

Introduction to Enablement and Written Description in a Patent Application: *What's needed for a strong application?*

A Presentation to West Virginia University

Presented by:

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Representative Clients



ANZU
PARTNERS



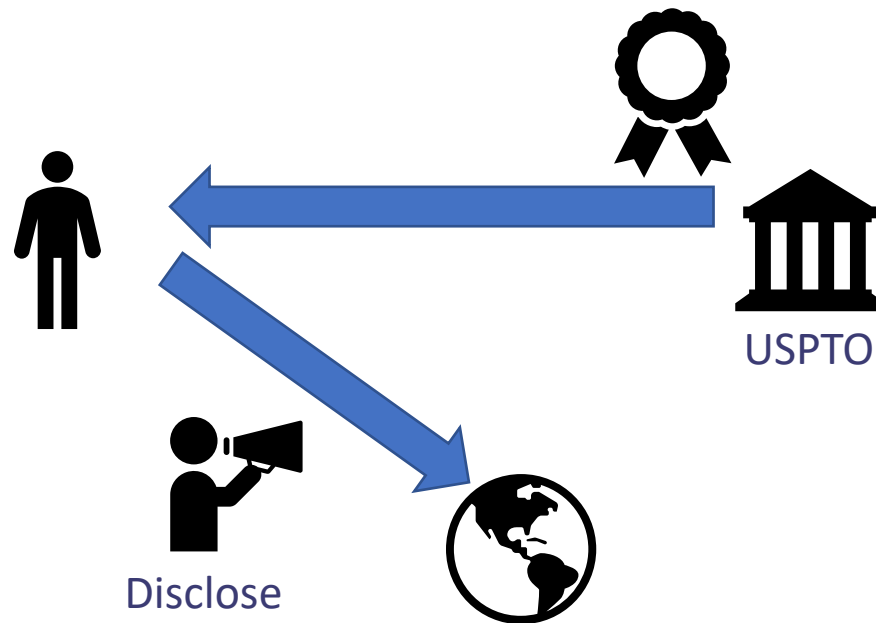
and a growing team



What is a Patent?

