

## **Pharma and Chemical Patent Applications: Meeting Written Description Requirement**

Demonstrating Evidence of Possession of the Invention,  
Navigating the Guidelines, Maintaining Chain of Priority

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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# Outline

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- I. Written description requirements
- II. Court treatment
- III. Best practices for preparing and prosecuting the application—written description
  - A. Describe representative number of species
  - B. Identify physical or chemical characteristics common to the claimed genus
  - C. Avoid functionally defined genus claims
- IV. How a lack of written description support can be used in an AIA inter partes review before PTAB
- V. How a lack of written description support can be used before PTAB to attack claims by breaking the chain of priority to pre-AIA date benefit in an AIA post-grant review

# Written Description Requirement: Statutory

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- 35 U.S.C. 112 Specification.
  - (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.

*As of Sept. 16, 2011, AIA amended §282 so failure to disclose best mode can no longer be grounds for invalidity or unenforceability in “proceedings commenced on or after Sept. 16, 2011.”*

# Written Description Requirement: Purpose and Scope

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## General Policy:

- The requirement of an adequate disclosure assures that the public receives *quid pro quo* for the limited monopoly which is granted to the inventor.
  - *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142, 122 S.Ct. 593, 151 L.Ed.2d 508 (2001) (“The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’” quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484, 94 S.Ct. 1879, 40 L.Ed.2d 315 (1974)).

# *SATISFYING §112*

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

Careful drafting to insure compliance with § 112 pays dividends in both prosecution and litigation.

USPTO Examiner Training Materials for §112 found at [www.uspto.gov](http://www.uspto.gov)

MPEP §§ 2171-2174



# *Description Of Invention*

- Should “convey clearly to those skilled in the art the information that applicant has invented the specific subject matter later claimed.”
  - Build spec with support for every embodiment disclosed.
  - Obvious insufficient.
  - One skilled in the art should “reasonably conclude” that patentee had “possession” by describing claimed invention and all limitations.
- Burden on USPTO to show failure to comply with requirement.

*See MPEP §2161-2163.07*

# *Description Of Invention: Show Possession*

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Actual reduction to practice.

- Show making of an embodiment.
- Describe deposit.

Clear depiction of invention in drawings.

Give as much information as you can about proprietary material(s).

Disclosure of “sufficiently detailed relevant identifying characteristics”.

- Complete or partial structure or other physical properties.
- Functional characteristics coupled to known correlation between structure and function.

# §112 REQUIRES MORE THAN “HOPE” OR “PLAN”

- *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir.), *cert. denied*, 125 S.Ct. 629 (U.S. Nov 29, 2004)
  - "Method of treatment" claim recites utilizing a specific biochemical pathway to decrease pain.
    - A method "comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment ... in which the compound inhibits the enzymatic activity of the PGHS-2 gene product, and has minimal effect on enzymatic activity of PGHS-1."
  - DC: Invalid for lack of written description.
    - Patent did not specify any compound that could actually utilize that pathway.

# §112 Requires More Than “Hope” Or “Plan”

- *Univ. of Rochester* (con’t)
  - FC: Affirmed. Rochester patent is invalid for lack of the written description because the patent discloses no compound for performing the claimed method and there was no evidence that such a compound was known.
    - *Describes compound's desired function, but does not identify any compounds that can be used in claimed methods of treatment.*
    - Rochester did no more than invent a “method of identifying a selective COX-2 inhibitor,” not a “method of using a compound to inhibit COX-2.”
    - Not good enough for written description support.
      - No disclosure of compound for performing the claimed method and no evidence that such a compound was known.

# §112 Requires More Than “Hope” Or “Plan”

## *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011)

- Centocor’s asserted claims cover human variable regions and fully-human antibodies like Abbott's Humira®.
- In order to win, Centocor’s asserted claims must be supported by adequate written description in the 1994 CIP applications.

1991: patent application filed disclosing A2 mouse antibody and the chimeric antibody

1994: CIP describes the A2 mouse antibody and the single chimeric antibody that Centocor made based on A2's mouse variable region.

2006: '775 patent issued fully-human antibodies

# §112 Requires More Than “Hope” Or “Plan”

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## *Centocor* (con’t)

- FC: Claims invalid for lack of written description.
  - Specific claim language was not added until 2002 and is not part of the 1994 CIP applications as filed.
  - “while the patent broadly claims a class of antibodies that contain human variable regions, the specification does not describe a single antibody that satisfies the claim limitations.”
  - “There is nothing in the specification that conveys to one of skill in the art that Centocor possessed fully-human antibodies or human variable regions that fall within the boundaries of the asserted claims.”
  - “the asserted claims constitute a wish list of properties”
  - No possession of desired result.

# *Written Description Separate From Enablement: Ariad Pharmaceuticals v. Eli Lilly Rehearing En Banc*

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§112, first paragraph, contains a written description requirement separate from enablement.

- “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.**”
- Asserted claims invalid for failure to meet the statutory written description requirement.
  - “the claims recite methods encompassing a genus of materials achieving a stated useful result, but the specification does not disclose a variety of species that accomplish the result....’”

# *Other Teachings from Ariad*

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Question of fact how much disclosure is required; no bright-line rule: “the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”

Obviousness not enough: “a description that merely renders the invention obvious does not satisfy the requirement”

“Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of ‘invention’-that is, conceive of the complete and final invention with all its claimed limitations-and disclose the fruits of that effort to the public.”



