Developments in Section 112: Written Description, Enablement, and Definiteness

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35 U.S.C. § 112

(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.

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

AIA amended to change paragraph numbers to letters and added reference to “joint inventor,” but otherwise did not change §112; effective Sept. 16, 2012.
Satisfying §112

- Analyze §112(b) before §112(a) requirements

  §112(b): “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”

- Two requirements of §112(b):
  - (1) **Definiteness of claim scope**: one skilled in the art must be able to determine with a reasonable degree of certainty the meets and bounds of the claim.
    - Claims cannot be vague or indefinite and must clearly set forth the boundaries of protection.
  - (2) Subject matter claimed must be what the inventor(s) believe(s) is the invention – cannot claim other subject matter.
Satisfying §112(b) Definiteness Requirement

- **Distinguish between §112 (a) and (b):**
  - USPTO rejections often confuse first and second paragraphs of §112
    - **Breadth ≠ indefiniteness** → broad claim with clear scope satisfies para. (b)
      - In re Miller, 441 F.2d 690 (CCPA 1971); MPEP § 2173.04
    - Often see rejections as “vague and indefinite” based on requirement for “particularly pointing out and distinctly claiming.”

- **Definiteness** → clear claim scope, boundaries of claimed subject matter
Assessing Compliance - §112(b) Definiteness Requirement

- Proper perspective for §112(b) definiteness requirement:
  - Compliance should be determined from the perspective of one of ordinary skill in the art at the time the application was filed
  - Claim should be considered as a whole
    - In re Larsen, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished)
  - Claim language should be read in light of the specification and in view of prior art
    - Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565 (Fed. Cir. 1986); S3 Inc. v. nVidia Corp., 259 F.3d 1364 (Fed. Cir. 2001).
Proper Perspective for Assessing Compliance - §112(b) Definiteness Requirement (cont’d)

  - “stretch rate”
    - *no formula in specification* for calculating stretch rate
    - was uncontradicted evidence in the record that, *at the time the application was filed, "stretch rate" meant to those skilled in the art* the percent of stretch divided by the time of stretching, and that the latter was measurable, for example, with a stopwatch.
    - the *post-filing date development* of varying formulae, including inventor’s later addition of a formula in his corresponding Japanese patent, is *irrelevant*.

  → Not indefinite
  - *Claim language in prior art can evidence definiteness if one skilled in art could understand terms in context of invention.*
Ensuring Compliance - §112(b) Definiteness Requirement

- Avoid issue by including **definitions** in specification!
  - Put yourself in shoes of a judge who is ignorant of the relevant technology and of patent law.

- **Words of degree** can be risky and require special attention.
  - Substantially
  - Essentially
  - Faster
  - Stronger
  - More stable
FRUSTRATION OVER “INDEFINITENESS”

- **Enzo Biochem, Inc. v. Appliera Corp., 599 F.3d 1325 (Fed. Cir. 2010), reh’g denied, 605 F.3d 1347 (2010)**
  - Claim term: “not interfering substantially”
  - FC: Not indefinite
  - In dissent from denial of rehearing, Judge Plager:
    - “Despite the varying formulations that this court has used over the years in describing its ‘indefiniteness’ jurisprudence …, the general conclusion from our law seems to be this: if a person of ordinary skill in the art can come up with a plausible meaning for a disputed claim term in a patent, that term, and therefore the claim, is not indefinite.” (emphasis added)
Definiteness requirement does not require greater precision than the subject matter permits.

- Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986): “the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more.”

If precision is challenged, consider Rule 132 declaration of expert explaining the degree of precision available (or lack thereof) in the relevant art at the relevant time.

Interview – ask what Examiner wants.
SATISFYING §112(b):
ABILITY TO DETERMINE BOUNDARIES OF CLAIM

- **Halliburton Energy Services, Inc. v. M-I LLC**, 514 F.3d 1244 (Fed. Cir. 2008)
  - “Proof of indefiniteness …is met where an accused infringer shows by clear and convincing evidence that a skilled artisan **could not discern the boundaries of the claim** based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area.”
  - Claim: “A method for conducting a drilling operation in a subterranean formation using a **fragile gel drilling fluid[.]**” was indefinite.
  - Specification defined “fragile gel” as “becomes **less gel-like and more liquid-like**”
DISCERN THE BOUNDARIES

  • "[o]nly claims not amenable to construction or insolubly ambiguous are indefinite."

• "The district court's contrary conclusion was based on its misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process. But we disclaimed any such approach in Invitrogen Corp. v. Biocrest Manufacturing, L.P., 424 F.3d 1374, 1384 (Fed. Cir. 2005). … ‘The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention.’"
Biosig Instruments, Inc. v. Nautilus, Inc., --F.3d-- (Fed. Cir. April 26, 2013)

- “spaced relationship”

- DC summary judgment that claim invalid for indefiniteness because could not determine precise boundaries.

