

- Because the additional elements integrate the mathematical relationships into a practical application, claim 1 is not directed to an abstract idea
- Reversed examiner's rejection under Section 101
- PTAB also reversed lack of written description rejection under Section 112(a)

Key Takeaways

- Make sure to expressly disclose both an existing problem and how the invention provides a solution in the form of a technical improvement when drafting your application
- Draft your application to highlight how the invention integrates any algorithms or other mathematical features into a practical application

US Approaches to Subject Matter Eligibility - AI

Can Inventions Made Using AI be Patented?

Short Answer – Yes (USPTO Guidance on AI and Patents, issued on February 13, 2024, with updated Examples 47-49 issued July 17, 2024)

- The use of an AI system by a natural person(s) **does not preclude** a natural person(s) from qualifying as an inventor(s) if the natural person(s) significantly contributed to the claimed invention
- One can file patent applications for inventions created using AI as a tool, like other tools, but only if a human made a "significant contribution" to the invention
- Such inventions still need to have proper inventorship and meet the requirements for patentability
  - Proper inventorship by human inventors
  - 101 – Patentable Subject Matter
  - 112 – Written Description and Enablement
  - 102/103 – Novelty and Non-Obviousness

US Approaches to Subject Matter Eligibility - AI

Can Inventions Made Using AI be Patented?

- USPTO Guidance on AI and Patents, issued on July 17, 2024 (with updated Ex. 47-49)
- While it is common for claims to AI inventions to involve abstract ideas, examiners must draw a distinction between claims that "recite" an abstract idea (and require further analysis) and claims the are based on an abstract idea (see MPEP 2106.04(a)(1))
- For subject matter eligibility analysis under 101, whether an invention was created with the assistance of AI **is not a consideration** in the application of the *Alice/Mayo* test.
- How an invention was developed is not relevant to subject matter eligibility
- New examples relate to:
  - Application-specific integrated circuits (ASICs) for an artificial neural network comprising certain elements to detect anomalies (Example 47 – Anomaly Detection)
  - A speech separation method using a deep neural network to separate speech from background noise (Example 46 – Speech Separation)
  - A post-surgical fibrosis treatment method that uses genotyping patient data to identify certain patients based on risk scores generated by an AI model and administering appropriate treatment (Example 49- Fibrosis Treatment)

EPO Approaches to Subject Matter Eligibility

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EP Approaches to AI Inventions – Patentability

Can Inventions Made Using AI be Patented in Europe?

- Patentable inventions are **not** limited to human-made invention under the European Patent Convention
- How an invention was made plays no role in the European patent system
- AI generate inventions are generally considered to be patentable
- However, applications listing an AI as inventor **will be refused** by the European Patent Office

The European Parliament:

"…[t]akes the view that technical creations generated by AI technology must be protected under the IPR legal framework in order to encourage investment in this form of creation and improve legal certainty for citizens, businesses and, since they are among the main users of AI technologies for the time being, inventors." [European Parliament resolution of 20 October 2020 on intellectual property rights]

Subject matter eligibility

Mathematical methods, performing mental acts, presentations of information *as such* are excluded from patentability

- An invention must have a technical character or solve a technical problem.

- A computer program itself is not patentable, but if it produces a further technical effect when run on a computer, it can be considered. For example, controlling a technical process or improving the internal functioning of the computer.

- Only technical features are considered in the assessment of inventive step.

Board of Appeal Decision T 2677/16

"A computer-implemented method for identifying a drug discovery target" is not technical

Claim 1:

- providing an ontology for storing and accessing genomics information in a database…
- querying the database to generate a profile including a collection of nodes connected by directed edges…
- identifying, within the profile, a disease-related pathway to the disease state…
- identifying each of the actor concepts involved in each biological relationship as a drug discovery target

- "the intellectual activity of modelling disease-related metabolic pathways, irrespective of its purpose, … does not serve a technical purpose." [T 2677/16, Reasons 5]
- "claim 1 does not involve an inventive step over a general-purpose computer comprising a queryable database in any of the requests on file (Article 56 EPC)." [T 2677/16, Reasons 7]
- the step of "querying the database" implicitly involves a computer, i.e. technical means, which renders the method of claim 1 … an invention within the meaning of Article 52(1) EPC.