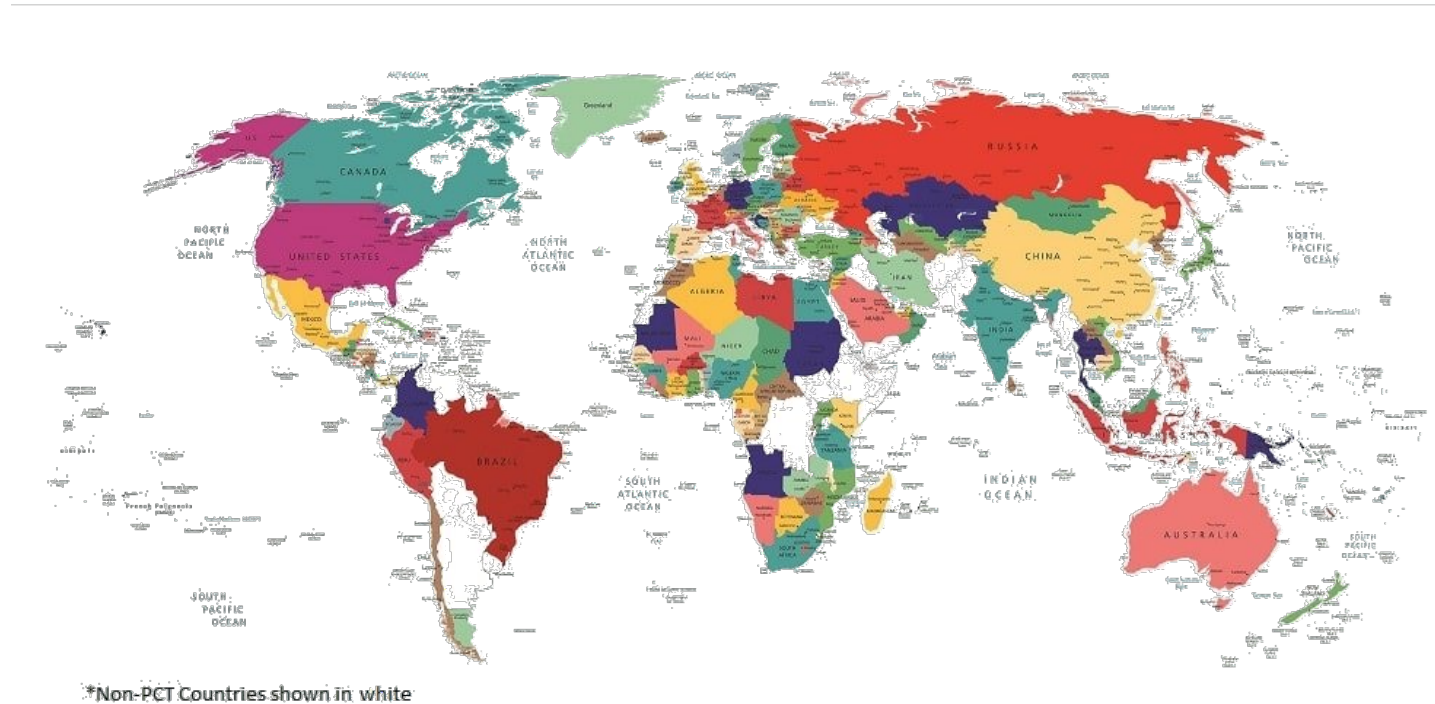
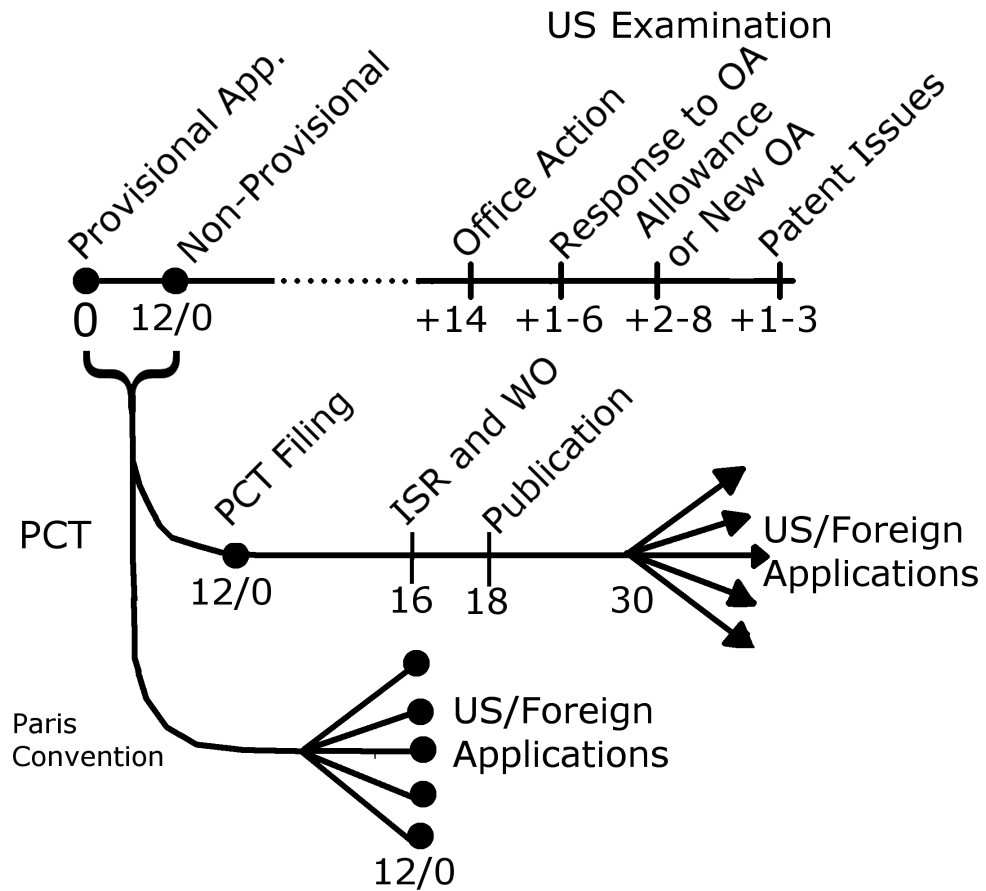
- A government issued **legal monopoly** for an invention
- Right to **exclude others** from making, using, offering to sell, selling any patented invention, within the United States
- Right to **exclude others from importing** the patented invention into the United States
- US patent rights are **limited to the US**
- US utility patent rights **limited to 20 years** from the effective filing date