# *Knock-Out Punch in Ariad*

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“Whatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims. ...Here, the specification at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF- $\kappa$ B activity. Yet the asserted claims are far broader. We therefore conclude that the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description, and thus hold the asserted claims invalid.”

# *Provisional Applications And Written Description*

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*Novozymes A/S v. DuPont Nutrition Biosciences*, 723 F.3d 1336 (Fed. Cir. 2013)

- Provisional application disclosed 33 possible positions for mutation targets in any of 7 parent enzymes by deletion, addition, or substitution; also disclosed variations in temperature, pH
  - 7 x 33 x (at least 40) -> you can see where this is going...
  - No disclosure that any one of the 33 sites is preferred or whether single or combined mutations are preferred.
- Claims: modified enzymes and required an amino acid substitution at position S239 and increased thermostability at 90°C, pH 4.5, and 5 ppm calcium.
- DC: Claims invalid for inadequate written description.
  - provisional disclosed “a potential enormous number” of enzyme variants but did not point out the specific variants later claimed in the patent

# *Provisional Applications And Written Description*

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## *Novozymes (con't)*

- FC: Affirmed.
  - 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.
  - “[N]othing in the 2000 application indicates that Novozymes then possessed what it now claims.”
  - “[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.”
  - Case is like *Univ. of Rochester*.

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*Written Description Requirement:  
What Is Required*

# *How to Meet Written Description Requirement in Pharma/Chem Patent Applications*

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- “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ...  
*i.e.*,
  - complete or partial structure, other physical and/or chemical properties,
  - functional characteristics when coupled with a known or disclosed correlation between function and structure, or
  - some combination of such characteristics.”

(Manual of Patent Examination and Procedure)

# *Is Disclosure of One Species or Embodiment Enough?*

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- ▶ Some language in *Ariad* suggests that disclosure of a sufficient embodiment or example would satisfy WD. For example, the opinion describes one of the "few broad principles that hold true across all cases" as follows:
  - ▶ We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006).
- ▶ This passage supports the view that examples are not *necessary* but that a specific example falling within a claim may be *sufficient* to satisfy WD.

# *When Is Disclosure of More Than One Species Or Embodiment Required?*

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Other language in *Ariad* suggests that a single example may not always suffice:

- Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. *Compare Eli Lilly*, 119 F.3d at 1567 (holding an amino acid sequence did not describe the DNA sequence encoding it), *with In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (discussing how it is now a "routine matter" to convert an amino acid sequence into all the DNA sequences that can encode it).

# *When Is The WD Adequate?*

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- ▶ From CAFC *Eli Lilly, Fiers*, and *Enzo* decisions:
  - ▶ Sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so a POSA can "visualize or recognize" the members of the genus.
  - ▶ An adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials.
  - ▶ Functional claim language can meet the written description requirement when the art has established a correlation between structure and function.



# *Ariad Did Not Provide Specific Guidance*

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The majority opinion provides only a vague directive:

- ***“But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.”***

# *When Do WD Problems Typically Appear?*

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- Broad claim with little support in specification such as a genus claim or functionally described structure with few or no species described in specification;
- Attempts to cherry pick the original disclosure to specifically claim narrow subject matter later discovered to be valuable;
- Substantial claim amendments made during prosecution; and
- Reliance on earliest priority/benefit date, often when priority/benefit application is a provisional.

# Broad Claim Supported By One Example: Sufficient?

## ▶ No.

- ▶ *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005)
  - ▶ Specification provides only one method for claimed subject matter, but claim scope not limited to one method.
  - ▶ Claim not invalid/unpatentable simply because insufficient embodiments representing the full scope of the invention. **Claim invalid because the disclosure does not convince a person of skill in the art that the inventor possessed the invention and enabled such a person to make and use the invention without undue experimentation.**
    - ▶ POSITA would only understand that the inventor invented a method for making claimed subject matter by the one method described, not generically.
    - ▶ “[Allowing the claim] would lead to sweeping, overbroad claims because it would entitle an inventor to a claim scope far greater than what a person of skill in the art would understand the inventor to possess or what a person of skill in the art would be enabled to make and use. . . . ***A patentee cannot always satisfy the requirements of section 112 . . . merely by clearly describing one embodiment of the thing claimed.***”

# *Broad Claim Supported By Specification Containing Patent Profanity: Sufficient?*

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- **No.**
  - *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998)
    - No shape limitation to claimed cup implant, but specification only described conical cups.
    - Specification used “patent profanity” and described the conical shape as “extremely important”
      - “Such statements make clear that the... patent discloses only conical shaped cups and nothing broader. The disclosure ...does not support the ...generic subject matter [claimed].”
      - “the written description ...does not attempt to identify other, equally functional shapes or talk in terms of a range of shapes....”

# *Broad Specification Language Sufficient to Support Broad Claim Language?*

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- **Yes.**
- *Energy Transp. Group, Inc. v. William Demant Holding A/S*, 697 F.3d 1342 (Fed. Cir. 2012)
  - Claim to a hearing aid with a programmable filter.
  - No limitation as to where the programming occurs, how frequently it occurs, or what structure provides the programming.
  - WD support for programmable filter to be adaptive?
  - POSITA would understand that the programmable filter could be an adaptive filter.
  - Inventors were in possession of a programmable hearing aid that could use adaptive filtering for feedback.

