

Stronger Life Science Patents

ASHLEY SLOAT, Ph.D. | September 18, 2023

This presentation is for information purposes only and does not constitute legal advice.



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President & Director of Patent Strategy



an illogical, unpredictable, chaotic mess...

– Federal Circuit Chief Judge Paul Michel (retired)



made it difficult for inventors, businesses, and other patent stakeholders to **reliably and predictably** determine what subject matter is patent eligible

– Elizabeth Prelogar, U.S. Solicitor General



innovation cannot thrive in uncertainty

– Kathi Vidal, USPTO Director and Under Secretary of Commerce



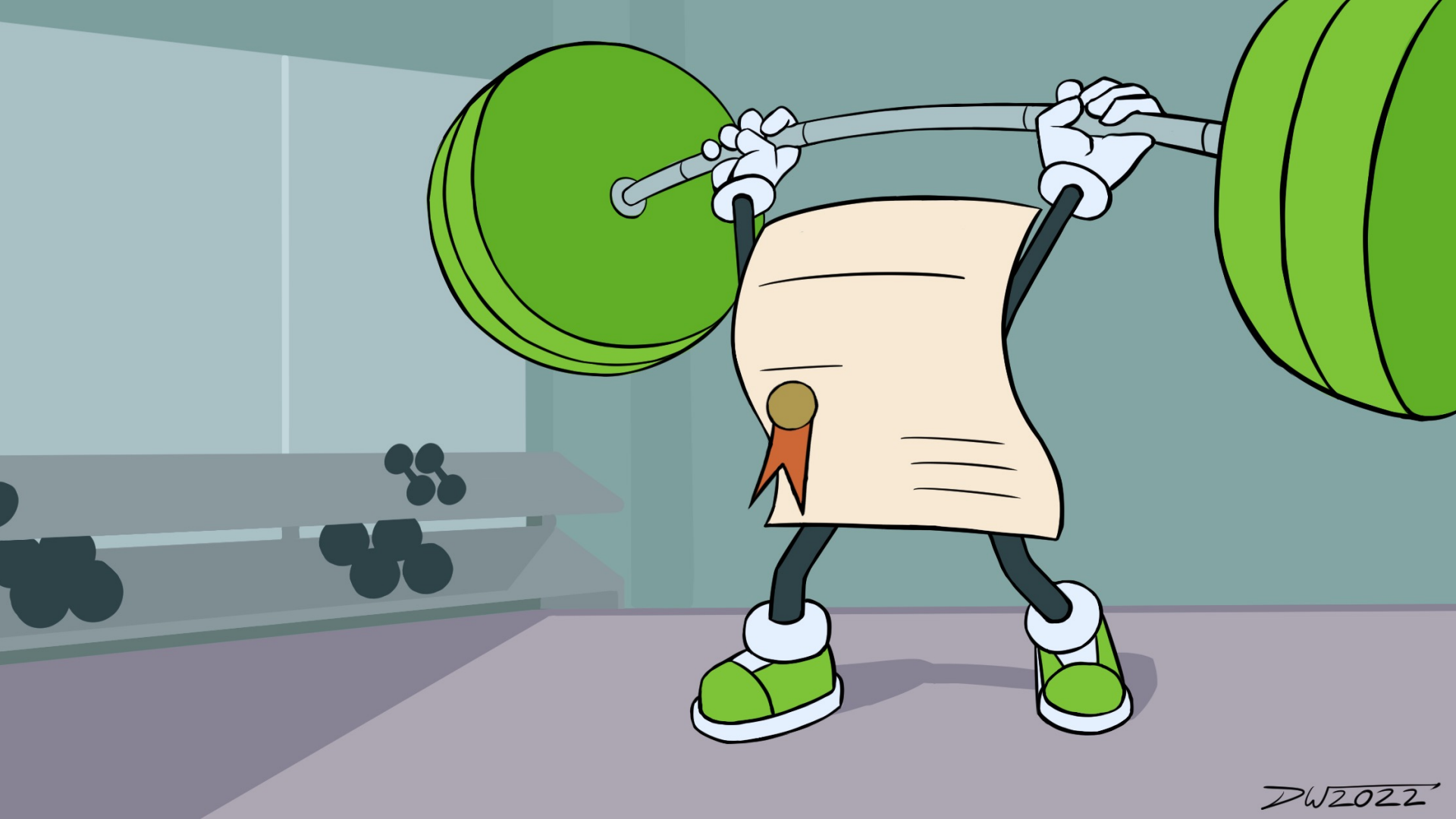
innovation does not include patentable subject matter

Innovation doesn't wait.