Purpose of Granting Patents

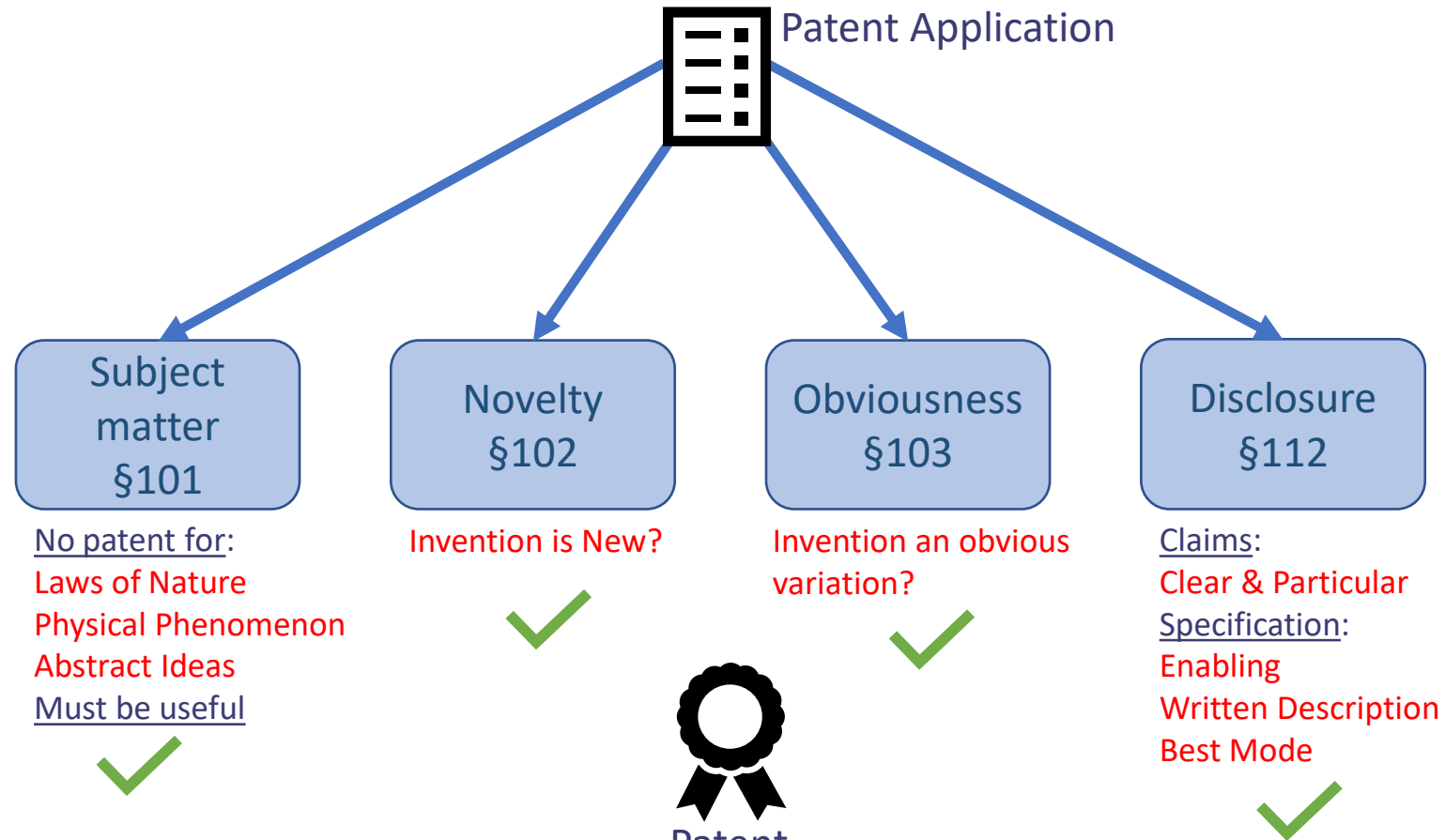


- Goal of Patent Law is to **promote the progress** of useful arts
- Patent law facilitates **dissemination** of technical information and follow-on innovation
- Patent **quid pro quo**: Receive legal monopoly, and in return you publicly disclose your invention

The patent process can vary dramatically by country or region and the application you file may need to support the requirements for each



How do you acquire a patent?



Patent

Basic Requirements of Patentability: US v. EP

US

- Patent Eligibility
- Utility
- Novelty
- Nonobviousness
- Written Description
- Enablement
- Best Mode

EP

- Patent Eligibility
- Industrial Applicability
- Novelty
- Inventive Step
- Clarity
- Enablement

Written Description and Enablement in the US Find Their Origins in 35 U.S.C. §112(a)

- This section embodies Patent Law’s goal of promoting the useful arts
- “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.”
- The statute sets out three basic requirements:
 - **Written Description** Requirement
 - **Enablement** Requirement, and
 - **Best Mode** Requirement

Written Description

Written description is about telling people what you have actually done and convey what you at least arguably have possession of.

The Written Description Requirement

- The Written Description Requirement serves TWO purposes:
 1. To clearly allow persons skilled in the art to recognize that the inventor invented what is claimed, and
 2. **Limit claim scope to what is disclosed in the specification**: The specification should allow a person skilled in the art to clearly determine that the inventors possessed the claimed invention. That is: *Patentee cannot claim more than he discloses*

US Written Description Requirement compared to other jurisdictions

- Often referred to as “Clarity” or “Adequacy of the disclosure” requirements, essentially all jurisdictions have an analogous requirement as the US Written Description Requirement.
- Historically, the requirement was viewed in many ways as a heightened requirement in other jurisdictions such as Australia, Europe, and the United Kingdom.
- Recent US case law is trending to harmonize some of those requirements, especially in the unpredictable arts.

The Written Description Requirement compared to other requirements

- The Written Description Requirement is directed to the *adequacy of the disclosure*, so the emphasis is on the specification in view of what is claimed and what is the state of the art.
- This is contrast to the requirements for novelty and non-obviousness where the emphasis is on the claims in view of the prior art.
- A poorly drafted specification can lead to invalidity of the claims and at the least can seriously limit the applicant's ability to amend the claims during prosecution ...

The specification defines how pieces can move ...

- The content of the specification is fixed at the time of filing, however the specification must satisfy 35 USC § 112(a) for the final claims.
- The claims will almost always change during prosecution, and even minor additions or deletions of a word from a claim can call into question whether the change is supported under 35 USC § 112(a).