# Exact Language Required for WD Support?

- ▶ **No.**

- ▶ **Pozen Inc. v. Par Pharmaceutical, Inc., 696 F.3d 1151 (Fed. Cir. 2012)**

- ▶ ***Claim: 5. A therapeutic package for dispensing to, or for use in dispensing to, a migraine patient, which comprises:***
  - ▶ ***(a) one or more unit doses, each such unit dose comprising:***
    - ▶ ***(i) X and (ii) Y; wherein the respective amounts of said X and said Y in said unit dose are effective, upon concomitant administration to said patient of one or more of said unit doses, to reduce migraine relapse or produce longer lasting efficacy compared to the administration of said X in the absence of said Y or the administration of said Y in the absence of said X, and***
  - ▶ ***(b) a finished pharmaceutical container therefor, said container containing said unit dose or unit doses, said container further containing or comprising labeling directing the use of said package in the treatment of migraine.***

# *Exact Language Required for WD Support?*

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▶ *No.*

▶ *Pozen (con't)*

- ▶ Specification discloses several dosage forms, including an oral unit dosage, to teach treating migraines by concomitantly administering therapeutic amounts of sumatriptan and naproxen.
- ▶ Exact language not required if description sufficient for POSITA to understand inventor had possession of claimed invention.
- ▶ POSITA would understand that pharmaceutical dosages are administered to a patient in containers or packages.

# *Description Of Invention: Species Claims*

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- Actual reduction to practice or not.
- If not, check drawings and disclosure.
- Complete structure of species or not.
- If not, any relevant identifying characteristics.
  - In view of level of skill and knowledge.
  - Partial structures, functional characteristics, or correlation between.
  - Less information needed for mature art.



# *Description Of Invention: Genus Claim*

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Sufficient description of a representative number of species.

- Actual reduction, drawings, disclosure.
- Representative of “entire genus.”
  - Number depends on homogeneity in genus.
  - Inverse function of knowledge and skill.

# Description Of Invention: Genus Claim

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- ▶ *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011)
  - ▶ Claim: Drug-eluting stents using either rapamycin or a macrocyclic lactone analog of rapamycin as the therapeutic agent.
  - ▶ Specifications did not demonstrate possession of analogs of rapamycin that might work in a stent. [but what possible prior art effect against later inventions?]
  - ▶ No examples.
  - ▶ FC affirmed summary judgment of invalidity for lack of written description support:
    - Specifications did not demonstrate possession of analogs of rapamycin that might work in a stent.
    - “. . . the claims cover tens of thousands of possible . . . analogs.”
    - Relevant specifications did “not identify any specific species of rapamycin analogs”
    - “insufficient correlation between the function and structure of rapamycin and its analogs to provide adequate written description support for the entire genus of macrocyclic lactone analogs of rapamycin.”

# Description Of Invention: Genus Claim

- *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)

- Claim 29. A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a koff rate constant of  $1 \times 10^{-2} \text{ s}^{-1}$  or less, as determined by surface plasmon resonance.

- Defendant: “AbbVie's patent disclosure is limited to a family of closely related, structurally similar antibodies that are all derived from Joe-9, whereas AbbVie's functionally defined claims cover antibodies having widely varying structures[.]”

- Jury: claim invalid for lack of written description.

# *Description Of Invention: Genus Claim*

- *AbbVie* (con't)

- FC: Affirmed.

- “claimed invention is a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen.”

- AbbVie's patents “only describe one type of structurally similar anti-bodies and that those antibodies are not representative of the full variety or scope of the genus.”

- “no evidence to show any described antibody to be structurally similar to, and thus representative of” the allegedly infringing product.

# Description Of Invention: Genus Claim

- *AbbVie* (con't)

- FC: Affirmed.

- “It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date. ... However, the record here does not indicate such an established correlation. ... The asserted claims attempt to claim every fully human IL-12 antibody that would achieve a desired result, i.e., high binding affinity and neutralizing activity, and cover an antibody as different as [the allegedly infringing product], whereas **the patents do not describe representative examples to support the full scope of the claims.**”

# *Description Of Invention: Genus And Species*

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Bigham v. Godtfredsen, 857 F.2d 1415 (Fed. Cir. 1988)

- A generic term such as “halogen” normally sufficient to describe all members of the class unless patentable distinctness between the members of the class is asserted.
- Count 1 - iodo or bromo
- Count 2 - chloro, alkylsulfonyloxy and toluenesulfonyloxy
- FC: disclosure of halogen and chloro did not serve as an adequate written description of bromo and iodo compounds.

# Written Description

*GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725  
(Fed. Cir. 2014)

Claim: dutasteride and its pharmaceutically acceptable solvates.

Banner: claim invalid because lack of written description for term “solvates” “whether that term is limited to crystalline structures (as Defendants argue) or covers crystalline and non-crystalline structures, produced through reaction with a solvent or precipitation or crystallization from a solution.

DC: Defendants failed to prove the inadequacy of the written description.

FC: Affirmed.

Term “solvate” is defined by structure and by the process of creating it, not by what the molecule does.

“The claim term and its corresponding description, however broad, identify certain structures produced by certain processes. We have not required more for an adequate written description that matches claim scope.”