Let us be clear: investments in the biotech industry are based entirely on patents. Without strong patents, we cannot raise money to find cures for disease.

– Hans Bishop, Founder at Altos Labs & former Head of Juno Therapeutics



DW2022'

Overview: **Stronger Life Science Patents**

- Eligibility and enablement
- State of the law
- Funding sources and regulatory delays
- Practical tips
- Recent legislative movements

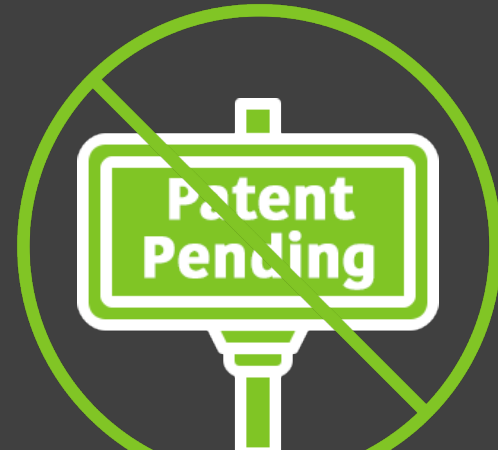
“

There are seven
days in the week
and **SOMEDAY** isn't
one of them.



Rejection & Invalidation Gates

- **Section 101** – patent ineligibility or lack of utility
- Section 102 – lack of novelty
- Section 103 – the claimed invention is obvious and/or
- **Section 112** – lack of adequate description



Eligibility.

What subject matters are eligible for patent protection?

Enablement.

The fundamental deal of the patent system.

Eligibility: Patentable Subject Matter

“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.”

35 U.S.C. § 101

Eligibility: Judicial Exceptions

- Laws of nature
- Natural phenomena
- Abstract ideas



Eligibility: Judicial Exceptions

- scientific principles
- **naturally occurring phenomena**
- mental processes
- mathematical algorithms



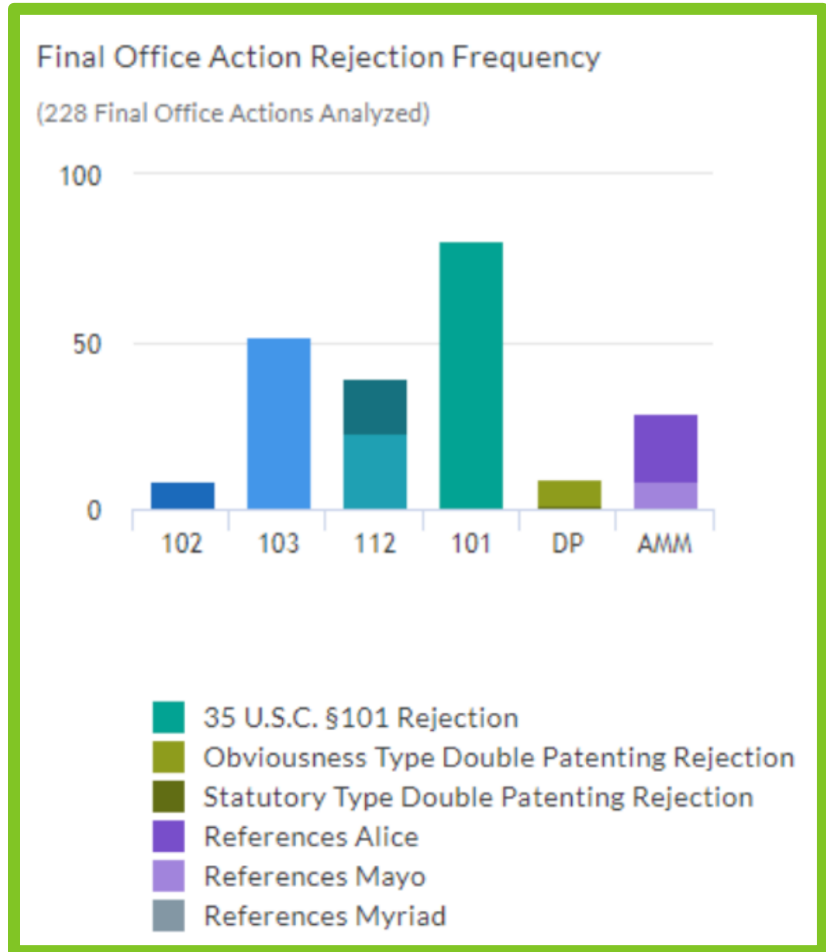
Life Science Challenge:
Practical application of
natural phenomenon



