



Jackrel Consulting, Inc.

Patent Agent, Expert Witness and
Consulting Services for companies
and individual inventors.

Unpredictable Art

Patenting Chemical, Biological and Emerging Technologies



Overview

- MPEP 2164.03 “Relationship of Predictability of the Art and the Enablement Requirement”
- Predictable vs. Unpredictable Technologies
- Chemical and Biological Technologies
- Emerging Technologies

MPEP 2164

The Enablement Requirement



“The enablement requirement refers to the requirement of **35 U.S.C. 112(a)** or pre-AIA 35 U.S.C. 112, first paragraph that **the specification describe how to make and how to use the invention**. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.”

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art **without undue experimentation**.” United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)

MPEP 2164.03



Relationship of Predictability of the Art and the Enablement Requirement

- “The amount of guidance or direction needed to enable the invention is inversely related to the **amount of knowledge** in the state of the art as well as the **predictability in the art**. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).”
- “The ‘predictability or lack thereof’ in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention.”
 - “[I]n the field of **chemistry** generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular **broad statement** put forward as **enabling support for a claim**.” In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)
- “The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, **a disclosure of every operable species is not required**.”

Unpredictable Art & Emerging Technologies

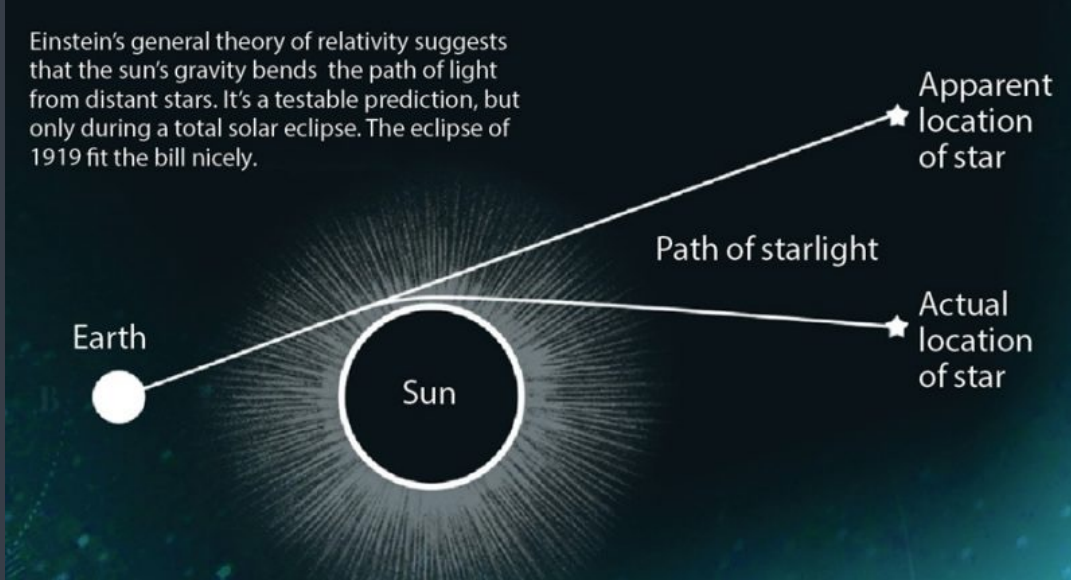


- Chemical & Biological
 - All variations of a claimed species must be enabled in the specification
 - *E.g., for chemical species with substitutable groups – the specification must “teach how to make and use” all of the claimed species*
- Emerging Technologies
 - “New fields” (even if “predictable”) need more description to satisfy disclosure obligations than more mature fields
 - *E.g., broad claims that cover different embodiments need to enable all of the variations with sufficient description (without undue experimentation)*

Predictable

vs.

Unpredictable

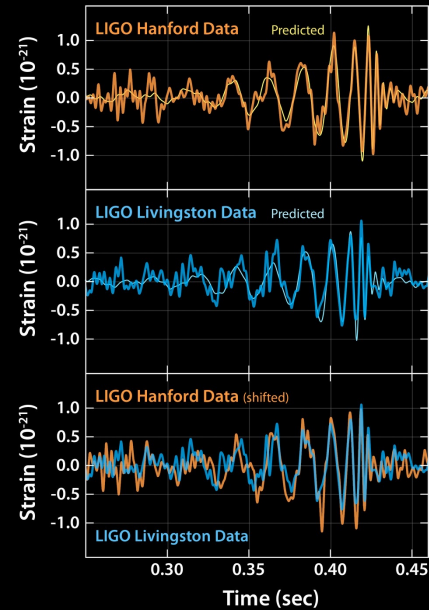


- In 1916 Einstein published his theory of general relativity, stating that mass curves space-time
- May 29, 1919, English scientists – led by Sir Arthur Eddington – traveled to the island of Príncipe off the west coast of Africa to observe a total solar eclipse, and confirmed that light from stars was bent by the gravity of the sun

Predictable

vs.