## *With Proper Disclosure, Claims Broader Than Specification May Have WD Support*

- *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009)
  - Claims related to microorganisms useful for production of DHA, an essential omega-3 fatty acid.
  - Earlier application contains no working examples that consolidate cells from different strains.
  - FC: Affirmed claims not invalid.
    - Earlier application had an adequate written description of the claimed invention, therefore claim entitled to priority date and not anticipated.
    - “a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed. . . .”
    - Expert testimony that one of ordinary skill in the art would understand earlier application as describing consolidation process



# *Support In Prior Applications*

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- *Chen v. Bouchard*, 347 F.3d 1299 (Fed. Cir. 2003)
  - Chen = junior party; originally filed an application disclosing methods he said produced mixtures of 7 $\alpha$ - and 7 $\beta$  fluorotaxols.
  - Later, he discovered the methods in fact produced cyclopropataxol derivatives.
  - Chen claimed the cyclopropataxol derivatives in a continuing application and was granted a patent in 1992.
  - In 1993, petition to withdraw and continuing application filed with all prior claims cancelled and new claims to cyclopropataxol and cyclopropabaccatin III derivatives.
  - Later filed a CIP claiming 7,8-cyclopropataxols.

# *Support In Prior Applications*

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## ■ FC: Priority to Bouchard

- Chen not entitled to benefit of priority applications as proof of prior conception and reduction to practice.
- No explicit disclosure of compounds of counts in priority applications.
- No one of ordinary skill in the art would understand Chen's application to show possession of the subject matter of the count (7,8-cyclopropataxols).
- Methods described in applications actually produced compounds not covered by counts.

# “Reasonable Variations”

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Only if reasonably conveyed to one skilled in the art that inventor had possession at time application filed.

“necessarily” described

*Martin v. Mayer*, 823 F.2d 500, 504 (Fed. Cir. 1987): It is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device." quoting *Jepson v. Coleman*, 314 F.2d 533, 536 (CCPA 1963).

Rendering later-claimed invention obvious insufficient to meet the written description requirement.

- *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998).

# *New Name*

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*Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347 (Fed. Cir. 2000)

- Claims (original): leukocyte interferon.
- 6 months later, new terminology to describe interferons, “IFN- $\alpha$ .”
- Claims amended to substitute “IFN-  $\alpha$ ” for “leukocyte interferon.”
- FC: No new matter. Amendment merely explained that the leukocyte interferon he had isolated and produced now had a new scientific name.

# Description Of Invention: As Claimed

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- ▶ *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004)
  - ▶ Claim: Improved dental floss made of expanded polytetrafluoroethylene ("PTFE") filaments coated with microcrystalline wax ("MCW") having a COF between 0.08 and 0.25.
  - ▶ CIP claim: dental floss made of expanded PTFE filaments coated with MCW. (*SPECIES*)
    - ▶ One example.
    - ▶ Described MCW as a suitable friction enhancing coating for a PTFE dental floss.
  - ▶ Second CIP claim: dental floss made from at least one PTFE strand "having a coating of at least one material capable of increasing the coefficient of friction." (*GENUS*)
  - ▶ No WD support for second CIP in first CIP
    - ▶ One skilled in the art not placed in possession of a genus where there is unpredictability in the performance of certain species or subcombinations.
    - ▶ Argument that one species is unique and different cannot support assertion that overall genus has the same qualities
    - ▶ Balance arguments of unpredictability for patentability over the prior art vs. narrowing effects such arguments might have in assessing the adequacy of written description

# *Description Of Invention: Inherency*

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A structure, process or property not explicitly described may satisfy the written description requirement if the structure, process, or property is “inherent” in what is described.

- “inherent”: necessary and inevitable
  - *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419 (Fed. Cir. 1987)
- But a disclosure that merely renders claim obvious does not satisfy the written description requirement.

# Written Description Support For Ranges

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*In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976)

Swiss App.  
Filed  
April 2, 1965

CIP App. No. 537,679  
Filed  
March 28, 1966

App. No. 96,285  
Filed  
Dec. 8, 1970

solids concentration  
of 25-60% with  
specific examples of  
36% and 50%

–U.S. claims: solids concentration of “at least 35%” and  
“between 35 and 60%”

# Written Description Support For Ranges (con't)

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## *In re Wertheim* (con't)

- Board: Upheld rejection of claims under 35 U.S.C. §132 for new matter.
  - Claims added to the instant application by amendment were not supported in the original disclosure.
- CCPA: Reversed.
  - “at least 35%” not supported because read on embodiments outside of 25-60% range of Swiss app.
  - “between 35 and 60%” not literally supported, but PTO failed to establish prima facie case of lack of WD.
    - Original range (25%-60%) plus example at 36%, reasonably conveyed possession of invention with 35%-60% range.



# Written Description Support For Ranges

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*In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977)

- 1963 application: genus of polymers, included 26 examples describing 15 species of polyarylene polyethers (including species “1” and species “2”).
- Interference over subject matter of species “1”, priority awarded to adverse party.
- To exclude subject matter of lost interference counts, Johnson filed CIP with claims stating that the two precursor compounds “may not both include a divalent sulfone group [or]” a divalent carbonyl group linking two aromatic nuclei.”
  - 1972 Claim: linear thermoplastic polyarylene polyether polymers composed of recurring units of two precursor compounds, both bonded to ether oxygens through aromatic carbon atoms.
  - Proviso excluded species “1” and species “2.”