The Reality of Past 5 Years

1631 Art Unit

Molecular Bio,
Bioinformatics, Nucleic
Acids, Recombinant
DNA/RNA, Gene
Regulation



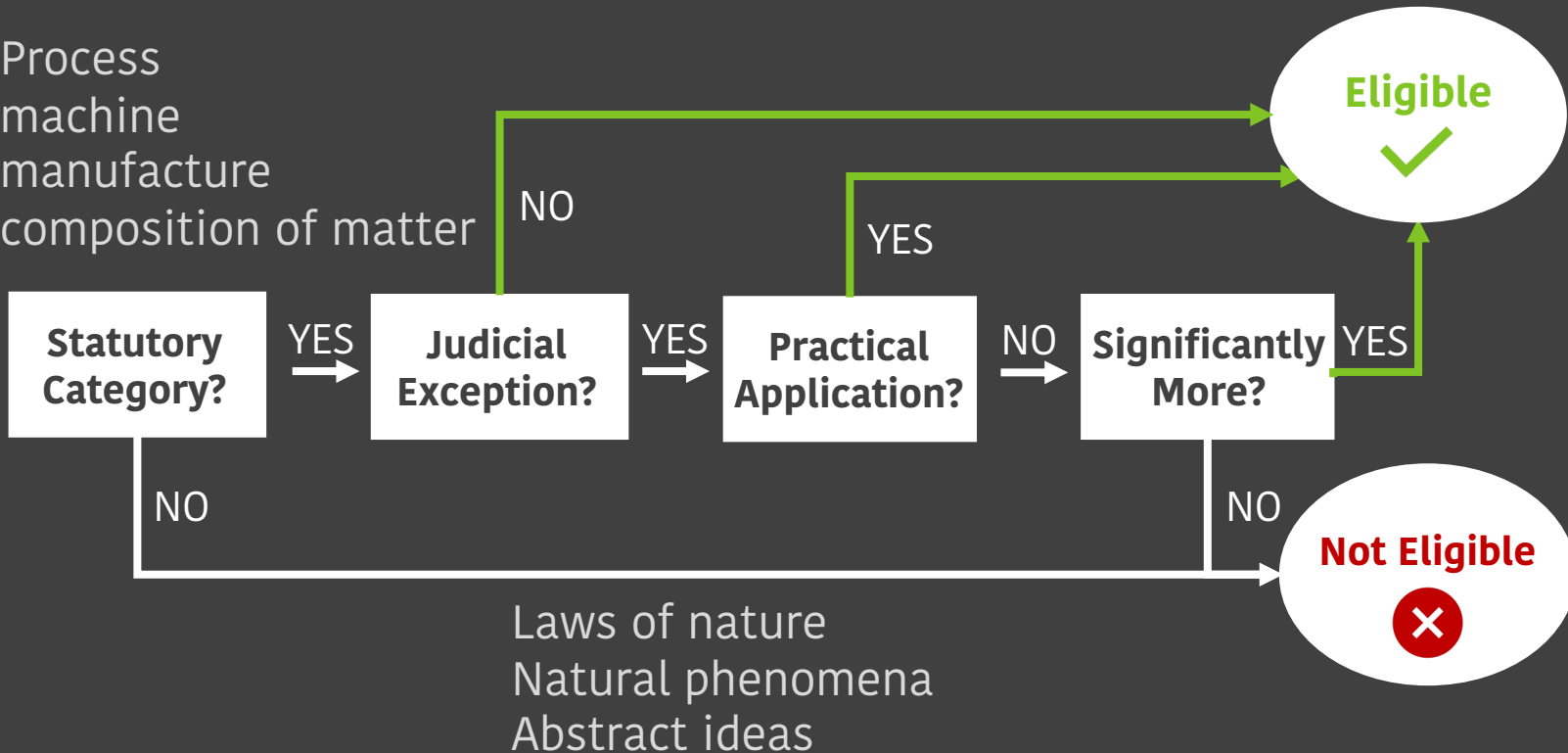
Mayo Collaborative Services v. Prometheus Laboratories, Inc.