Board of Appeal Decision T 1910/20

“A collection system for automatically displaying patterns in glucose data” is not technical

Claim 1:

- characterized in that said algorithm is a pattern enhancement algorithm for enhancing patterns that exist within the glucose data signal…
- calculating a cluster center for each of the groups of clustered segments, wherein the cluster center is based upon a mean of one of the groups of clustered segments; and
- presenting, automatically, the cluster centers on the electronic display

- “Building a therapy plan, which should not be confused with practising a method of therapy on the human body, is a purely intellectual exercise, **not** a technical task. It is analogous to the purely intellectual deductive decision phase in diagnosis” [T 1910/20, Reasons 1]
- “the presented cluster centres are **not** an internal state of the underlying technical system, namely the collection system. Instead, they arguably relate to the internal state of a patient” [T 1910/20, Reasons 3]

Summary

- In the US and EP, AI systems can be used to create a patentable invention, BUT an AI cannot be listed as an inventor on patent applications
- A method that implicitly involves a computer is a technical invention and thus patent eligible subject matter
- Only technical features are considered in the assessment of inventive step.
- Methods involving an AI can be inventive if they control a technical process, improve the internal functioning of the computer, or serve a technical purpose

Recent Developments at the EPO and in the US related to the On-Sale Bar

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EPO Law on the On-Sale Bar

The novelty provision of the EPC: Article 54

- An invention shall be considered to be **new** if it does not form part of the state of the art.

- The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, **by use**, or in any other way, before the date of filing of the European patent application.

Availability to the public – G 1/92

Enablement and Reproducibility are critical for a product to be state of the art

- The chemical composition of a product **is** state of the art when the product as such is available to the public and **can be** analysed and reproduced by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition. [G 1/92 – Headnote]

- Technical Board of Appeal handling T 438/19 perceived a divergence in case law how the above guidance was applied.

- Three questions were referred to the Enlarged Board seeking to clarify a product and technical information describing that product are prior art for a patent application.

Solar Cell – G 1/23

3 Questions referred

1. Is a product put on the market … excluded from the state of the art … for the sole reason that its composition or internal structure could not be analyzed and reproduced without undue burden?

2. If the answer to question 1 is no, is technical information about said product … (e.g. by publication of technical brochure, non-patent or patent literature) state of the art …, irrespective of whether the composition or internal structure of the product could be analysed and reproduced?

3. If the answer to question 1 is yes or the answer to question 2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden within the meaning of opinion G 1/92?

Solar Cell – G 1/23

Preliminary Opinion and Oral Proceedings before the Enlarged Board

- A product put on the market before the filing date of a European patent application is **NOT** excluded from the state of the art solely because its composition or internal structure could not be analyzed and reproduced without undue burden.

- Technical information about such commercial products (e.g., in brochures or data sheets) **DOES** constitute state of the art regardless of whether the product itself could be analysed and reproduced.

- The Board seemed to favor the view that **“a physical product is by definition enabled by being put on the market”** and that “analyzability and reproducibility are **not** required.”

US Law on the On-Sale Bar

Pre-AIA - 35 U.S.C. § 102(b) (2006)

- Barred patentability of an invention that was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent"
- Under the Supreme Court's two-prong test in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), application of the pre-AIA on-sale bar requires:
  1. "the product must be the subject of a commercial offer for sale" and
  2. "the invention must be ready for patenting" 525 U.S. at 67

Post-AIA – 35 U.S.C. § 102(a)(1) (2012)

- Congress amended 102 to bar patentability of an invention that was "patented, described in a printed publication, or in public use, **on sale, or otherwise available to the public** before the effective filing date of the **claimed** invention" (emphasis added)

US Law on the On-Sale Bar

Celanese Intl. Corp. v. Intl. Trade Comm'n, No. 2022-1827, 2024 WL 3747277 (Fed. Cir., August 12, 2024)

- Certain entities infringed patents to **process** to make Ace-K® (sweetener)
- Undisputed Facts:
  - patented process was in secret use in Europe more than one year before critical date
  - Patentee sold Ace-K in US using the secret process before the critical date
- Motion for SJ - on-sale bar - Patentee sold products using the patented method more than one year before critical date
- Patentee: Maybe on-sale under pre-AIA law, but not under post-AIA law
  - Congress amended § 102 from "invention" to "claimed invention" in the AIA, thus AIA on-sale bar can be triggered only when product sold is also what is claimed
  - Only sales were of Ace-K, not the claimed process, thus the on-sale bar should not apply

US Law on the On-Sale Bar

Celanese Intl. Corp. v. Intl. Trade Comm'n, No. 2022-1827, 2024 WL 3747277 (Fed. Cir., August 12, 2024)

- FC: Under *Helsinn Healthcare v. Teva Pharm. USA, Inc.*, 586 U.S. 123 (2019), Congress reenacted the "on sale" language
  - Long-settled pre-AIA precedent – sales of products made with secret process trigger bar
  - "claimed invention" and "invention" are used interchangeably
  - Congress' use of "claimed invention" in the AIA was "no more than a clerical refinement of terminology for the same meaning in substance"
  - The rationale for the on-sale bar is to prevent someone from exploiting an invention commercially only to later seek patent protection for that invention and effectively gain additional patent term

Key Takeaways

- AIA's on-sale bar applies when there has been a pre-critical date sale of a product made even with a secret process
- Inventors should file their patent application for both a product and a method of making before any sales of the product made by that process