Unpredictable

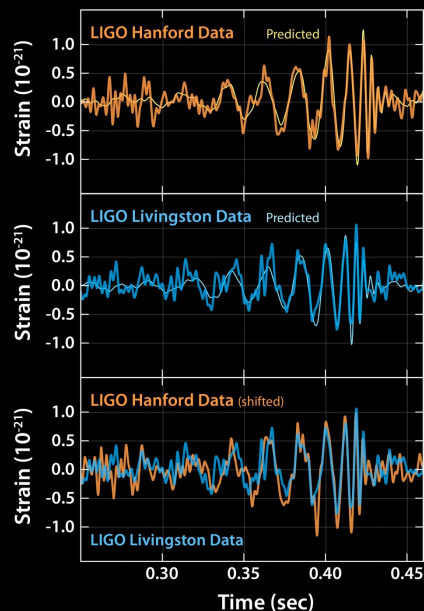


- In 1916, Einstein predicted the existence of gravitational waves in 1916 in his general theory of relativity
- In 2016, LIGO, the Laser Interferometer Gravitational Wave Observatory, confirmed the first observation of gravitational waves

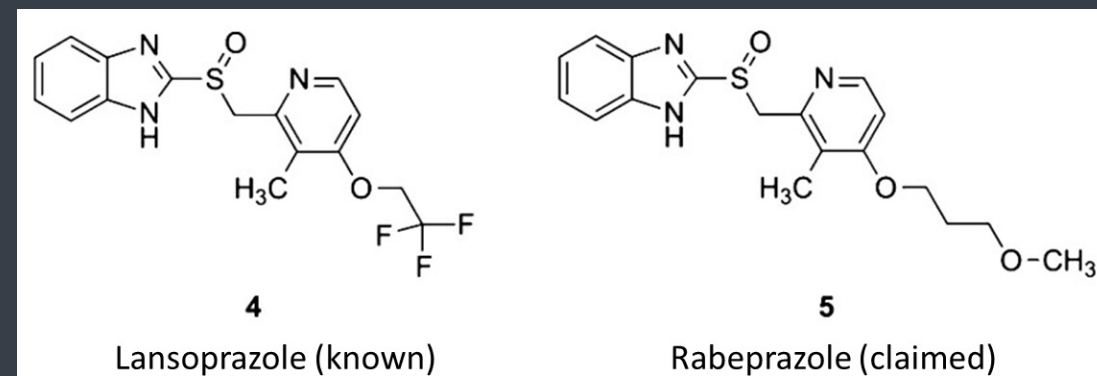
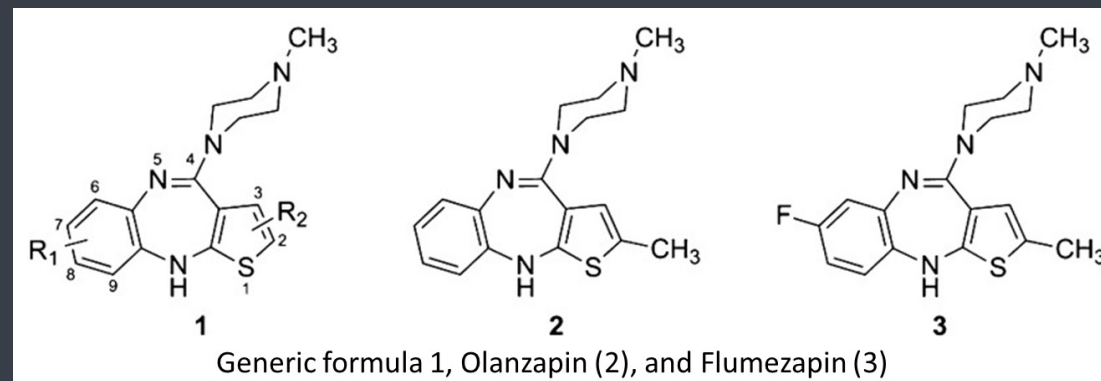
Predictable

vs.

Unpredictable



- In 1916, Einstein predicted the existence of gravitational waves in 1916 in his general theory of relativity
- In 2016, LIGO, the Laser Interferometer Gravitational Wave Observatory, confirmed the first observation of gravitational waves



- Organic molecules with biological effects, such as psychoactive effects or for treating ulcers