Unpatentable natural laws transformed into patent-eligible applications of those laws?

Subject Matter Eligibility Guidance

Process
machine
manufacture
composition of matter



Ariosa Diagnostics, Inc. v. Sequenom, Inc.



A significant, but unpatentable, contribution to the medical field.

The **solution** lies in the **intent**

“...in applying the §101 exception, we must distinguish between patents that claim the **building blocks of human ingenuity** and those that integrate the **building blocks into something more**, thereby transforming them into a patent-eligible invention”

Alice Corp. v. CLS Bank Int'l SCOTUS opinion

The **solution** lies in the **intent**

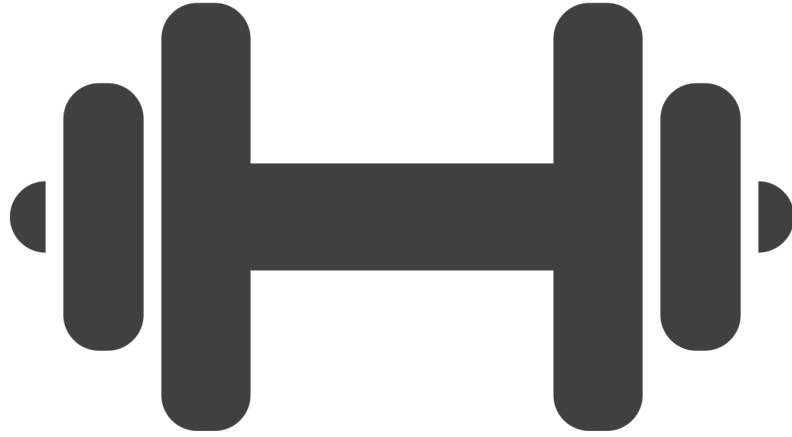
“At some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. **Applications of such concepts to a new and useful end** ... remain eligible for patent protection.”

Alice Corp. v. CLS Bank Int'l SCOTUS opinion

Key Tips for Derisking **Eligibility**

Building blocks into something more

- **Practical** applications.
- **Improvement** over prior art methods.
- **Overcome** a particular technical challenge.
- **Different** claim types.



"Unless you puke, faint or die, keep going!"

– Jillian Michaels

Enablement.

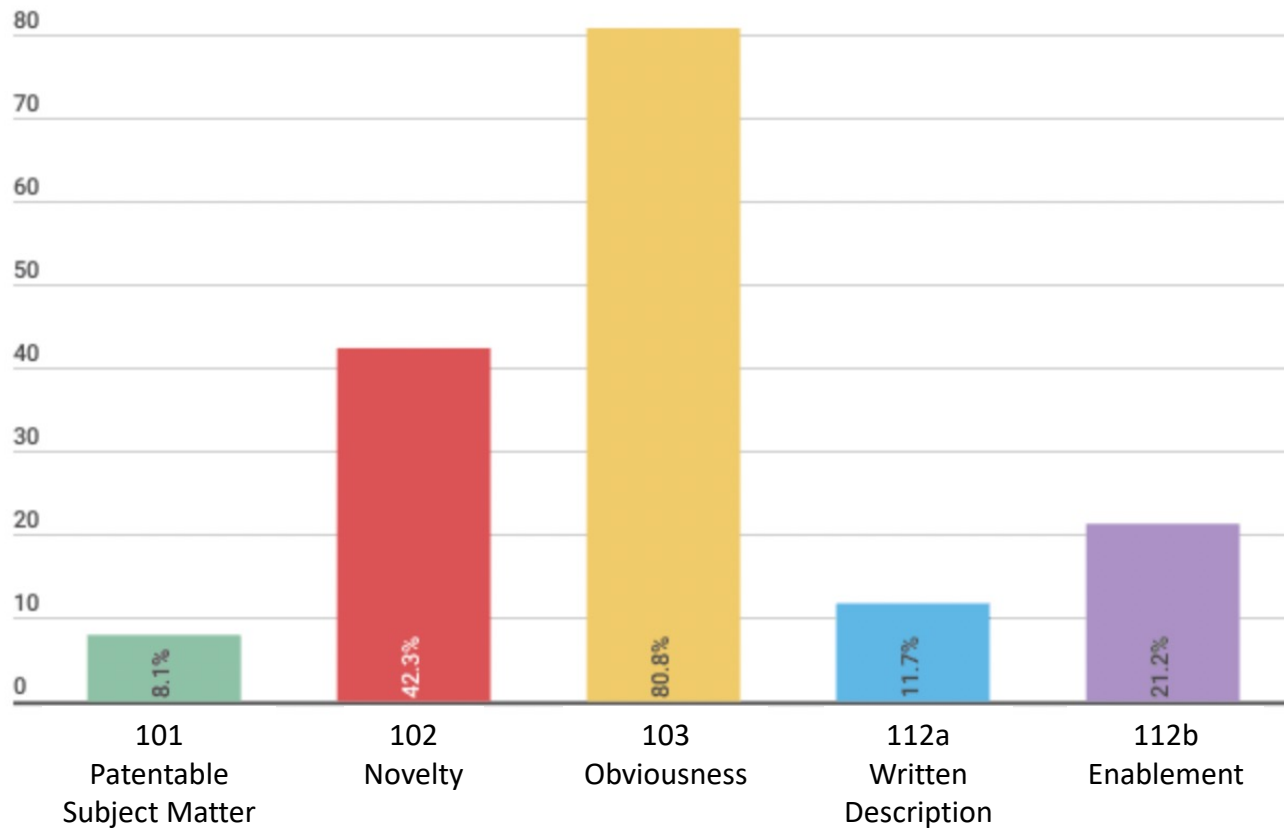
The fundamental deal of the patent system.