- FC: Claim term definite - “discloses certain inherent parameters of the claimed apparatus, which to a skilled artisan may be sufficient to understand the metes and bounds of “spaced relationship.”
Second Part of §112(b)

- § 112(b) “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”

- Subjective inquiry based on opinion of inventor(s).

- Rejection requires evidence that the inventor(s) considers invention different from what is defined by the claims.
BEST MODE OF PRACTICING 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**

- Remains requirement of §112, so best practice to disclose!
  
  – See MPEP §2165-2165.04
BEST MODE OF PRACTICING THE INVENTION: STILL STATUTORY REQUIREMENT TO DISCLOSE

- Only required to **disclose** best mode, not **claim**.

- No need for greater knowledge or more specific description of the best mode compared to any other enabling means *(Randomex)*.

- Must disclose even if not part of invention claimed and not developed by inventor (e.g. process of making claimed invention).

- In general, do not have to disclose commercial production details.
HOW TO MAKE AND USE THE INVENTION: 
QUESTION OF LAW

- Reviewed de novo by the Federal Circuit.

- Based on fact determinations reviewed for clear error.

- Fact-specific inquiry.

- Standard is clear and convincing evidence.

- TIP: establish as clear and comprehensive a record as is practically possible during prosecution.
HOW TO MAKE AND USE THE INVENTION: INSUFFICIENT DISCLOSURE

- Sufficiency of disclosure depends on subject matter
  - “reasonable certainty” with respect to specific subject matter
    - Capon v. Eshhar, 418 F.3d 1349 (Fed. Cir. 2005)
  - novel aspects of invention must be enabled by specification though, not by reference to one of ordinary skill in the art
Disclosure can still comply with the requirements of §112 even if it leaves some technological problems unresolved so long as one of ordinary skill in the art could resolve them in reasonable time.

- Only objective enablement required.

- Routine experimentation OK but undue experimentation is not.

- No need for production blueprint.
  - Koito Mfg Co., Ltd. v. Turn-Key-Tech, LLC, 381 F.3d 1142 (Fed. Cir. 2004).
HOW TO MAKE AND USE THE INVENTION: TESTING REQUIRED UNDUE OR ROUTINE? WANDS FACTORS

1. Quantity of experimentation necessary;
2. Amount of direction or guidance provided;
3. Presence or absence of examples;
4. Nature of the invention;
5. State of the prior art;
6. Relative skill of those in the art;
7. Predictability or unpredictability of the art; and
8. Breadth of the claims.
TESTING REQUIRED
UNDUE OR ROUTINE?

- **Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009)**
  - Claim potentially covered about 10,000 organisms with one working example in the specification -> **invalid** for lack of enablement.
  - Claims encompassing only 22 possibilities -> **valid**. Undue experimentation was not needed to make and use the full scope of the invention in the dependent claim.

- **Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc., 418 F.3d 1326 (Fed. Cir. 2005)**
  - Two working examples but not enabled.
    - One of skill in the art would have had to resort to undue experimentation in order to make claimed formulations beyond those disclosed in the patent's two working examples.
“COMPLICATED” TESTING DOES NOT AUTOMATICALLY MEAN “UNDUE” EXPERIMENTATION

- **Cephalon, Inc. v. Watson Pharmaceuticals, Inc.,** 707 F.3d 1330 (Fed. Cir. 2013)
  - Disclosure only described a dosage form with a single compound effervescent agent; no teachings directed to formulating and co-administering two separate dosage forms, so undue experimentation necessary to practice the invention.
  - DC: Claim not enabled.
  - FC: Reversed.
    - Because patent presumed valid, standard of proving lack of enablement is by clear and convincing evidence.
      - Testimony that formulation would be “complicated” insufficient.
      - “Watson has not presented evidence showing why these formulations for [dosage form] do not provide sufficient guidance for a skilled artisan to calculate formulations. … Nor does Watson show that the resulting experimentation in this case would be excessive, e.g., that it would involve testing for an unreasonable length of time.”
CONSIDERATIONS WHEN ARGUING LEVEL OF SKILL IN THE ART

- Establishing high level of skill in the art may be in the best interest of a patent applicant for overcoming enablement rejection.

- Establishing low level of skill in the art may be in the best interest of a patent applicant for overcoming obviousness rejection.

- Balance -> don’t shoot yourself in the foot with estoppels.
CONSIDERATIONS WHEN ARGUING CLAIM CONSTRUCTION

- Broad claim construction may be in the best interest of a patent applicant for infringement.

- Narrow claim construction may be in the best interest of a patent applicant for §112.