Chemical and Biological

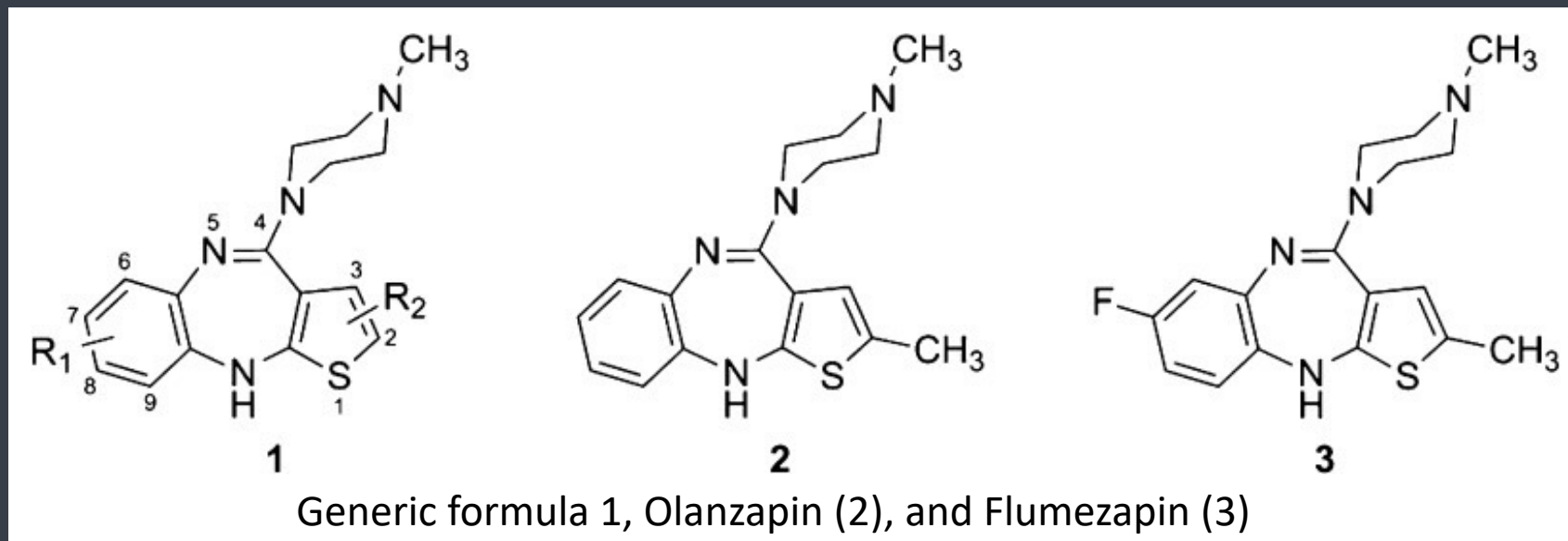


- It can be difficult for a skilled person to predict which function or activity a chemical or biological substance may possess
 - **Advantage:** a newly found substance (and its use) is more likely to be deemed “not obvious” to the skilled person, and hence, meet the statutory requirement of inventive step (§ 103)
 - **Burden:** when claiming a group of compounds, “providing one synthetic route and the activity data of one compound may not be sufficient to support the assumption that all claimed permutations of this compound can be synthesized and are active”

Chemical and Biological



- A generic structural formula does not necessarily inherently disclose the specific compounds falling under the formula (*otherwise no future chemistry inventions would be possible since all conceivable new compounds fall under one known generic formula or another*).



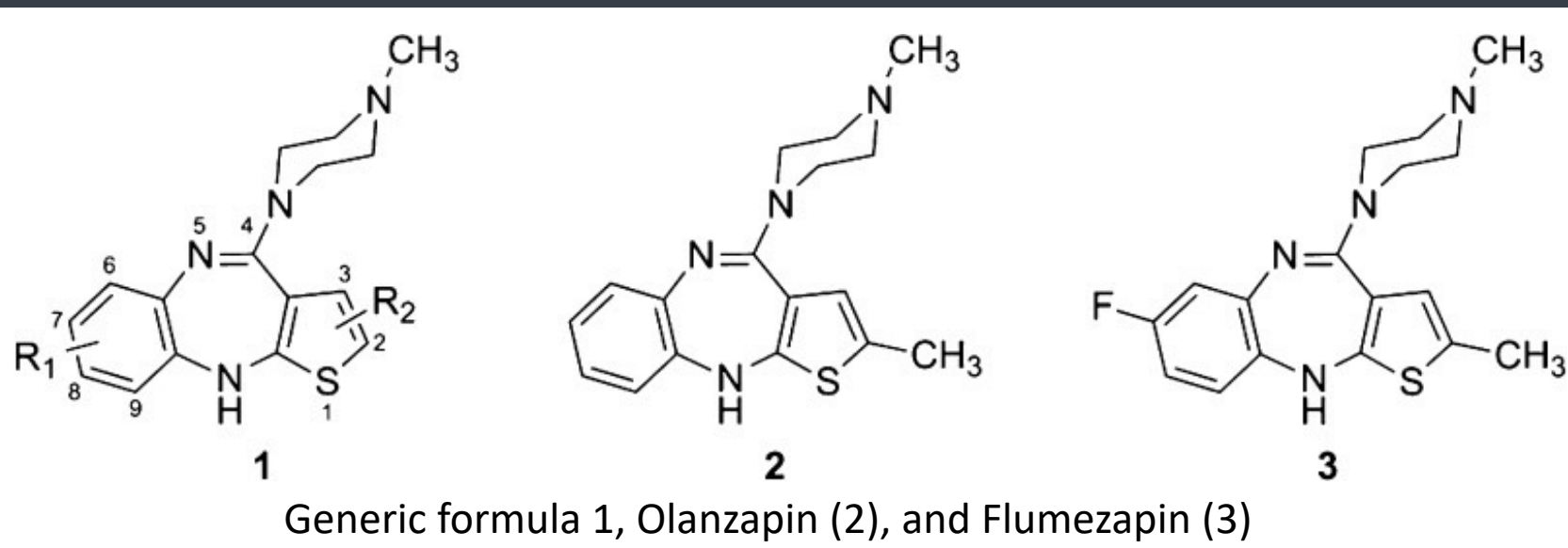
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4416422/>

https://media.bardehle.com/contentdocuments/broschures/IP_Report_2009_1.pdf

Chemical and Biological

- German Federal Supreme Court case (2008)
- “generic” 4'-(N-methylpiperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine (1) with the unspecified residues R1 and R2
- General formula 1 does not disclose 2
- **Is compound 2 rendered obvious by compound 3?**

German Federal Patent Court originally revoked Eli Lilly’s patent on Olanzapin on the basis of lack of novelty, but that decision was reversed in a ground-breaking decision of the Federal Supreme Court in 2008.