Enablement: Adequate Description

“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 make and use the same...”

35 U.S.C. § 112

All Rejection Bases



Source: IPW 112 Rejections: Where They Are Found and How Applicants Handle Them

Top Art Unit Groups for 112 Rejections



1660

Plants



1620

Organic Chemistry



1640

Immunology



1780/1790

Food



1630

Molecular Biology



1750

Electrochemistry



1650

Fermentation



1610

Organic Compounds



1670

Chemistries & Diagnostics

Life Science Challenge:
Higher disclosure bar for
unpredictable arts



Enabling **Unpredictable Arts**

“the **scope of enablement ... varies inversely with the degree of unpredictability** of the factors involved”

Application of Joseph D. Fisher, 427 F.2d 833 (C.C.P.A. 1970)

Mechanical arts
Physics

Digital Health

Chemical arts
Life Sciences



Predictability

Enablement

The Enablement **Test**

“...**as to enable** any person skilled in the art ... to make and use the ... invention.”

35 U.S.C. § 112

“...**without undue experimentation**”.

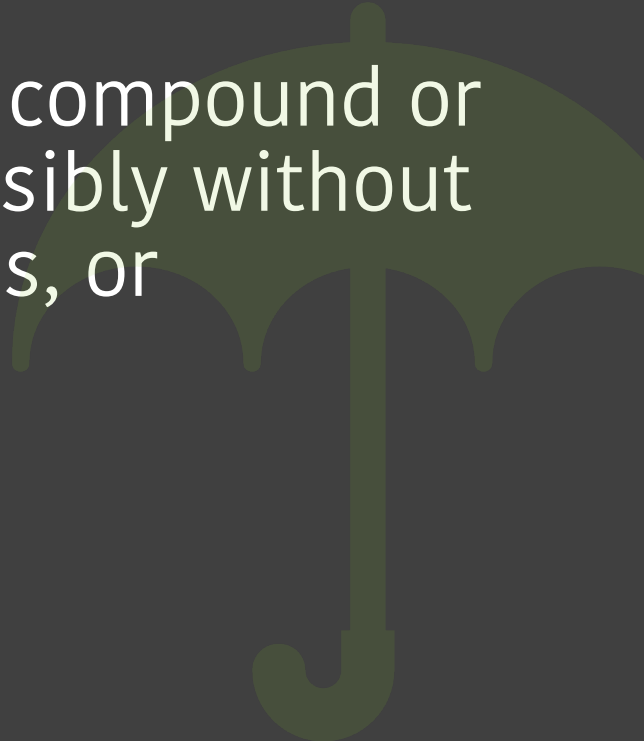
Minerals Separation Ltd. v. Hyde

... **coupled with information known in the art ...**”.

United States v. Telectronics, Inc

Genus Claim: covers a group of related chemicals

Species Claim: covers a single compound or narrow slice of compounds possibly without coverage of analogs, derivatives, or compounds in the same family





...the law has changed dramatically in the last thirty years, to the point **where it is nearly impossible to maintain a valid genus claim.** Courts almost always hold them invalid, either at trial or on appeal.