# Written Description Support For Ranges (con't)

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- ▶ *In re Johnson* (con't)
  - ▶ CCPA: Entitled to the benefit of the 1963 filing date.
    - ▶ Invention recited is "disclosed in the manner provided by the first paragraph of section 112" in the 1963 application.
    - ▶ "1963 disclosure is clearly directed to polymers of the type claimed."
    - ▶ Appellant is claiming less than the full scope of his disclosure.
    - ▶ "It is for the inventor to decide what bounds of protection he will seek."

# *Exclusion Must Be Supported*

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*In re Bimeda Research & Development Ltd.*, 724 F.3d 1320 (Fed. Cir. 2013)

- Original claim: A prophylactic method of controlling infection in a mammary gland by a mastitis-causing organism comprising sealing a teat canal of a mammary gland with a seal formulation so as to provide a physical barrier in the teat canal.
- New claims:
  - “wherein the seal formulation is free of an agent that is antiinfective...”  
ALLOWED
  - seal formulation “has no bacterial action.” ALLOWED
  - seal canal had an “acriflavine-free” formulation REJECTED
    - acriflavine well-known, but no mention of in original disclosure so no demonstration of possession.

# *Exclusion Must Be Supported*

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## *In re Bimeda (con't)*

- Board: Upheld rejection
  - No “blaze marks” guiding POSITA to exclusion of particular species
  - No support for claim excluding specific antiinfective but permitting others.
- Federal Circuit: Affirmed
  - Disclosure inconsistent with formulation that excludes acriflavine but could include other antiinfectives or antibiotics.
  - Excluding species invalid for lack of written description when the specification describes exclusion of the entire genus.

# Support for Negative Limitation

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- ▶ *Santarus, Inc. v. Par Pharmaceutical, Inc.*, 694 F.3d 1344 (Fed. Cir. 2012)
  - ▶ Claim:
    - ▶ A method for treating an acid-caused gastrointestinal disorder comprising the step of administering to a subject suffering from said disorder a solid pharmaceutical composition comprising:
      - ▶ (a) about 10 mg to about 40 mg of non-enteric coated omeprazole; and
      - ▶ (b) sodium bicarbonate in an amount of 0.2 mEq to 5 mEq per 2mg omeprazole;
    - ▶ wherein the composition contains no sucralfate and the sodium bicarbonate is present in the composition in an amount sufficient to substantially prevent or inhibit acid degradation of at least some of the omeprazole by gastric acid upon administration to the subject.

# *Support for Negative Limitation*

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## Specification:

- “H2 antagonists, antacids, and sucralfate ... have certain disadvantages associated with their use.... Proton pump inhibitors such as omeprazole represent an advantageous alternative[.]”
- “sucralfate ‘possibly the ideal agent for stress ulcer prophylaxis,’...was known to have occasional adverse effects.”

## Support for the “no sucralfate” limitation? **Yes**

- “The claim limitation that the Phillips formulations contain no sucralfate is adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate.”

# *Support for Negative Limitation*

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*Inphi Corp. v. Netlist*, 805 F.3d 1350 (Fed. Cir. 2015)

- Negative limitation added by amendment limited claimed invention to exclude three particular types signals.
  - “DDR chip selects that are not CAS, RAS, or bank address signals.”
- In inter partes reexam, examiner declined to reject claims.
- PTAB affirmed.
  - Identified three parts of the original specification that reasonably supported the negative limitation (including an incorporation by reference), even though not express.
  - Unrebutted expert testimony that a POSITA would understand “a DDR chip select to be exclusive of RAS, CAS, and bank address signals”
- Federal Circuit affirmed.
  - Santarus did not create a heightened written description standard for negative claim limitations and that properly described, alternative features are sufficient to satisfy the written description standard of §112, ¶1 for negative claim limitations.”

# Support for Negative Limitation

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## *Inphi Corp. v. Netlist* (con't)

- Federal Circuit affirmed.
  - “The question that remains is whether properly describing alternative features - without articulating advantages or disadvantages of each feature - can constitute a ‘reason to exclude’ under the standard articulated in *Santarus*. We hold that it can.”
  - “*Santarus* simply reflects the fact that the specification need only satisfy the requirements of §112, ¶1 as described in this court’s existing jurisprudence, including through compliance with MPEP §2173.05(i)...and *In re Johnson*[.]”
  - “The ‘reason’ required by *Santarus* is provided, for instance, by properly describing alternative features of the patented invention.” [citing *Johnson*]
  - “specification makes it clear that there was substantial evidence that Netlist possessed the negative claim limitation as of the filing date”
  - Distinguished *Bimeda*



# *Support for Negative Limitation*

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*Nike v. Adidas*, 812 F.3d 1326 (Fed. Cir. 2016)

- PTAB denied motion to substitute claims as unpatentable (but found there was written description support in the original disclosure).
- Fed. Cir.: Affirmed.
  - Quoted *Inphi*: “Substantial evidence supports a finding that the specification satisfies the written description requirement when the essence of the original disclosure conveys the necessary information—regardless of *how* it conveys such information, and regardless of whether the disclosure's words are open to *different interpretations*.”
  - “Adidas is incorrect that any sort of heightened standard applies.”
  - Based on the Figures, the disclosures in the written description, and the expert testimony, we conclude that substantial evidence supports the Board's decision that the proposed substitute claims are adequately supported by the written description”

# *MPEP 2173.05(i) Negative Limitations*

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“The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. ... Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) .... See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.”