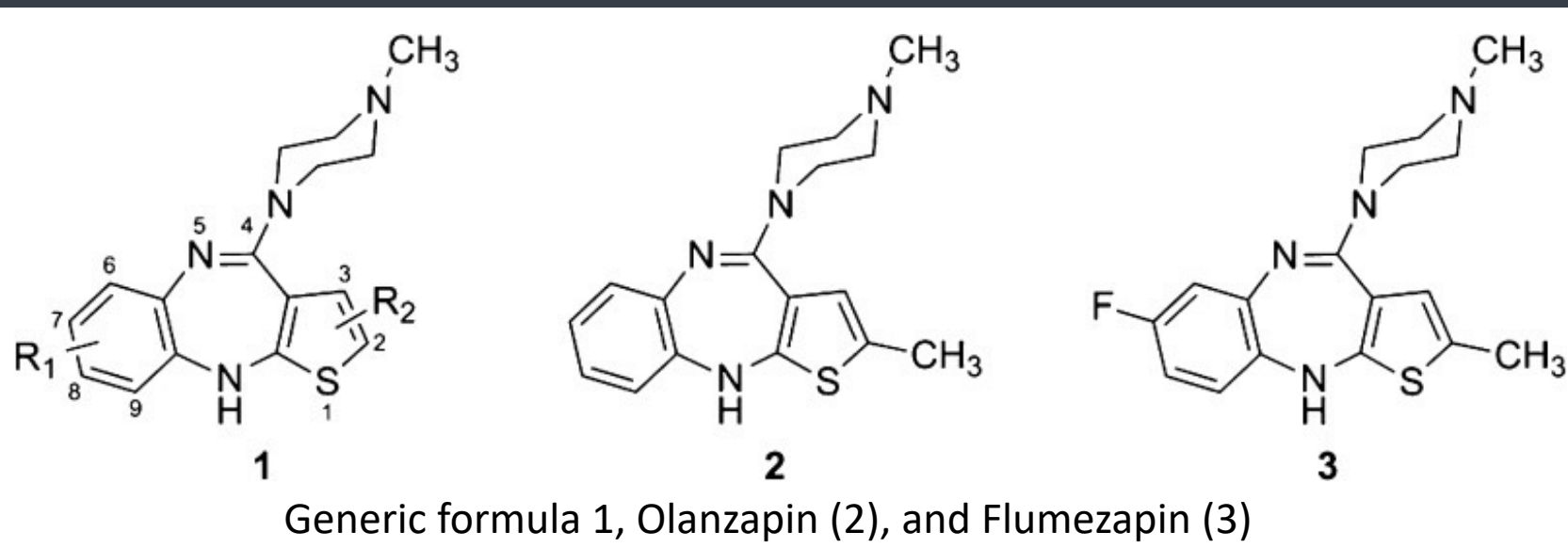
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Chemical and Biological

- Is compound 2 rendered obvious by compound 3?
- Activity data in the prior art → a POSITA would reasonably expect the fluorine to enhance the antipsychotic potency of the compound
- Also, prior art had no individualized compound under the generic formula 1 that was not halogenated
- → POSITA had no **reason or incentive** to modify Flumezapin to compound 2 with no halogen

In this decision, the Federal Supreme Court stated that it will change course, and that a general formula does not disclose the individual compounds falling in its scope.