US Law on the On-Sale Bar

Crown Packaging Technology, Inc. v. Belvac Production Machinery, Inc., 122 F.4th 919 (Fed. Cir., December 10, 2024)

- Crown sued Belvac for infringing patents on necking metal cans
- DC granted MSJ for Crown - patents not invalid for on-sale bar (pre-AIA 102)
  - Letter Crown sent was an invitation to make an offer, but not an offer itself
- Jury confirmed patents not-invalid, but not infringed either – both sides appealed
- Belvac - patents invalid for on-sale bar by US sale by Crown before critical date
- Crown – conceded machine was ready for patenting, fell within claims, and letter was sent before the critical date
- Crown – BUT - sent letter from UK, so not “in this country,” and only a “quotation,” not a commercial offer for sale and company never purchased a machine

US Law on the On-Sale Bar

Crown Packaging Technology, Inc. v. Belvac Production Machinery, Inc., 122 F.4th 919 (Fed. Cir., December 10, 2024)

- FC - statute requires:
  1. the subject of the offer for sale must embody the claims of the patent;
  2. the offer for sale must have been "in this country;" and,
  3. the offer for sale must occur before the critical date of the asserted patent;
  4. under *Pfaff v. Wells Electronics, Inc*., 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998), before the critical date: the invention is "the subject of a commercial offer for sale," and
  5. "ready for patenting"
- Look to the language of the proposed offer under contract law
  - Directed to specific company and signed by Crown representative
  - Detailed description of the machine, price, and delivery
  - Crown used the same letter to make sales to other companies after the critical date
  - All the "hallmarks of an offer for sale, thus the "quotation" was a commercial offer for sale

No matter that the letter was sent from UK, still an offer to US company in the US

US Law on the On-Sale Bar

Crown Packaging Technology, Inc. v. Belvac Production Machinery, Inc., 122 F.4th 919 (Fed. Cir., December 10, 2024)

- If an offer for sale is “made in this country” then the invention would be “on sale” in this country even if the invention was sold for use outside the US

Key Takeaways

- Post-AIA difference - 102(a)(1) does not require the sale to have been made "in this country"
- Thus, for post-AIA patents, similar analysis, but factor 2 in Crown case does not apply
- Note that Factors 2 (if applicable) and (3) do not typically require much analysis, because it is usually clear when and where an alleged offer was made
- Inventors should file their patent application before making any offer for sale of the invention

Comparison to On-Sale Bar in the US

Requirements for an on-sale bar in the US:

1. subject of the commercial offer for sale must embody the claims of the patent;
2. commercial offer for sale must have been “in this country” (Pre-AIA only);
3. offer for sale must occur before the critical date of the patent;
4. the invention is “the subject of a commercial offer for sale;” and
5. the invention must be “ready for patenting” (reduced to practice or enabling disclosure - not merely experimental)

- Purpose: This rule helps ensure that inventors file for patents promptly and prevents them from extending the patent term by delaying the filing after commercializing the invention

Requirements for an on-sale bar in the EPO:

- An on-sale bar is expected with the awaited decision of G 1/23.
- In contrast to the US, the EPO has no grace period for inventor originated disclosures including products put on the market.

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Thank You!

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Peter helps clients from start-ups to multinationals to develop competitive worldwide patent strategies and to establish solid and defensible patent portfolios. He performs competitive patent analyses, identifies third-party patent risks, and provides patentability, due diligence, and freedom-to-operate opinions. Peter also has experience in opposing and defending patents before the European Patent Office and in U.S. litigation and post-grant proceedings.

Peter has experience in, for example, medical therapeutics, diagnostics, devices, and imaging, microfluidic systems, liquid biopsy, nucleic acid sequence analysis systems and software, cancer therapies, cell culturing and bioprocessing, molecular biology, complex biomedical systems, optics, machine tools, and lasers.

Specific applications include, e.g., cancer antibodies and small molecules, engineered AAV systems, microfluidic analysis of circulating tumor and fetal cells, cell-free DNA analysis, next generation sequence analysis, dendritic cell- and DNA- based vaccines, nanoparticle and vector-based delivery, blood analysis systems, nucleic acid probes, laser and machine tool systems, tissue engineering, infusion pumps, biochips, green energy systems, and diagnostic and therapeutic methods for, e.g., cancer, autism, diabetes, and arthritis.

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In advising clients, Moritz looks to the future, anticipating challenges, changes, risks, and opportunities. Diligent and hardworking, he delves into the details of each invention to build strong and effective patents. When taking on a case, he studies the history, science, and law, listens to and learns from his clients, and then determines the best path forward to achieve the client's goals.

When third parties challenge a client's patent, Moritz is well prepared to defend that client's rights before the European Patent Office.

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