# *Best Practices: The Double-Edged Sword*

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- ▶ On the one hand, when claiming a genus, describe the structure of the genus and structures of as many species as possible that are embodiments of the invention.
  - ▶ Goal is a description that could reasonably allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed.
- ▶ Balance that against creating prior art against later subgenus and species inventions.
  - ▶ In a regulated area like pharmaceuticals, those later inventions could be much closer to the approved drug substance, drug product and be the patents that the owner preferentially desires to enforce.

# *Best Practices: The Double-Edged Sword*

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- ▶ Attempt to identify relationship between structure and function of useful materials.
- ▶ And how about 35 U.S.C. § 112 (f)?
  - ▶ “35 U.S.C. 112, sixth paragraph, states that a claim limitation expressed in means-plus-function language ‘shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.’” MPEP § 2181.
- ▶ A narrow claim can have great benefit in enforcing, for example, an approved drug product in Hatch Waxman litigation.
  - ▶ And an increased chance of surviving an IPR with BRI claim construction.

# *Best Practices: The Double-Edged Sword*

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- Try to avoid issues with amended claims by drafting the specification with potential future claim amendments and “fall back” positions in mind.
  - Remember, amending claims so far nearly impossible in AIA post-grant proceedings.
- Err on side of disclosing a lot of detail and alternative claim language in priority application - invest more now for future value of valid patent, rather than less now for zero future value or worse.

# *Best Practices: Drafting Claims and Spec*

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Be wary of adequacy of written description when preparing all patent applications, **but especially provisional applications** - they are a trap, a prior disclosure or offer for sale may be enough to render claimed invention obvious, but not satisfy written description.

And even though in AIA, priority/benefit can be secured even if best mode is not in the earlier document, in both pre-AIA and AIA, written description is still required to be entitled to priority/benefit.

# Drafting Specification: Patent Profanity: Judicious Use

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## Case examples where profanity hurt patent owner

- “Very important”
  - *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350 (Fed. Cir. 2006)
- “Critical,” “Special,” “Peculiar,” “Superior”
  - *Bayer AG v. Elan Pharmaceuticals Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000)
- “Critical,” “Essential,” “Key”
  - *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373 (Fed. Cir. 1999)
- “Necessary”
  - *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006)
    - “it is necessary to have a catalyst containing solely chromium.”
    - Shows how patentability argument can cause problems later.

# *But Would Patent Drafter Want To Consider Alternative Use Of “Patent Profanity”?*

- PTAB and PTO ex parte: broadest reasonable claim construction and interpretation (BRI).
- Profanity could put limits on BRI and could be advantageous to the patent owner.



# *Patent Profanity: What Is It?*

- **Words of characterization**
  - Chief, Majority - Vital
  - Critical, Essential, Necessary - Fundamental
  - Solely, Only, Is - Important
  - Main - Principal
  - Significant

# *Words That Make Other Words Profanity*

- Surprising
- Unexpected (?)
- All (?)
- Only (?)
- Each (?)
- “The invention is...” or “This invention...”

# What About “Preferable”?

- Claim includes embodiments beyond “preferable”
  - *Lampi Corp. v American Power Products, Inc.*, 228 F.3d 1365 (Fed. Cir. 2000)
- Only “preferred” embodiments within scope of claim
  - *Wang Laboratories, Inc. v. American Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999)
  - *Scimed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001)
  - *Oak Technology, Inc. v. ITC*, 248 F.3d 1316 (Fed. Cir. 2001)