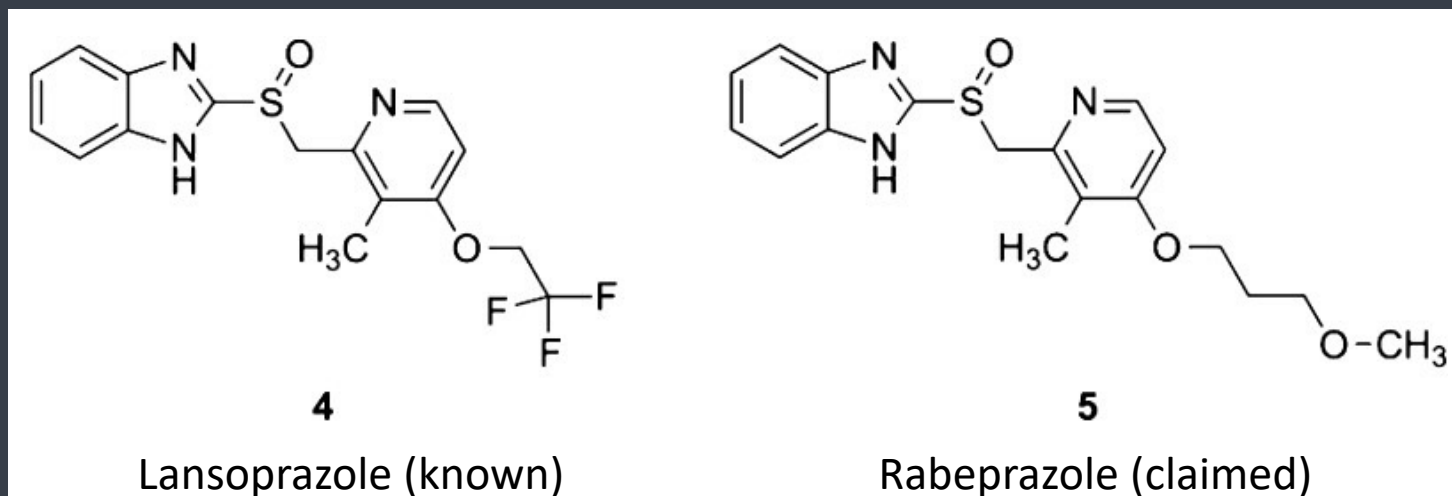
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- there needs to be **no explicit motivation** in the prior art to modify a given teaching to arrive at the claimed subject-matter
- when there is a need to solve a problem and there is **a finite number of identified, predictable solutions**, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp
 - if this leads to the claimed solution, the same is likely an obvious product of ordinary skill and not the product of innovation
- underlying KSR is technology from **predicable art** (a mechanism for combining an electronic sensor with an adjustable automobile pedal)
 - All elements as such and their function were known from the art, and the result of the combination was predictable and hence obvious.

KSR and Unpredictable Arts

- US Court of Appeal for the Federal Circuit (CAFC) – there still needs to be some **reason (motivation) to modify** a starting compound in order to arrive at the claimed compound.
- E.g., Lansoprazole (known from the art) is structurally similar Rabeprazole (claimed compound).
 - However, the CAFC did not find any **motivation** in the art to substitute the active groups.
 - The court stated: “The record shows no discernible reason for a skilled artisan to begin with Lansoprazole **only to drop the very feature, the fluorinated substituent, that gave this advantageous property** [lipophilicity].”



United States Court of Appeal for the Federal Circuit.
 EISAI v. DR. REDDY'S LABORATORY and TEVA
 PHARMACEUTICALS No. 07-1397 (Fed. Cir. July 21, 2008)

Unpredictable Arts

Detailed Description – Supporting Examples



- Chemical and Biological patents have to show that a **class of compounds** is supported by a set of examples
 - **enabled** over the whole claimed range
 - in full **possession** of the invention on the filing date (e.g., actual or constructive reduction to practice)
 - the **activity** underlying the claimed compounds is also present over the whole range claimed

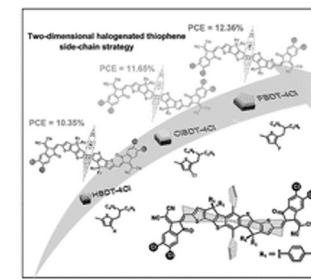
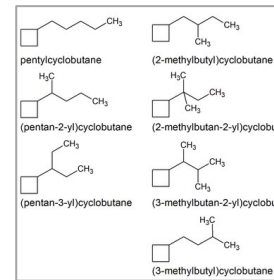
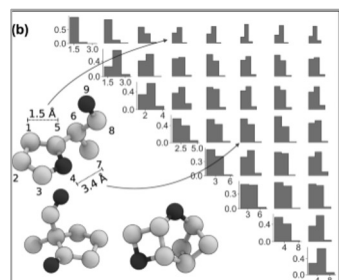
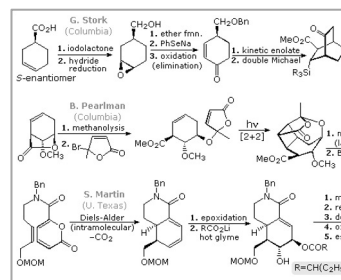
Unpredictable Arts

Detailed Description – Supporting Examples



- AbbVie v. Janssen Biotech, CAFC (2014)
 - invalidated a claim for a class of antibodies with **no structural definition** (only defined functionally in terms of a certain disassociation constant to a binding site)
 - “the claimed scope reaches beyond what the inventors have contributed to the art,” (since the inventors did not provide structural examples of antibodies that fulfill the claimed function)
- Wyeth v. Abbott Laboratories CAFC (2013)
 - invalidated a broad genus claim directed at Rapamycin and its derivatives
 - the disclosure **only supported one single compound** within the scope of the claims (Sirolimus)
 - the skilled person would have to synthesize and biologically evaluate thousands of compounds to see if they have the claimed properties

Unpredictable Arts – What to do



Cover as much breadth as possible with examples and data (synthesis and activity)

Provide guidance in the description how to extrapolate from these examples/data to the remaining scope

