Patents and the Written Description Requirement
Navigating Section 112 Disclosure Obligations and Withstanding Invalidity Challenges

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Patents and the Written Description Requirement

Navigating Section 112 Disclosure Obligations and Withstanding Invalidity/Unpatentablity Challenges in Preparation, Prosecution, and Litigation

by

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Ariad v. Lilly

- Implications of the decision
  - on patent prosecution
  - for predictable arts
  - for non-predictable arts
  - on patent litigation

- Best practices to meet the written description requirement
Written description requirement: Purpose and Scope

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.

  (Bonito Boats v. Thunder Craft Boats)
Written description requirement: Purpose and Scope

35 U.S.C. § 112, ¶ 1:

- 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 of carrying out his invention.
Written description requirement: Purpose and Scope

- **Purpose**: Describe exactly what the grant covers

  - “The specification shall contain a written description of the invention and the manner and process of making and using it, …”

  - Must “convey clearly to those skilled in the art the information that applicant has invented the specific subject matter claimed.” ([Carnegie Melon v. Hoffman La Roche](http://example.com) quoting [Vas-Cath v. Mahurkar](http://example.com))

- Requires more than a “hope” or a “plan.” ([Fiers v. Revel](http://example.com))

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Finnegan Goodwin Procter
Written description requirement: Purpose and Scope

- Purposes of the Written Description Requirement:
  - Before the introduction of a claims requirement (1836), the written description served to define the metes and bounds of the patented invention.
  - This requirement kept the inventor from “pretending that his invention is more than what it really is.” (*Evans v. Eaton, 20 U.S. 434-435 (1835)*)
Written description requirement: What is Required

- The written description must describe the invention “in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.” (University of California v. Eli Lilly & Co.)

- An inventor must be able to “describe [the] invention with particularity.” (Fiers v. Revel)

- An applicant describes the invention “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” (Lockwood v. American Airlines, Inc.)
The written description requirement also can be satisfied by:

- “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)
Written description requirement: What is Required

- The written description does not require:
  - examples (*Falkner v. Inglis*);
  - actual reduction to practice (*Falkner v. Inglis*);
  - word for word disclosure (*Fujikawa v. Wattanasin*);
  - the same type of written description for every type of invention (*Capon v. Eshhar*); or
  - express disclosure of each and every species of a genus (*In re Robins*).
Applying the Written Description Requirement:

- Compliance is a question of fact.

- Would the ordinary skilled artisan have understood that the inventor was in possession of the claimed invention at the time of filing?

- Compare the patent claims with the patent disclosure.

- The requirement is not met if the claimed invention lacks sufficient specificity in the disclosure.
Applying the Written Description Requirement:

The requisite level of detail to meet the requirement is based on factors:

- the nature and scope of the claims;
- the predictability of the relevant technology;
- the existing knowledge in the field;
- the prior art;
- the maturity of the field.
What Is Not Required

A few broad principles hold true across all cases. The written description does not require:

- actual reduction to practice;
- any particular form of disclosure;
- word for word disclosure;
- the same type of written description for every type of invention; or
- express disclosure of each and every species of a genus.
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 is *sufficient* to satisfy WD.
When Is More Disclosure of More Than One Species Or Embodiment Required?

- 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).
What Problems Are On The Horizon?

- The *Ariad* opinion does not resolve the potential for confusion between the written description requirement and the enablement requirement as means to regulate the scope of the claims.

- The *Ariad* opinion does not develop the WD analysis of “possession of the invention” in terms of other patent law concepts regarding the invention.

- Can a specification that expressly describes a genus and adequately discloses one or more species fail to satisfy WD because it does not show sufficient "possession" of the genus invention?

- Is a description inadequate when it defines a generic class in terms of a desired result and what species of the genus *do* instead of what they *are*?
The Ariad Court's explanation of when a written description is inadequate never gets to the heart of the matter. The opinion simply reiterates generalities from its *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
No Specific Guidance Is Provided

- 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.”
The law is the same for both the predictable and unpredictable arts.

In practice, it generally is more difficult to satisfy the written description requirement in the unpredictable arts.

*Ariad* may heighten attention to the separate written description requirement as it applies to litigation, opinion work, and patent prosecution.
Ariad’s Impact

- Can a specification that expressly describes a genus and adequately discloses one or more species fail the written description requirement because it does not show possession of the genus invention?

- Is a written description inadequate if it defines a generic class in terms of a desired result and the species in terms of function?
Ariad’s Impact

- Dennis Crouch’s 2010 study: 2,858 BPAI patent opinions in 2009
  - Written description issues were decided in 123 decisions (4.3%)
    - None of the 123 outcomes would have ultimately changed if the written description requirement had been eliminated.
    - New-matter written description rejections determined the outcome in 20 of the 2,858 cases (1%).