W. D. Example: LizardTech v. ERM¹

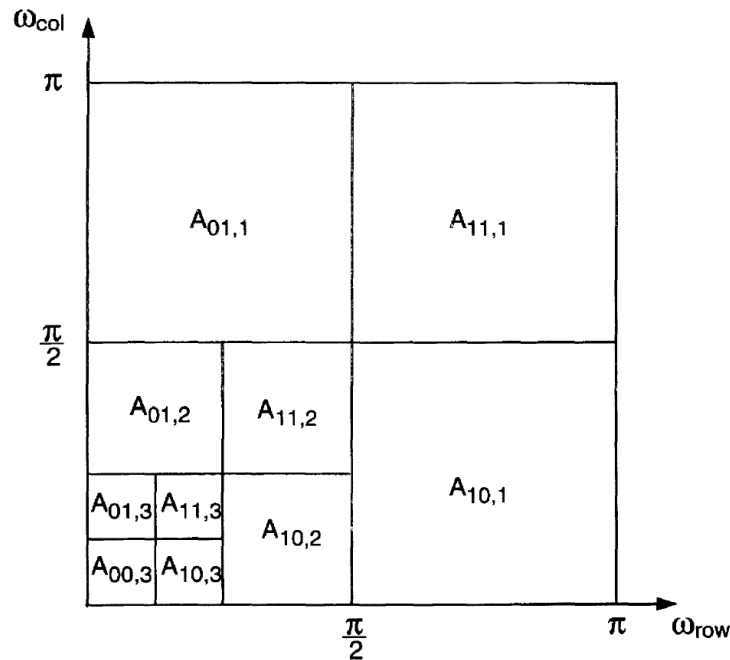


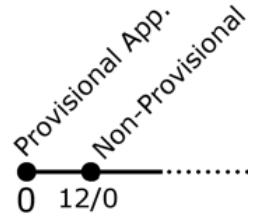
Fig. 4

- LizardTech invented an **image compression algorithm** that uses Discrete Wavelet Transform (**DWT**) to compress large images
- To reduce memory requirement, DWT is calculated for “**tiles**” within an image
- DWT of a tile is modified by **summing coefficients** for that tile determined during earlier DWTs of adjacent tiles
- Summed coefficients are compressed and **transferred to secondary memory**

W. D. Example: LizardTech v. ERM

- Claim 21 of LizardTech patent describes the DWT algorithm, **but does not recite the “summing coefficient”** step
- Court ruled that **claim 21 is invalid** because the specification **does not include** a written description of the DWT algorithm **without the summing coefficient step**
 - The specification **describes only one way** of determining the DWT of the entire image—by performing the summing of coefficients step
 - The specification **does not provide a more generic or general way** of determining the DWT of the entire image without the summing coefficient step
 - Without disclosing even one another way of determining the DWT of the entire image, the specification **does not show possession** of the broader generic DWT transformation

Written Description – Provisional vs. Non-Provisional Application (1)



- Case: *Novozymes A/S v. DuPont Nutrition Biosciences*
- Written description as provided in the provisional application affects the ability to claim priority of what is described in the non-provisional application.
- Novozymes application history
 - Provisional application disclosed 33 possible positions for mutation targets in any of 7 parent enzymes by deletion, addition, or substitution, but not disclose that any one of the 33 sites is preferred or whether single or combined mutations are preferred (for the non-biologist, simply saying there are seven possible sites that can be mutated is a large number of possibilities, i.e., 7 x 33 x (at least 20) -> you can see where this is going, that were not described at all.
 - Non-provisional application claims specific modified enzymes such as an amino acid substitution at position S239 that increased thermostability at 90°C, pH 4.5, and 5 ppm calcium.

Written Description – Provisional vs. Non-Provisional Application (2)

- The case was decided against Novozymes regarding whether the claimed mutant was supported by the provisional application written description. The Federal Circuit ruled:
 - Generalized guidance inadequate, generalized guidance to narrow claims.
 - Although each of the limitations could be found in the provisional, Novozymes never presented them together in any particular embodiment or highlighted them among other disclosed options.
 - “[O]ne of ordinary skill in the art reading the 2000 application would have understood that Novozymes had only predicted that at least some mutations at position 230 would yield variants with increased thermastability, not that it possessed or had definitively identified any mutations that would do so.”
 - A patent, however, "is not a reward for the search, but compensation for its successful conclusion." For that reason, the written description requirement prohibits a patentee from "leaving it to the . . . industry to complete an unfinished invention."

Support for subsets...