Emerging Technologies

- How much does a patent specification rely on the **knowledge** of a person of ordinary skill in the art (POSITA) to provide support for certain claimed embodiments?
- Can be tension between a company's desire to protect valuable **trade secrets** versus the need to provide an enabling disclosure

Emerging Technologies & Enablement



- Historically, **predictable arts** can be enabled by a single example
 - Spectra-Physics, Inc. v. Coherent, Inc. (Fed. Cir. 1987)
- “**New fields**,” however, even if “**predictable**,” may not rely on knowledge of a POSITA to satisfy disclosure obligations to the same extent to which inventions in more mature fields may
 - Automotive Technologies International v. BMW of North America (CAFC 2006)
- New guidance – can a POSITA make and use the entire claimed scope “**without undue experimentation**”
 - Trustees of Boston University v. Everlight Electronics Co., Ltd. (CAFC 2018)
 - Guidelines on Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. 112 (USPTO, Jan 2019)

Emerging Technologies

Automotive Technologies International v. BMW of North America, CAFC '06



- The CAFC found all claims invalid due to **lack of enablement**
- Crash sensing devices used to determine when air bags were deployed
- The specification of the patent (US 5,231,253) described an embodiment of the device utilizing a mechanical sensor in **considerable detail**
- It also described utilizing an electronic sensor, but included **less detail** and relied on the POSITA's knowledge.
- At trial, Automotive Tech's expert testified that POSITA could use **off-the-shelf components and well-known circuit design and programming**

→ When the patent application was filed in 1992, air bag deployment sensors were arguably still an **emerging technology**.

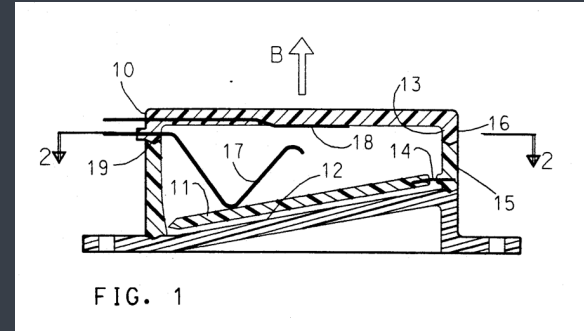


FIG. 1

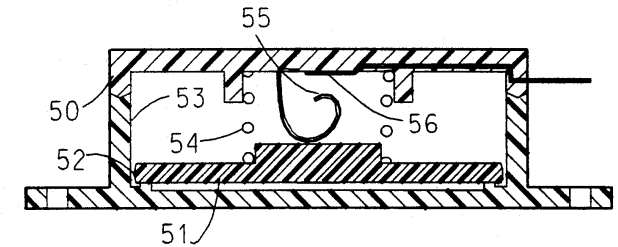


FIG. 6

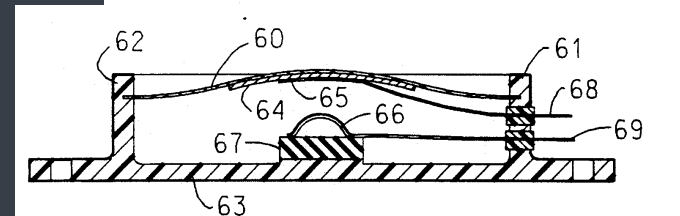


FIG. 7

<https://www.womblebondnickinson.com/us/insights/articles-and-briefings/patenting-emerging-technologies-determining-how-far-artisans-knowledge-goes>

<https://cafc.uscourts.gov/sites/default/files/opinions-orders/06-1013.pdf>

Emerging Technologies

Automotive Technologies International v. BMW of North America, CAFC '06



1. A side impact crash sensor for a vehicle having front and rear wheels, said sensor comprising:

- (a) a housing;
- (b) a mass within said housing movable relative to said housing in response to accelerations of said housing;
- (c) **means** responsive to the motion of said mass upon acceleration of said housing in excess of a predetermined threshold value, **for initiating an occupant protection apparatus**; and
- (d) means for mounting said housing onto at least one of a side door of the vehicle and a side of the vehicle between the centers of the front and rear wheels, in such a position and a direction as to sense an impact into the side of said vehicle.