Ariad’s Impact

- *Ariad* did not change the law or written description, but drew more attention to it.

- PTO guidelines have not changed.

- Biotechnology patents and pioneer inventions may face greater scrutiny and limited scope.
**Ariad’s Impact**

- Inventors may/should delay filing to further develop inventions?
  - Weigh risk of losing rights in FITF post-March 15, 2013, system against written description requirement.
  - No benefit to rushing incomplete application to file before March 16, 2013; application deficient in written description will require filing post-March 15, 2013, anyway.

- Increased attention both in ex parte prosecution and post-grant proceedings, as well as litigation, to reject/cancel/invalidate on written description grounds.
  - Mapping the claims (37 CFR 1.105; MPEP § 704.11(b)): Provide a side-by-side chart comparing claims and written description support in specification.
Practical Implications:
Litigation and Opinion Work

- Possible increase in the ease with which a party may challenge a patent based on the written description in litigation and both clearance and freedom-to-operate opinions.

- Claims limited to subject matter actually reduced to practice are unaffected.
Practical Implications: Prosecution

- Existing PTO guidelines probably unaffected.

- Possible decrease in the scope of protection afforded to pioneering-type inventions, especially in unpredictable arts.
An unpredictable impact on the number of patent applications being filed as it becomes more difficult to strike the right balance of when the written description is satisfied.

Possible increase in rejections of all claims by Examiners in the USPTO for lack of written description (both original and amended).
Practical Implications After Ariad: Where are We?

- Possible increase in the opportunity to challenge a patent based on the written description in clearance and freedom-to-operate opinions, AIA post-grant proceedings (particularly Inter Partes Review (IPR) and Post Grant Review (PGR)), contesting priority/benefit in reexam, and ITC and district court litigation.

- Claims limited to subject matter actually reduced to practice are unaffected.
When Do WD Problems Typically Appear?

- 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?

- **Claim:** A method for selectively viewing areas of an image at multiple resolutions in a computer ... comprising the steps of:
  - storing a complete set of image data array;
  - performing one or more discrete wavelet transformation (DWT)-based compression processes;
  - electing a viewing set of said image data array to be viewed at a desired resolution.

- POSITA would understand that the DWT-based compression processes recited in claim create a seamless DWT of the image.

- Specification provides only one method for creating a seamless DWT, but claim scope is broader than one method.
  - No limitations in claim as to how the seamless DWT is accomplished.

Problem: No written description support for such a broad claim in the specification.
- Specification directed at describing a single, particular method for creating a seamless DWT.
- No evidence that the specification contemplates more than that one method.

Claim not invalid/unpatentable simply because there are not 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 a seamless DWT by the one method described, not generically.

Broad Claim Supported By One Example: Insufficient?

- Description of one method for creating a seamless DWT does not entitle the inventor to claim any and all means for achieving that objective.

- Applicable quote: “[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?

Claim

An acetabular cup prosthesis comprising a body extending generally longitudinally and terminating into front and rear surfaces, said front surface extending substantially transversely to said body; and at least one fin for securing said cup to a prepared acetabulum cavity.

No shape limitation to claimed cup implant.

But specification only described conical cups.

- Only discussion of different cup shapes in specification was in relation to prior art.
- Distinguished prior art shapes as inferior; praised the advantage of conical shape.
- Nothing suggested that shapes other than conical necessarily part of disclosure.

Was there written description of cups broader than conical?

Specification used “patent profanity” and described the conical shape as “extremely important”

Applicable quotes:

“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….”

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

- **Claim:**
  
  A method comprising administering a compound X that selectively inhibits activity of Y to a human host in need of such treatment, wherein said compound inhibits the activity of Y and has minimal effect on activity of Z.

- Specification does not specify way that compound X could actually inhibit activity of Y.

- Not good enough for written description support.
  - Describes compound's desired function, but does not identify any compounds that can be used in claimed methods of treatment.
  - No disclosure of compound for performing the claimed method and no evidence that such a compound was known.

Source: *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004)
§112 Requires More Than “Hope” Or “Plan”

**Claim**

1. An isolated recombinant X anti-body or antigen-binding fragment thereof, said antibody or antigen-binding fragment comprising a human constant region, wherein said antibody or antigen binding fragment (i) competitively inhibits binding of Y to human X, and (ii) binds to a neutralizing epitope of human X in vivo.

2. The antibody or antigen-binding fragment of claim 1, wherein the antibody or antigen binding fragment comprises a human constant region and a human variable region.

Specification described mouse antibody.

No description in specification of a single antibody that satisfied the claim limitations.

- Only wish list of properties to obtain a desired result
- If have not invented the desired result -> no possession.