- Balance -> don’t shoot yourself in the foot with estoppels.
  - See line of cases where broad claim construction came back to undermine compliance with §112:
    - Sitrick v. Dreamworks, LLC, 516 F.3d 993 (Fed. Cir. 2008),
    - Automotive Technologies Intern., Inc. v. BMW of North America, Inc., 501 F.3d 1274 (Fed. Cir. 2007)
    - Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007)
    - Alza Corp. v. Andrx Pharms., LLC, 603 F.3d 935 (Fed. Cir. 2010)
ENABLED THROUGHOUT SCOPE OF CLAIMS

- If claim broadly but disclosure is narrow, may not be sufficient to satisfy §112
  
  
  - *MagSil Corp. v. Hitachi Global Storage Technologies*, 687 F.3d 1377 (Fed. Cir. 2012)
    
    - claim term: “at least 10%”; one example at 11.8%
    - Claim was not enabled through the full scope of the claim (infinity at the upper end of the range).
    - “a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage”.

BROAD CLAIM TERM NOT ENABLED

- If claim construed broadly, but specification explicitly criticizes or teaches against an embodiment that would be captured by construction, claim may be found not enabled.

- AK Steel Corp. v. Sollac, 344 F.3d 1234 (Fed. Cir. 2003), cert. denied, 124 S.Ct. 2390 (U.S. May 24, 2004)

  - AK Steel’s patents
    - Claims: “the coating metal including aluminum or aluminum alloys.”
    - Specification: “Most hot dip aluminum coatings contain about 10% by weight silicon. This coating metal is generally defined in the industry as Type 1. … Commercially pure hot dip aluminum coatings, otherwise known as Type 2 in the industry, are preferred for our invention[.]”

  - DC: construed as encompassing Type 1 aluminum and concluded that the patent was not enabling.
  - FC: Affirmed. Claims as construed not enabled.
    - Specification inadequate as a matter of law with respect to Type 1 aluminum because it expressly teaches against it.
ENABLEMENT REQUIREMENT IS DYNAMIC

Example:

– Applicants sought to claim methods for treating cancer using a broad genus of compounds on the basis of data obtained for only a small subset.

– Earlier case, cancer considered incurable, so showing insufficient (*In re* Buting, 418 F.2d 540 (C.C.P.A. 1969)).

– Later case, cancer treatment not incredible. Compounds at issue “have a close structural relationship” to prior art compounds “known to be useful in cancer chemotherapy,” so showing enabled entire genus (*In re* Jolles, 628 F.2d 1322 (C.C.P.A. 1980)).
Applicant may submit additional evidence in support of enablement after the filing date, as long as the evidence uses teachings known in the art at the time of filing.

- Knoll Pharmaceutical Company, Inc. v. Teva Pharmaceuticals USA, Inc., 367 F.3d 1381, 1385 (Fed. Cir. 2004) (per curiam)
WRITTEN DESCRIPTION SEPARATE FROM ENABLEMENT:
ARIAD PHARMACEUTICALS V. ELI LILLY
REHEARING EN BANC

- Questions briefed:
  - Does §112, first paragraph, contain a written description requirement separate from the enablement requirement?
  - If so, what is the scope and purpose of that requirement?

- Decision: reverse the district court's denial of JMOL.
  - Reaffirm that §112, first paragraph, contains a written description requirement separate from enablement.
    - “a separate requirement to describe one's invention is basic to patent law. 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

- Amended claims? Treated the same as original claims.

- Specification must show possession of invention: “the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.”

- 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”
IN THIS CASE

- No support

  - example of specific inhibitor not disclosed until 1991;
  - description of dominantly interfering molecules was “wish or plan”;
  - prophetic examples of decoy molecules cannot be used to satisfy WD requirement;
  - no working or even prophetic examples of methods that reduce NF-κB activity;
  - no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity;
  - “state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure.”
“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-κB 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.”
DESCRIPTION OF INVENTION

- Must “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

- Actual reduction to practice.
  - Show making of an embodiment.
  - Describe deposit.

- Clear depiction of invention in drawings.

- Give as much information as can about proprietary material.

- 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.
“a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed. . . .”

- **Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009)**

**BUT §112 requires more than “hope” or “plan”**

  - “Method of treatment” claim recited utilizing a specific biochemical pathway to decrease pain, but patent did not specify any compound that could actually utilize that pathway.
“REASONABLE VARIATIONS”

- 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, 136 U.S.P.Q. 647, 649-50 (CCPA 1963).

- Rendering later-claimed invention obvious insufficient to meet the written description requirement.
DESCRIPTION OF INVENTION: PROVISO

- In re Johnson, 558 F.2d 1008 (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”).
  - To exclude subject matter, 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.”

CCPA: Entitled to benefit of 1963 filing date. 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.”
PROVISO

- Santarus, Inc. v. Par Pharmaceutical, Inc., 694 F.3d 1344 (Fed. Cir. 2012)

  - Claim 1: A method for treating an acid-caused gastrointestinal disorder comprising …wherein the composition contains no sucralfate, ....

  - FC: Negative limitation had written description support.

    - “This exclusion narrowed the claims, as the patentee is entitled to do.”
    - “Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support need not rise to the level of disclaimer….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.”
DESCRIPTION OF INVENTION: INHERENCY

- 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.
Thank you.

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