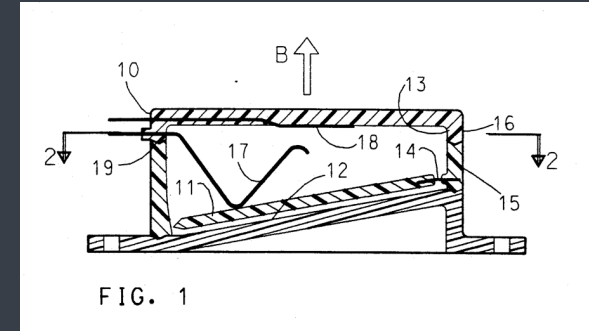


FIG. 1

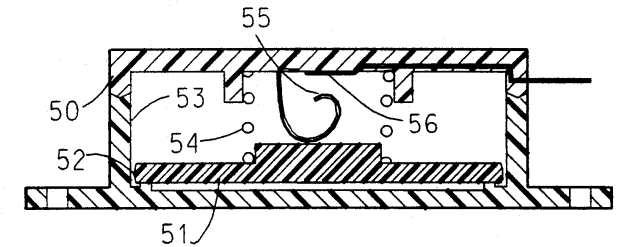


FIG. 6

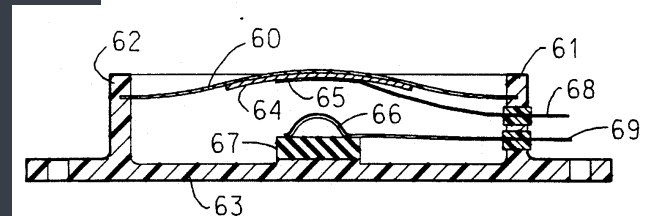


FIG. 7

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Emerging Technologies

Sitrick vs Dreamworks, CAFC '08



- The CAFC found all claims invalid due to **lack of enablement**
- Integrating a user's audio signal or visual image into a pre-existing **video game or movie**
- Defendants' two experts explained that a POSITA would not be able to take the teachings regarding **video games** and apply them to **movies**

→ “The district court...in a detailed and thorough opinion granted summary judgment in favor of Defendants because it found all asserted claims of the '864 and '825 patents invalid for lack of enablement **as to movies**. *Sitrick v. Dreamworks, LLC*, No. 03-4265 (N.D.Cal. July 21, 2006). The district court did not reach the issue of whether the asserted claims would have been enabled for **video games**. *Id.* at 73.”

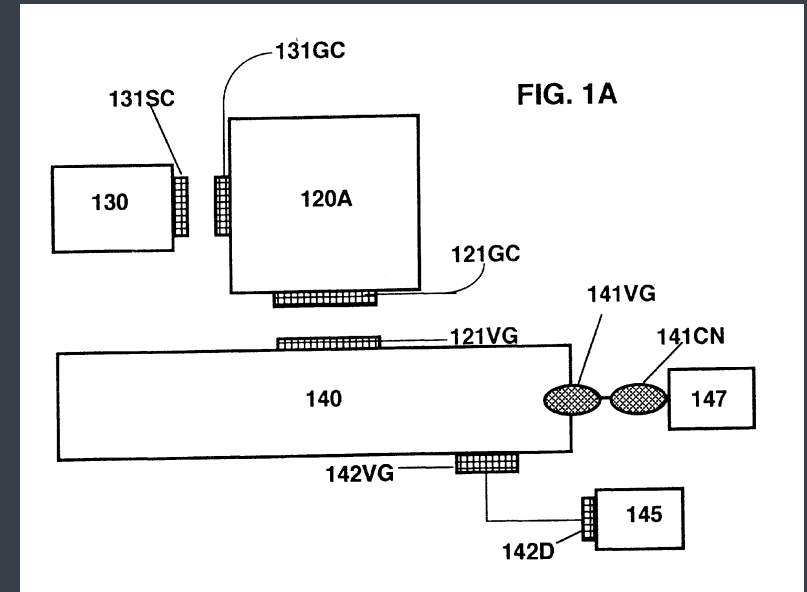


FIG. 1A illustrates an embodiment of a user image adapter interface system used in conjunction with a video game apparatus, a user image storage card, and a video game software or firmware card, in accordance with the present invention

Emerging Technologies

Sitrick vs Dreamworks, CAFC '08



54. A method of integrating a user voice image into a **presentation output**, the method comprising the steps of:

sampling a user's voice;

analyzing the sampled user's voice to provide user voice parameter data representative of the user voice image;

storing the user voice parameter data;

synthesizing and interjecting the user's voice into **the presentation output** responsive to the user voice parameter data comprising the step of associating a particular predefined character image within the presentation with the user's voice so that when the particular predefined character is speaking, the user voice parameter data is input as a model to a voice synthesizer that effects the integration of the user's voice into the presentation output as associated with the predefined character image.