- Case: *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918, (Fed. Cir. 2019).
- Claim in question:
 - A controlled release oral solid dosage form comprising: a controlled release matrix comprising a mixture of (i) from 2.5 mg to 320 mg oxycodone or a pharmaceutically acceptable salt thereof; and (ii) **a gelling agent comprising polyethylene oxide ("PEO") and hydroxypropylmethylcellulose ("HPMC")**, the gelling agent in an effective amount to impart a viscosity of at least 10 cP when the dosage form is subjected to tampering by dissolution in from 0.5 to 10 ml of an aqueous liquid; the controlled release matrix providing a therapeutic effect for at least 12 hours when orally administered to a human patient.
- Written description in Purdue patent:
 - In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, sugars or sugar derived alcohols, such as mannitol, sorbitol, and the like, starch and starch derivatives, cellulose derivatives, such as microcrystalline cellulose, sodium carboxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and **[HPMC]**, attapulgit, bentonites, dextrans, alginates, carrageenan, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesium aluminum silicate, the carbomers and carbopols, polyvinylpyrrolidone, polyethylene glycol, **[PEO]**, polyvinyl alcohol, silicon dioxide, surfactants, mixed surfactant/wetting agent systems, emulsifiers, other polymeric materials, and mixtures thereof, etc. In certain preferred embodiments, the gelling agent is xanthan gum. In other preferred embodiments, the gelling agent of the present invention is pectin.

Subsets need to be described...

- The Federal Circuite ruled that: "simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996); see *In re Ruschig*, 379 F.2d 990, 994-95, 54 C.C.P.A. 1551 (CCPA 1967)." In the Purdue disclosure, "PEO and HPMC are merely two of many undifferentiated compounds that fall within the genus of gelling agents. Such "laundry list" disclosures do not provide adequate specificity to constitute written description support for Purdue's claim of priority. To be sure, the language "mixtures thereof" suggests the possibility of combining two or more of the listed gelling agents. Without more, however, that language fails to highlight any preference for how many and which gelling agents to combine."
- What to do? Explicitly describe preferred or likely subsets from within a broad range.

Written Description: Takeaways

- Written Description Requirement is **Separate from the Enablement** Requirement.
 - A patent can be enabling but still lack written description
 - While enablement may be provided by prior art, written description **must be provided by the specification only**
- **Provide several examples**, in addition to the preferred approach, of alternate ways of performing the invention to support broader claims.
- If a step or **element is essential** to the invention, avoid broadening the claims with respect to the step or element.
- Be aware of the connection between a provisional application and its non-provisional counterpart.
- Broadly described ranges or sets (“genera) need to be supported by sub-ranges or sub-sets (“sub-genera) to allow for adequate support of narrower claims.

The Enablement Requirement

- The Enablement Requirement serves TWO functions:
 1. **Facilitate Information Dissemination**: Contribute to the general body of public knowledge and promote further research and improvements
 2. **Limit claim scope to what is enabled in the specification**: The specification should enable a person skilled in the art to make and use the claimed invention without undue experimentation. That is: *Patentee cannot claim more than he enables*

“Every patent must describe an invention. ...The specification must then, of course, describe how to make and use the invention (i.e., enable it), but that is a different task.”

(Ariad Pharmaceuticals v. Eli Lilly, Rehearing En Banc, 598 F.3d at 1344)

What is required for “enablement”?