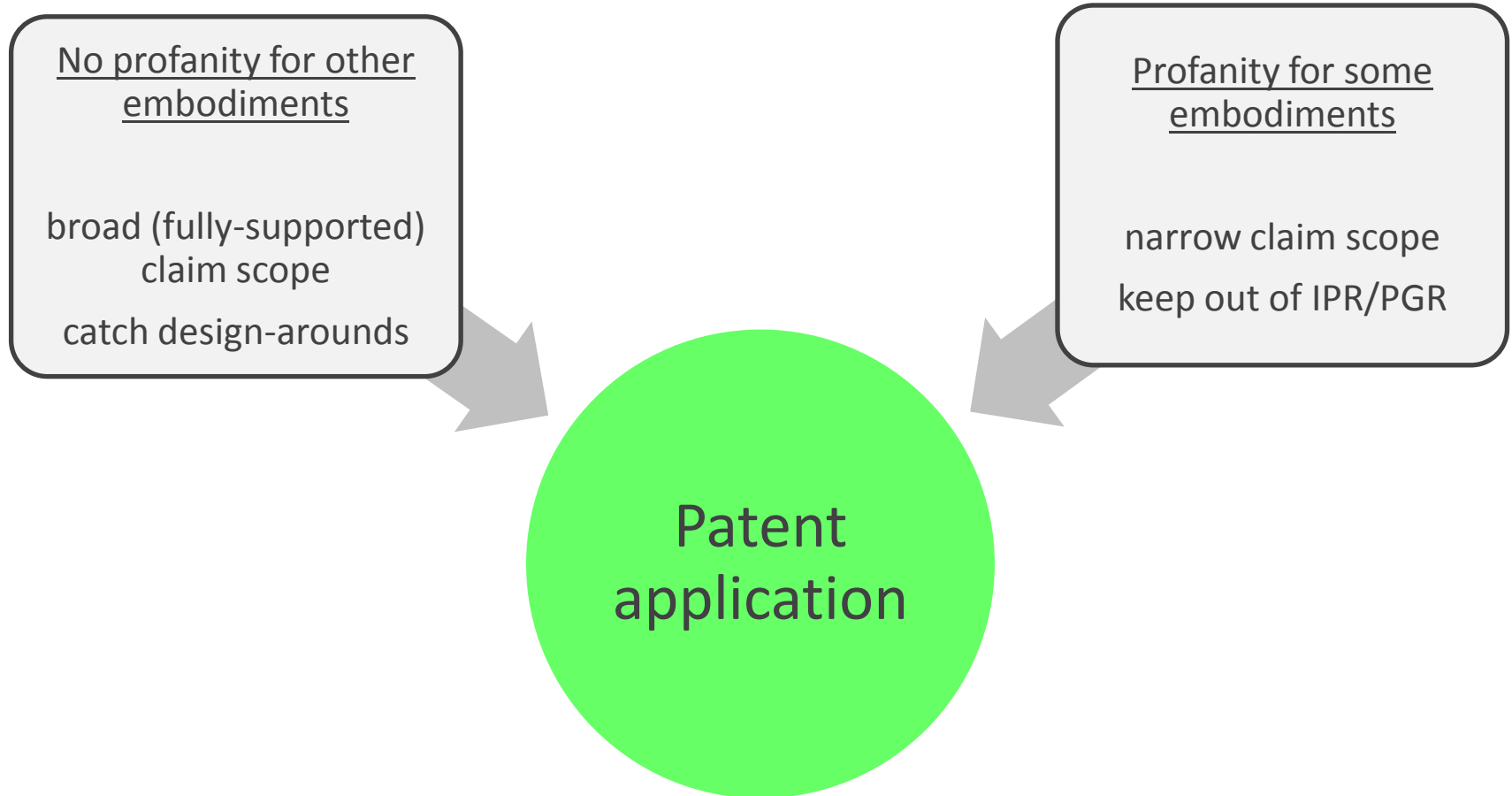
# “Invention Is...”

- *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004)
  - Claimed plug for hernias, but no claim language about plug surface.
  - Specification “consistently described as having pleats”
  - Summary of Invention, Abstract
- DC: No infringement.
  - Claim construed to require pleated plug.
- FC: Affirmed -> no infringement by plugs without pleats.
  - “because the patent globally defined the plug as having a pleated surface, the term “pleated” need not be repeated each time a term describing some other aspect of the plug is used.”
  - Statements of general applicability clearly define the claimed plug as “having” or “includ[ing] a pleated surface.”

# “Invention Is...”

- *C.R. Bard* (con’t)
  - FC: Explicitly relied on statements in the “Summary of the Invention” and the Abstract for its claim construction:
    - “**Statements that describe the invention as a whole**, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. [citation omitted] ...Accordingly, other things being equal, **certain sections of the specification [such as the Summary and Abstract] are more likely to contain statements that support a limiting definition of a claim term than other sections...** In this case, the plug claimed by the '432 patent is defined globally as requiring a pleated surface, which limits claim 20.”
    - See also, Edwards Life Sciences v. Cook, Inc., 582 F.3d 1322 (Fed. Cir. 2009)(“specification frequently describes an ‘intraluminal graft’ as ‘the present invention’ or ‘this invention,’ indicating an intent to limit the invention to intraluminal devices.”) ; Regents of University of Minnesota v. AGA Medical Corp., 717 F.3d 929 (Fed. Cir. 2013)

# *Drafting Claims And Specification To Withstand Challenges In District Court Litigation And PTAB Proceedings*



# *Best Practices: Responding to WD Rejections*

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- ▶ Attack WD rejection for lack of reasonable basis. There is a presumption that there is a sufficient written description. Examiner has to get over that presumption first.
- ▶ Examiner has failed to establish by a preponderance of the evidence why a skilled person would not recognize in the disclosure a description of the invention defined in the claims.
- ▶ Present claim chart with the claim language and written description support in a side-by-side comparison referencing specific portions in the specification.
- ▶ Claimed subject matter need not have literal support.
  - ▶ No requirement that the specification support the claim word for word.
  - ▶ Applicant needs to show identity of “that which is described” and that applicant had possession of what is claimed within the four corners of the specification.