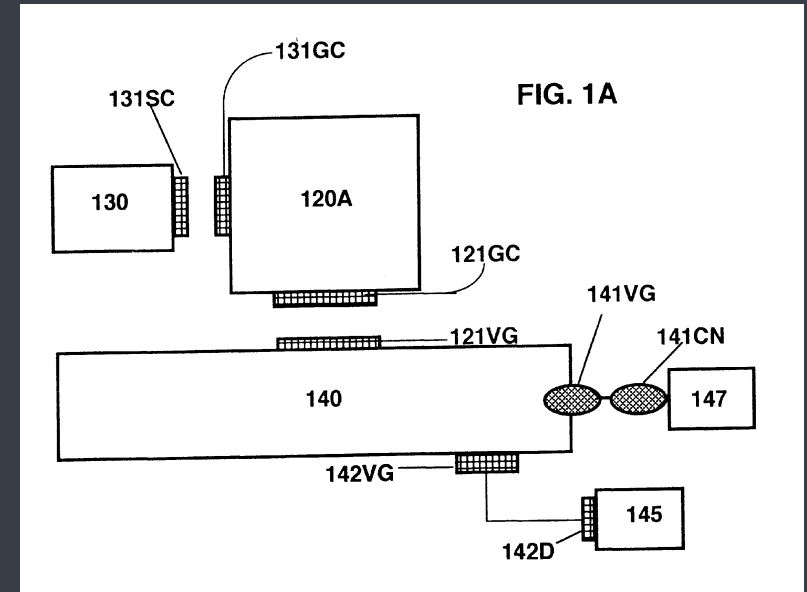
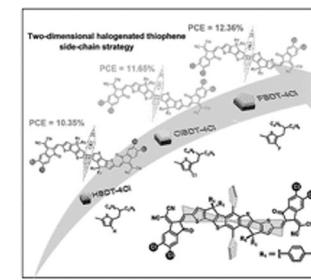
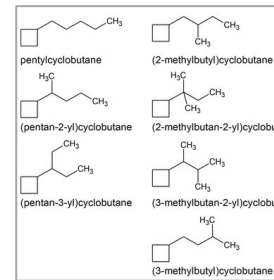
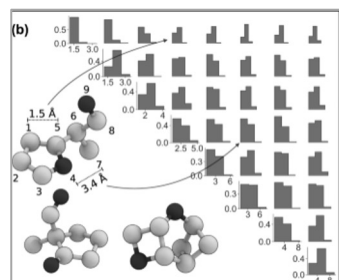
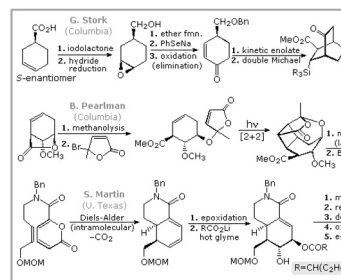


FIG. 1A illustrates an embodiment of a user image adapter interface system used in conjunction with a **video game** apparatus, a user image storage card, and a **video game** software or firmware card, in accordance with the present invention

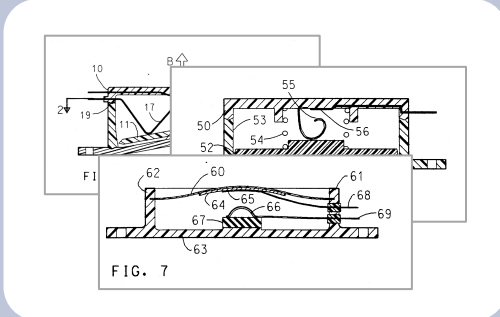
Unpredictable Arts & Emerging Technologies – What to do



Cover as much breadth as possible with examples and data (synthesis and activity)

Provide guidance in the description how to extrapolate from these examples/data to the remaining scope

Unpredictable Arts & Emerging Technologies – What to do



1. A method of integration of a user image into a pre-defined audiovisual image source, the method comprising the steps of:
providing a user image;
first providing a presentation output from the audiovisual image source;
then selecting a portion of the presentation output as a selected portion for user image associative integration;
then analyzing the presentation output associated with the selected portion;
then integrating the user image with the selected portion; and
providing a modified presentation output wherein the user image is associated with and integrated into the selected portion in the presentation output.



Comprehensively describe the technology, even those made from components that are “off-the-shelf”

Carefully consider the **scope of the claim terms** being construed

Consider not filing patents in certain areas to avoid disclosing **trade secrets**



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Thank You

Emerging Technologies



- “By classifying the field of Automotive Tech’s invention as a “new field” —despite using off-the-shelf components and well-known design techniques—the Federal Circuit appears to have eviscerated its predictable arts doctrine from Spectra-Physics, Inc., leaving a significant question of where the practitioner should draw the line on the amount of disclosure required in a patent specification for an invention in a new field versus a predictable art.”
- “For entities more concerned with trade secret protection, it is important for the practitioner to keep in mind that questions of patent invention enablement under 35 U.S.C. Section 112(a) are evaluated against “claimed” subject matter, with a focus on whether everything within the scope of each claim is enabled. If information to enable such claims cannot be easily reverse engineered and therefore has more value as a trade secret, the practitioner, in close partnership with the inventor or other subject matter experts, should consider omitting claims which might require disclosure of non-readily discernable information that would otherwise need to be disclosed in order to satisfy patent enablement standards.”
- “Finally, the lack of clarity on the extent to which a specification may rely on the artisan’s knowledge has important downstream effects on strategies taken by patentees looking to assert patents. With contradictory and unclear guidance on when and to what degree a patent disclosure may rely on the artisan’s knowledge to fill gaps in an otherwise non-enabling disclosure, patentees should carefully consider the scope of claim terms being construed through the lens of a careful and thorough analysis of not only the level of detail in a patent’s specification, but also the state of the art of the field of that invention at the time that the underlying patent application was first filed.”
- “For that reason, if, years after a patent application was originally filed, a patentee or its subject matter experts believes that there is a credible risk that the field of the patented invention may be determined to be “new” at the time of the underlying patent application’s filing, the patentee would benefit by either narrowing its claim term constructions and even not asserting claims that are found to have a less robust enabling disclosure, in order to avoid an enablement challenge that ultimately invalidates the entire patent, as was the case in the Fed Circuit’s 2008 decision in *Sitrick v. Dreamworks, LLC*. “