Source: *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011), reh’g denied (2011)
Written Description Of Invention For A Genus Claim

- 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

- **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.

- Applicable quotes:
  - “the claims cover tens of thousands of possible . . . 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.”

Source: *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011)
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)*

Source: *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004).
Description Of Invention: As Claimed

- 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

Source: In re Curtis, 354 F.3d 1347 (Fed. Cir. 2004).
Support for Negative Limitation

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.

Source: Santarus, Inc. v. Par Pharmaceutical, Inc., 694 F.3d 1344 (Fed. Cir. 2012)
Support for Negative Limitation

- 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

- Applicable quote: “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.”

Source: Santarus, Inc. v. Par Pharmaceutical, Inc., 694 F.3d 1344 (Fed. Cir. 2012)
WRITTEN DESCRIPTION SUPPORT FOR PROVISO


- **Swiss App.**
  - Filed
  - April 2, 1965

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

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

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

  - solids concentration of 25-60% with specific examples of 36% and 50%
In re Wertheim (con’t)

  - 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.

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.”
In re Johnson (con’t)
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.”
Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983) aff’d mem. 738 F.2d 453 (Fed. Cir. 1984)

Claim 1: “A process for ammoxidizing propylene”

Amended to exclude uranium.

Formula did not originally cover uranium.

Board: no written description for the negative limitation.

Express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded.

Original genus

uranium

• Easily distinguished
Claim:

A hearing aid comprising at least one input microphone, an output receiver, a signal transmission channel interposed between said microphone and said receiver, and a programmable delay line filter interposed in a feedback path between the input and output of said transmission channel, said programmable filter being programmed to effect substantial reduction of acoustic feedback from said receiver to said microphone.

Specification:

“the novel means employed for effecting automatic adjustment of the programmable filter to optimum parameter values as the speech level, room reverberation and type of background noise change.”

Disclosures teach adjustment of the programmable filter in the feedback path in response to a particular acoustic environment.

Broad Specification Language Supports Broad Claim Language

- 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

- WD SUPPORT: Inventors were in possession of a programmable hearing aid that could use adaptive filtering for feedback cancellation at the time of filing.

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.

Source: Pozen Inc. v. Par Pharmaceutical, Inc., 696 F.3d 1151 (Fed. Cir. 2012)
Exact Language Required?

- 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.

Source: Pozen Inc. v. Par Pharmaceutical, Inc., 696 F.3d 1151 (Fed. Cir. 2012)
Best Practices: The Double-Edged Sword

- 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

- Attempt to identify relationship between structure and function of useful materials.

- And how about 35 U.S.C. § 112 (f) [pre-AIA (6)]?
  - “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 seemingly narrow claim can have great benefit in enforcing, for example, an approved drug product in Hatch Waxman litigation.
Best Practices: The Double-Edged Sword

- Try to avoid issues with amended claims by drafting the specification with potential future claim amendments and “fall back” positions in mind.
  - On the other hand, consider downsides of “creating” too much prior art.

- 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.
  - Same “on the other hand” as just above.
Best Practices: Drafting Claims and Spec

- 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 in 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.
Draft claims for provisional patent applications.

In the written description, avoid “patent profanity” (“the invention”) and draft specification with language describing “an embodiment” and “a further embodiment.”
“Very important”


“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)
  - “chromium catalyst” excludes metal oxides and non-inert additives because statement in specification: “it is *necessary* to have a catalyst containing solely chromium.”
  - Shows how patentability argument can cause problems later.
Why To Avoid Written Description “Patent Profanity”

- U.S. specification and prosecution history will be used to construe U.S. patent claims

- De novo appellate review in the U.S. of claim construction

  • June 29, 2012, USSC requests Solicitor General’s views on whether to grant certiorari in *Retractable Technologies, Inc. v. Becton, Dickinson and Co.*, 653 F.3d 1296 (Fed. Cir. 2011), including question: “Whether claim construction, including underlying factual issues that are integral to claim construction, is a purely legal question subject to de novo review on appeal.” (The *Cybor Rule*).
Tips To Avoid Written Description Patent Profanity

- Minimize the use of words of characterization

  - Chief, Majority
  - Critical, Essential, Necessary
  - Solely, Only, Is
  - Main
  - Significant

- Vital
- Fundamental
- Important
- Principal
Written Description Words That Make Other Words Profanity

- Surprising
- Unexpected (?)
- All (?)
- Only (?)
- Each (?)
- “The invention is…” or “This invention…”
Best Practices: Prosecution

- Consider filing separate applications as structurally diverse means of attaining the desired result are discovered.
  - See balance above in deciding how much written description to disclose in “parent’ or “umbrella” patent application

- Consider keeping invention trade secret rather than file inadequate written description.
Best Practices: Responding to WD Rejections

- 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.
Thank You!  

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