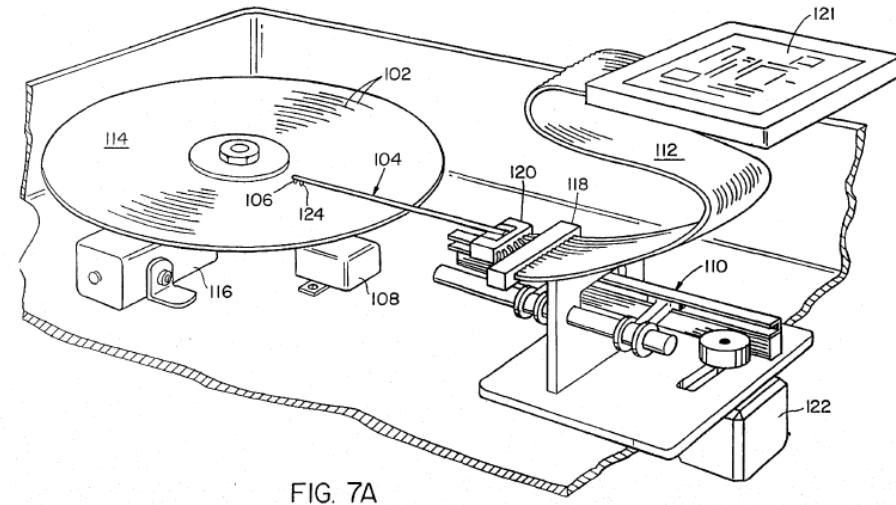
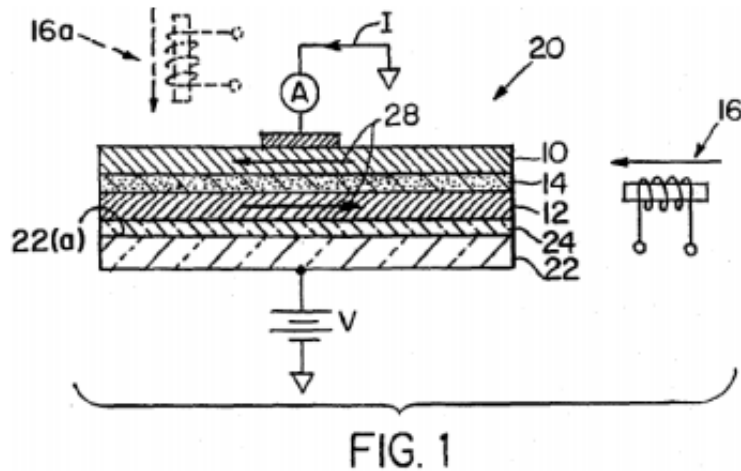
Disclosure can still comply with the enablement requirements even if it leaves some technological problems unresolved so long as one of ordinary skill in the art could resolve them in reasonable time. That is:

- Only objective enablement required.
- Routine experimentation OK but undue experimentation is not.
- No need for production blueprint.

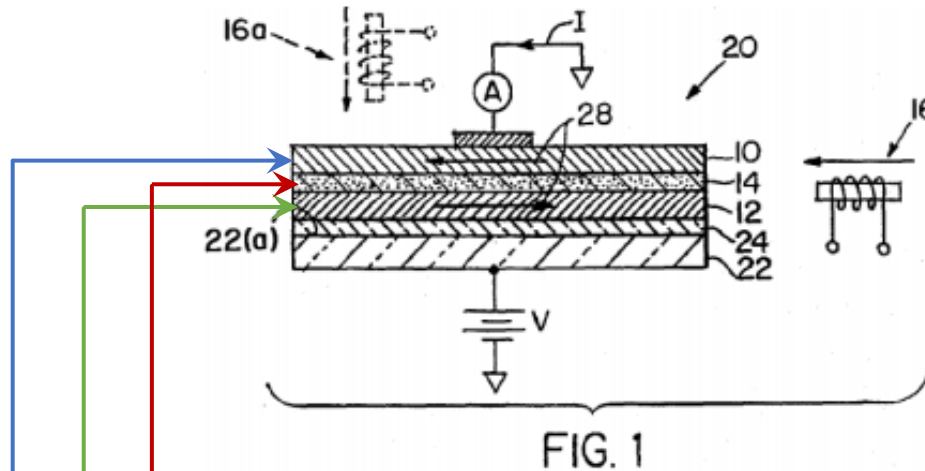
(Koito Mfg Co., Ltd. v. Turn-Key-Tech, LLC, 381 F.3d 1142 (Fed. Cir. 2004))

Enablement Example 1: MagSil v. Hitachi³

- MagSil sued Hitachi for allegedly infringing US Patent No. 5,629,922 (1997)
- Patent is directed to **read-write sensors** for hard disk drives