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*How A Lack Of Written  
Description Support Can Be  
Used In An AIA Inter Partes  
Review Before PTAB*



# Ground of Attack in PGR

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- *Peroxychem LLC v. Innovative Environmental Technologies, Inc.*, PGR2016-00002
  - Petition, Paper 1 (Nov. 19, 2015) challenged claims 1-26 on grounds of lack of written description support and lack of enablement.
  - Claim 1. A method for chemical oxidation followed by a biological attenuation process of an environmental medium containing one or more contaminants, the method comprising,
    - introducing persulfate and one or more trivalent metals into the environmental medium, wherein the one or more trivalent metals activate the persulfate in order to chemically oxidize the one or more contaminants, wherein amount of the persulfate is selected to chemically oxidize the one or more contaminants and amount of the one or more trivalent metals is between approximately 17-30% of molecular weight of the persulfate so that at conclusion of the chemical oxidation sufficient residual sulfate and sufficient residual trivalent metals remain such that:
      - naturally occurring facultative cultures utilize the residual sulfate and the residual trivalent metal as terminal electron acceptors to promote the biological attenuation process of the one or more contaminants; and
      - the residual sulfate and the residual trivalent metal prevent formation and accumulation of hydrogen sulfide which is a toxin to the facultative cultures.

# Ground of Attack in PGR

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- *Peroxychem LLC v. Innovative Environmental Technologies, Inc.*, PGR2016-00002
  - PTAB Institution Decision, Paper 9 (P.T.A.B. June 1, 2016)
    - Patent eligible for PGR review.
      - Application filed May 10, 2013, and did not claim benefit of any earlier filing date.
      - Patent issued on September 8, 2015.
      - Petition filed on November 19, 2015, within nine months of grant.
    - Highlighted phrase added in response to final rejection.
      - Ratio not described in specification, but Patent Owner explained in Remarks of Response as to how to derive (13 steps).

# Ground of Attack in PGR

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- *Peroxychem LLC v. Innovative Environmental Technologies, Inc.*, PGR2016-00002
  - PTAB Institution Decision, Paper 9 (P.T.A.B. June 1, 2016): Granted as to lack of written description ground.
    - “Petitioner asserts the ‘Thirteen Steps...confirm that the original specification did not contain a written description of the invention that is sufficiently detailed so that a POSA can reasonably conclude that the inventors had possession of the full scope of such claims on May 10, 2013,’ the filing date of the application that issued as the ‘245 patent...**We find Petitioner’s argument persuasive at this stage of the proceedings.**”
    - Specification did not convey to a POSITA that inventor had possession.
    - Record did not show that ratio was within knowledge of a POSITA.
    - *Note: Patent Owner did not file a POPR.*

# Ground of Attack in PGR

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- *Peroxychem LLC v. Innovative Environmental Technologies, Inc.*, PGR2016-00002
  - PTAB Institution Decision, Paper 9 (P.T.A.B. June 1, 2016): Denied as to lack of enablement ground.
    - “under § 112(a), enablement is separate and distinct from the written-description requirement. *Ariad*, 598 F.3d at 1344. Petitioner’s argument asserting lack of enablement, however, merely refers to its written-description challenge.”
    - “Petitioner does not provide proper enablement analysis based on the *Wands* factors. And we cannot conclude from the information set forth in the Petition that Petitioner is more likely than not to prevail in its enablement challenge.”
    - “The Specification of the ’245 patent discloses how the remedial materials are introduced. ...The Specification also explains the chemical oxidation and biological attenuation processes.”

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*How A Lack Of Written  
Description Support Can Be  
Used in IPR Before PTAB To  
Attack Claims By Breaking The  
Chain Of Priority To  
Pre-AIA Date Benefit In An  
AIA Post-Grant Review*

# *Priority Claim Attack*

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*Butamax<sup>TM</sup> Advanced Biofuels LLC v. Gevo, Inc.*, IPR2013-00539, Paper 33 (PTAB March 3, 2015)

- Petitioner challenged patent's priority claim back to the first two provisional applications.
- Using an expert declaration, Petitioner broke priority chain by establishing that the claim limitations contained in challenged claim 1 of the patent did not have written description support all the way back to the earliest two priority applications.
- PTAB Final Written Decision: No priority date.
  - The provisionals did not disclose a representative number of species falling within the scope of the claim, let alone “precise[ly] defin[e]’ a species falling within the scope of the claimed genus.”

# *PTAB Comment on Priority Attack*

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*SAP v. Lakshmi*, IPR2014-00414, Paper 24 (P.T.A.B. Aug. 17, 2015)

- Petitioner attacked priority claimed by patent.
- Patent Owner objected to § 112 issue in an IPR.
- PTAB:
  - We note the difference between compliance with the requirements of 35 U.S. C. § 112 and assessing the earliest priority date for a claim. ...the issue is not whether there is a sufficient written description in the '894 Patent, but whether the written description in the earlier applications supports Patent Owner's claim to priority. . . . **A review of the disclosure for purposes of identifying the priority date for the claimed subject matter is appropriate and within the scope of inter partes review.** *Nissan N. Am., Inc. v. Bd. of Regents, Univ. of Tex. Sys.*, IPR2012-00037, Paper 24, at 14-16 (PTAB March 19, 2013).

# *Showing Entitled to Priority Benefit*

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*Dynamic Drinkware, LLC v. National Graphics, Inc.*, 2015 WL 5166366 (Fed. Cir. Sept. 4, 2015)

- Claims survived IPR.
- Petitioner appealed.
- FC: Affirmed PTAB.
  - Petitioner had burden to prove that prior art patent was entitled to filing date of its provisional application;
  - Substantial evidence supported PTAB's determination that prior art patent did not relate back to its provisional application.
    - “A provisional application's effectiveness as prior art depends on its written description support for the claims of the issued patent of which it was a provisional. Dynamic did not make that showing.”



# Thank You!



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