Harvard Journal of Law & Technology: Death of the Genus Claim

USPTO Genus **Misinformation**



United States Patent and Trademark Office

MPEP



III. WORKING EXAMPLES AND A CLAIMED GENUS

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art ...would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.



Disputed by Third Parties

Community reports have identified this guidance as violating the Community Policy on Harmfully Misleading Information

Examples of the **Genus Claim** Deaths

- A nascent, unpredictable field ripe with failure can cause enablement issues
 - Enzo Biochem v. Calgene (Fed. Circ. 1999)
 - Claimed antisense DNA technology
- Iterative trial-and-error lead by spec can create enablement issue
 - Wyeth v. Abbott (Fed. Circ. 2010)
 - Rapamycin chemicals for treatment of restenosis

Death of the **Genus Claim**

- **Undue Experimentation** despite described screening process allowing for straightforward ID of working embodiments
 - Idenix Pharma v. Gilead (Fed. Circ. 2019)
 - 2-methyl nucleoside for treatment of HCV
- **Not Enabled** despite antibody science being well-known, guidance provided, working examples, identified specific amino acids for binding
 - Amgen v. Sanofi (Supreme Court 2023)

The **solution lies in the **intent****

A bargain between the inventor and society.

Wands Factors

1. Quantity of experimentation necessary
2. Amount of direction or guidance presented
3. Presence or absence of working examples
4. Nature of the invention
5. State of the prior art
6. Relative skill of those in the art
7. Predictability or unpredictability of the art
8. Breadth of the claims

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Key Tips for Derisking **Enablement**

- Provide ample **direction and specificity**.
- Build breadth through **examples**.
- Reinforce **genus with species**.
- Consider a **narrower claim** backstop.
- Disclose **experimentation tips**.
- File **continuation applications**.
- Consider **alternative strategies**.