Enablement Example 1: MagSil v. Hitachi

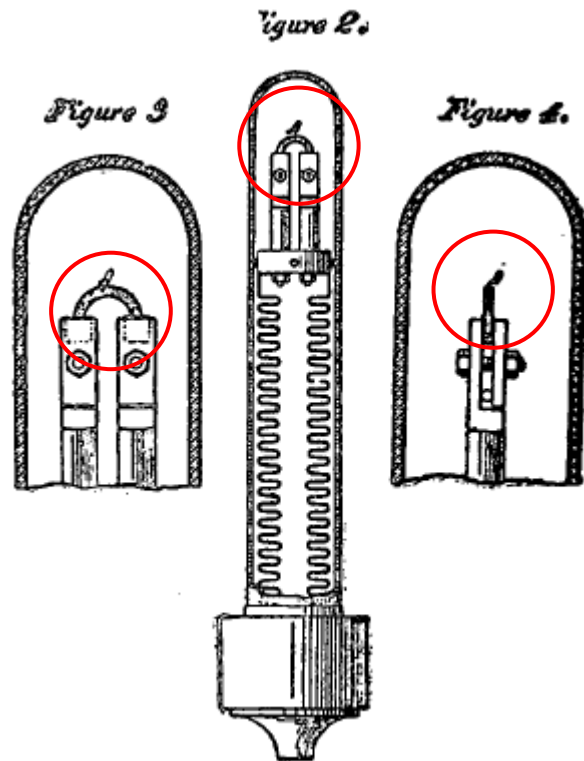


- Claim 1
 1. A device forming a junction having a resistance comprising:
 - a first electrode having a first magnetization direction,
 - a second electrode having a second magnetization direction, and
 - an electrical insulator between the first and second electrodes,wherein applying a small magnitude of electromagnetic energy to the junction reverses at least one of the magnetization directions and causes a change in the resistance by at least 10% at room temperature.

Enablement Example 1: MagSil v. Hitachi

- Claim Scope: $\Delta R/R = \text{at least } 0.1 = \text{any number greater than or equal to } 0.1!$
- Court ruled that the specification **does not enable** that wide a range of values
 - The specification teaches that the inventors' best efforts achieved a maximum change in resistance of only 11.8%
 - The specification **does not describe how** a person would achieve higher change in resistance values
 - The technology twelve years after the filing date of the application was only able to achieve $\Delta R/R = 6$, indicating the years of experimentation needed to reach that value
 - The specification enabled a marginal advance over the prior art (0.027), but did not enable values of even up to 0.2, let alone the recent achievements of values equal to 6
- Thus, the claims were ruled invalid because, based on the disclosure of the specification, a person skilled in the art would not be able to achieve the broad scope of the claim without undue experimentation

Enablement Example 2: Consolidated v. McKeesport⁴



- Consolidated sued McKeesport, a manufacturer of the **Edison incandescent lamp**
- Consolidated discovered that **carbonized paper** worked well as a conductor for an incandescent lamp
- Consolidated broadly claimed (in U.S. Patent No. 317,076) an **incandescent lamp** that uses a conductor made of **fibrous or textile material**
- The Edison incandescent lamp used a conductor made of **carbonized bamboo**, which Consolidated alleged infringed its claim

Enablement Example 2: Consolidated v. McKeesport

- The US Supreme Court decided that the Consolidated patent was **invalid for not enabling the claims**
 - The inventors **discovered only carbonized paper** as a suitable conductor, but proceeded to **claim the whole class** of fibrous or textile material
 - “[T]he fact that paper belongs to the fibrous kingdom **did not invest** the [inventors] with **sovereignty over this entire kingdom**”
 - Selecting a fibrous material for a conductor required **painstaking experimentation**
 - Edison experimented for several months with species of vegetable growth
 - Edison experimented with dozens of varieties of bamboo imported from Japan to arrive at its preferred material
 - Edison then experimented with dozens of sizes of the preferred bamboo to arrive at the conductor used in the Edison incandescent lamp
 - Disclosing only one specie of a genus does not enable the whole genus when arriving at the species requires undue experimentation

Enablement: Takeaway

- **Provide several example species:** Newer the technology, the higher the burden of providing examples commensurate with the scope of the claim. In Examples 1 and 2, the technologies were new, and therefore would likely need a lot of experimentation to make improvements
- **Describe the “how” and the “why” of the invention:** Providing how and why the invention works can provide the common property or feature that pervades the entire scope, and obviate undue experimentation to cover the broad scope of the claims
- **Enablement can be satisfied by the prior art for non-novel features** of the claim (e.g., you do not need to describe how a microprocessor works if the microprocessor is being used in the claim to merely implement the invention, and microprocessors are well known)