Life Science Challenges:
Funding Sources and
Regulatory Delays



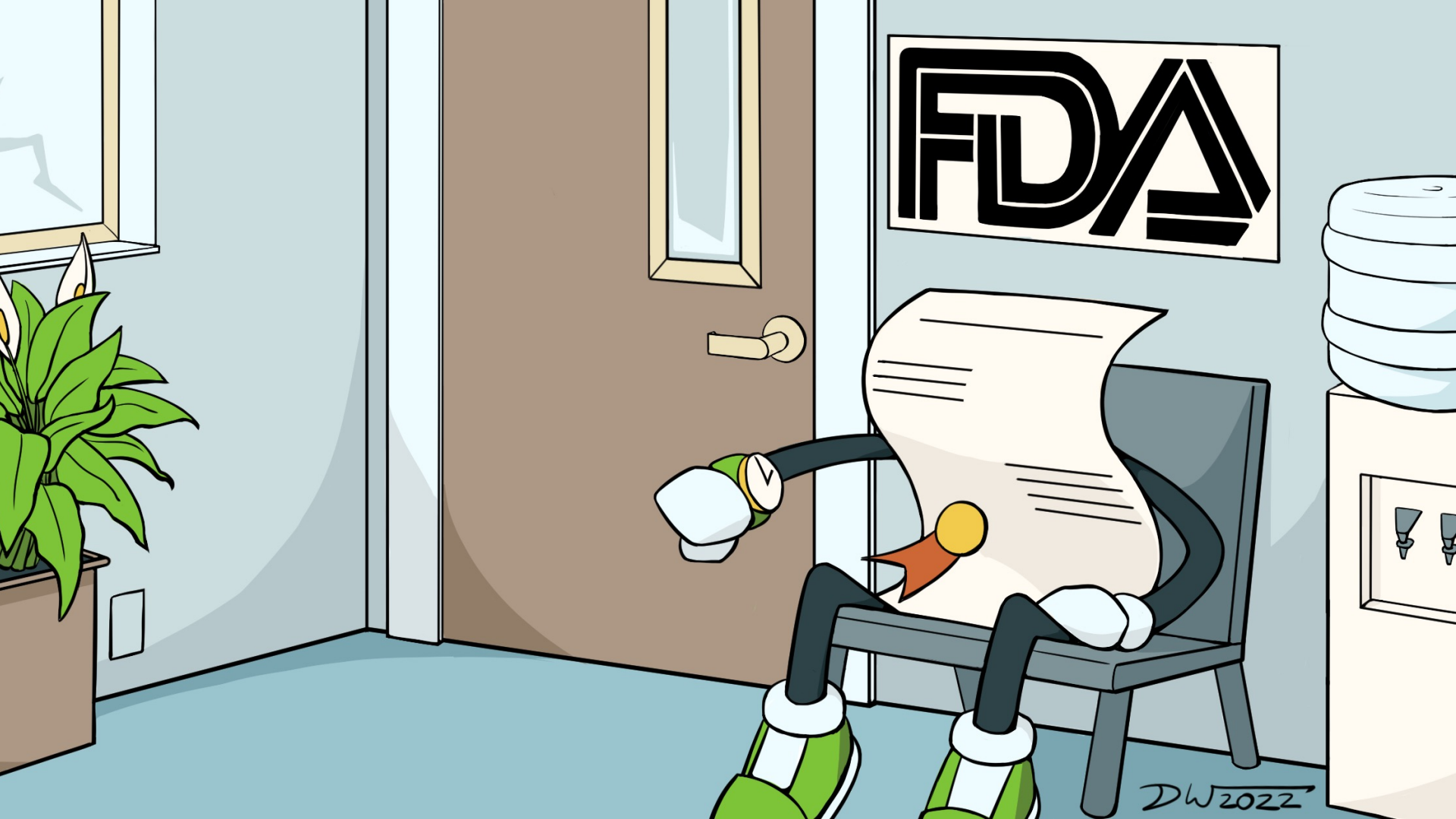


SBIR / STTR

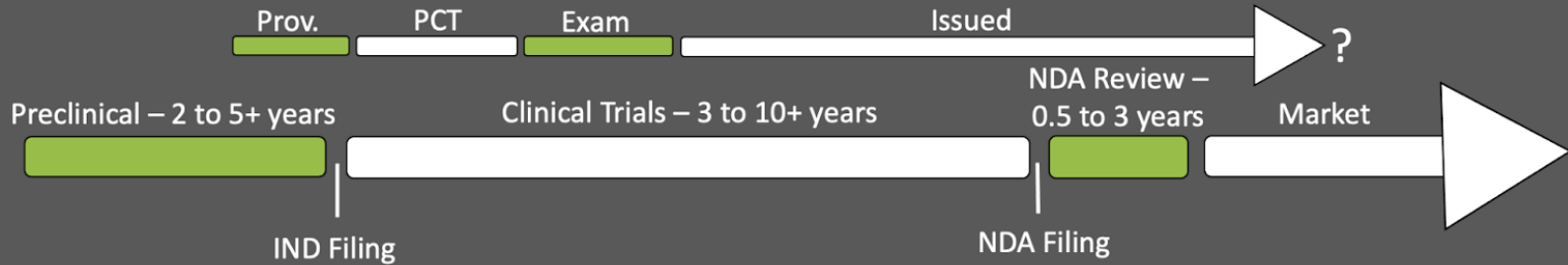
Gov't grants
come with
strings
attached...

Government Grant Gotchyas

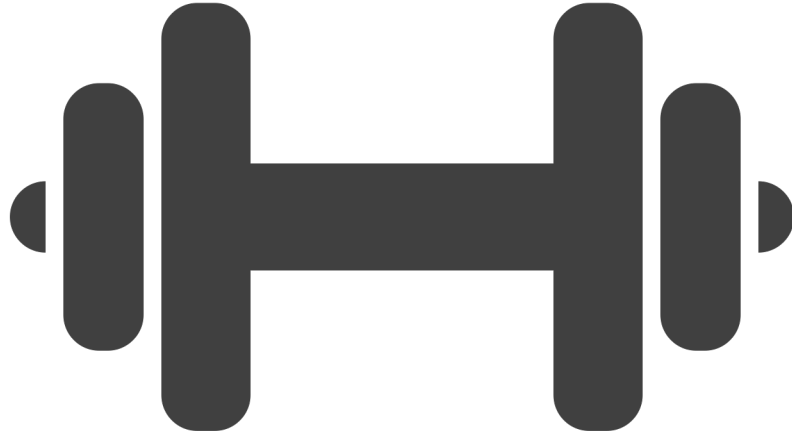
1. Actually reduce invention to practice before using money – otherwise Gov't has a **nonexclusive, nontransferrable, irrevocable, paid-up license** to practice the invention throughout the world
 - Even if your patent was filed before the grant...
2. If subject invention is unelected at 2 years, then **gov't receives title of invention.**
3. If hire subcontractor to perform some of the work, any subject invention from the subcontractor cannot be assigned to your company – **subcontractor retains ownership.**



Maximize Your Exclusivity Window



1. Patent Term Extension
2. New Drug Product Exclusivity
3. New Clinical Investigation Exclusivity



“trainers who say ‘last one’ are the
reason I have trust issues”

Reform on the horizon?

Current events and legislative solutions.

Patent Eligibility Restoration Act of 2023

- Would amend the U.S. Patent Act to clarify the application of 35 U.S.C. Section 101 and address uncertainty plaguing software and biotechnology inventions
- Effectively overruling Alice and previous SCOTUS cases such as Mayo
- Wide bipartisan and community support

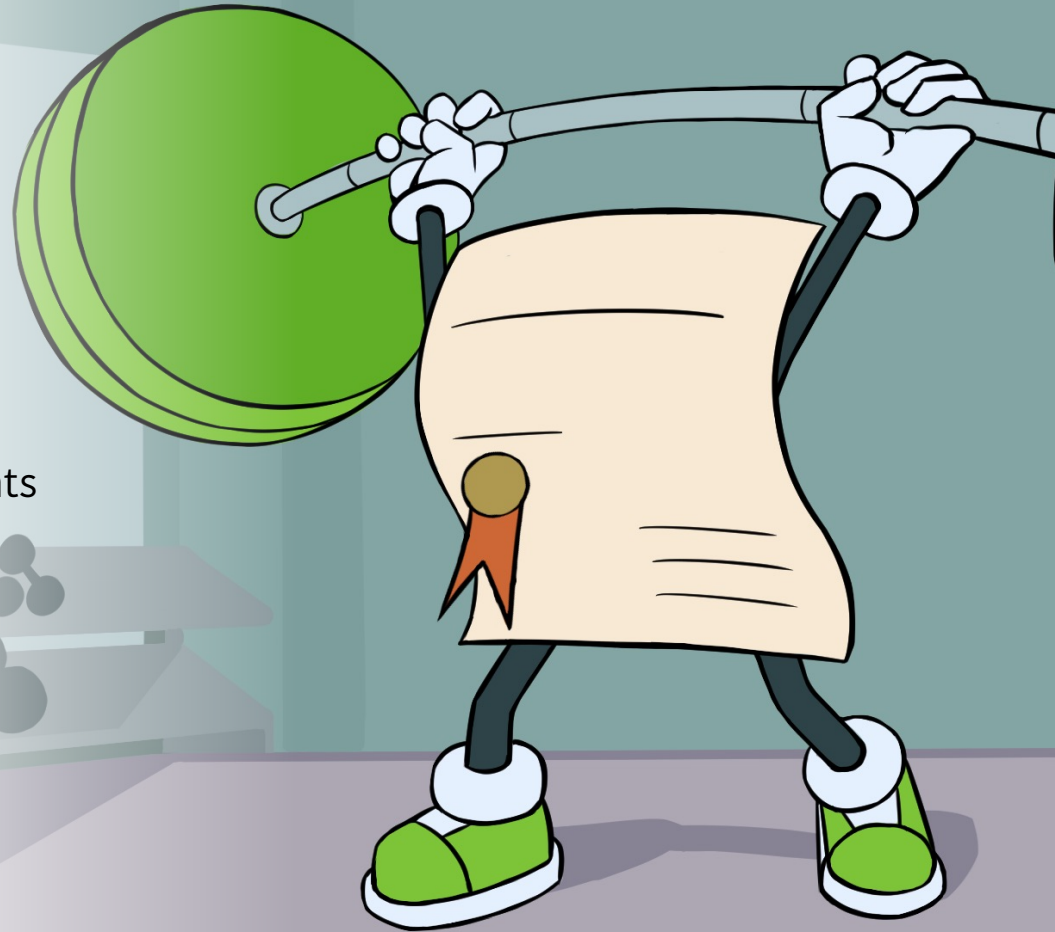
I wish I could outsource
my exercise.



som^{ee}cards

Stronger Life Science Patent Resources

- This **slide** deck
- **Blog posts** on timelines and exclusivity
- **Podcasts** on enablement and gov't grants





**Questions or Comments?
Contact us!**



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