Section 112(a) Enablement and Written Description: Leveraging CCPA and Early Federal Circuit Decisions

Capitalizing on Precedent to Withstand 112(a) Rejections and Attacks on Patent Validity and Patentability

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Outline

I. Lessons from the CCPA and early Federal Circuit decisions that reversed §112 rejections/invalidity holdings

II. §112 Federal Circuit decisions

Guiding Questions

• What lessons can patent counsel draw from CCPA decisions when making arguments of written description support and enablement?

• What steps can counsel for patentees take to meet the written description and enablement requirements and withstand invalidity/unpatentability challenges based on written description and enablement?

• What steps should patent counsel take going forward to avoid repeating mistakes of the past?
Satisfying §112

- Careful drafting to ensure compliance with §112(a) pays dividends in both prosecution and litigation, as well as in IPRs and PGRs before PTAB.
  - Establish as clear and comprehensive a record as is practically possible during prosecution.

- USPTO Examiner Training Materials for §112 found at https://www.uspto.gov/learning-and-resources/examiner-training-materials

- MPEP §§ 2161-2164
- MPEP §§ 2171-2174
35 U.S.C. §112(a)

(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.

AIA amended to change paragraph numbers to letters and added reference to “joint inventor,” but otherwise did not change §112; effective Sept. 16, 2012.
MPEP §2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 1, “Written Description” Requirement: “each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.”

But that support may be what is reasonably conveyed to the POSITA with reasonable certainty in view of what is disclosed and in view of the teachings available to the POSITA as of the filing date.
§112 and PTAB

While §112 cannot be a ground of unpatentability in IPRs, still arises in date benefit assertions of patents and prior art.

• If Petitioner, attack priority claim of challenged claims.

• If Patent Owner, attack priority claim of reference.

• And §112 can be a ground of unpatentability in PGRs.
Example: Challenging Enablement


- PTAB instituting trial on some of asserted grounds
  - “A specification is not enabling if one with ordinary skill in the art would be unable to practice the invention without “undue experimentation.” In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). A disclosure can be enabling even though some experimentation is necessary. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986). The issue is whether the amount of required experimentation is undue. In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991); In re Angstadt, 537 F.2d 498, 504 (CCPA 1976).

...In its Petition, DealerSocket does not identify with sufficient specificity what experimentation is needed. Notably, DealerSocket does not explain what amount of experimentation would be required of one with ordinary skill in the art, and why that amount of experimentation should be deemed undue, much less support such explanations with underlying factual evidence. In view of the foregoing, DealerSocket has not shown it is more likely than not that claims 1, 3-5, 7-9, 11-13, 15, and 16 are unpatentable, under 35 U.S.C. § 112, first paragraph, for lack of enabling disclosure.”
Example: Breaking the Chain in an IPR


- PTAB instituting IPR on some of asserted grounds.
  - Patent Owner knocked out one reference though by showing reference was not entitled to priority date asserted.
    - “as noted by Patent Owner ..., in order to qualify as prior art under 34 U.S.C. § 102(e), the disclosure of the Straus Published Patent Application must be supported by its parent application, ... ("the '110 application"), of which Straus is a continuation. See *In re Schneider*, 481 F.2d 1350, 1356 (CCPA 1973) ... Petitioner, therefore, has failed to demonstrate that there is a continuous chain from the '110 application to Straus, such that the '110 application ‘satisfies the requirements of § 112 with respect to the subject matter presently claimed,’ as required by *Schneider*. Thus, we conclude that Petitioner has failed to demonstrate that Straus is entitled to the filing date of its parent '110 application, and thus has not demonstrated that Straus is prior art to the '794 patent under 35 U.S.C. § 102 (a), (b), or (e).”
Example: Modern Application of Wertheim II


- Petitioner argued patent claims not entitled to priority date benefit.

- PTAB denied institution.
  - Petitioner did not adequately explain which claim limitations were unsupported.
  - Patent Owner entitled to priority date benefit, so asserted references were not prior art.

- Wertheim II: CCPA case where the “prior art description” relied on in a patent application has to chain back for “that description” to enable the patent application to be given an earlier “prior art” §102(e) date.

- The same thing may happen in AIA’s §102(a)(2) where “effectively filed” has to be satisfied in priority documents for the patent application to have an earlier §102(a)(2) date.
IPRs and §112(a): Motions to Amend Proposing Substitute Claims

§112(a) arises in IPRs in context of Motions to Amend.

- 37 C.F.R. §42.20(c) Burden of proof. The moving party has the burden of proof to establish that it is entitled to the requested relief.
- Patent Owner bears burden of showing written description support for any proposed substitute claims.

  - 37 C.F.R. § 42.121(b): Content. A motion to amend claims must include a claim listing, show the changes clearly, and set forth:

    1) The support in the original disclosure of the patent for each claim that is added or amended; and

    2) The support in an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought.
Successful Priority Claim Attack Meant Claims Eligible for PGR

*US Endodontics, LLC v. Gold Standard Instruments, LLC, PGR2015-00019*

- Petition granted because petitioner established claims not entitled to priority date -> references were prior art to challenged claims.

- Also meant claims only given their actual filing date, which was after March 16, 2013, so claims eligible for PGR!

- PGR instituted on §§ 102, 103, and 112(a) grounds.

- Paper 54 (P.T.A.B. Dec. 28, 2016) Final Written Decision all instituted claims unpatentable for lack of enablement, lack of written description, and anticipation.
“The court sits in banc to consider what case law, if any, may appropriately serve as established precedent. We hold that the holdings of our predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals (CCPA), announced by those courts before the close of business September 30, 1982, shall be binding as precedent in this court.”

And all of those CCPA cases were en banc.

Many, many are relied on in the MPEP.
Many of the CCPA cases to be discussed in this course were appeals of ex parte cases from the Patent Office.

That means the cases were decided by the always *en banc* CCPA under the Patent and Trademark Office (PTO) standards: broadest reasonable claim interpretation (BRI), no presumption of validity, and preponderance of the evidence burden on the PTO.

That means the CCPA cases are a great source of authority to cite in support of arguments made to and in preparation for argument before the Patent Trials and Appeal Board (PTAB), particularly as the Patent Owner tries to defeat institution in an inter partes review (IPR) or post-grant review (PGR).

Let’s look at examples of the use of CCPA cases before PTAB.
In re Robins, 429 F.2d 452 (CCPA 1970): Broad Can Be Enabled

Claim 19. A process for accelerating the urethane linkage forming reaction between isocyanate and hydroxyl groups in the formation of a urethane product, said process comprising reacting an organic compound having at least one reactive isocyanate group with an organic compound having at least one reactive hydroxyl group in the presence of a catalytic amount of an ionizable, halogen-free, monoorgano mercuric compound having a single carbon to mercury valence bond.

Examiner’s rejection: specification did not disclose “a suitable number of mercuric compounds falling within the scope of the claims to justify the language in the claims[.]”

CCPA: Reversed.

• “the specification contains a statement of appellant's invention which is as broad as appellant's broadest claims, and inasmuch as the sufficiency of the specification to ...enable one skilled in the art to practice appellant's process as broadly as it is claimed has not been questioned.”
In re Robins (con’t): Examples Are Not Necessarily Required For Enablement

CCPA: Reversed (con’t)

• “Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification (which is not the case here) mention of representative compounds may provide an implicit description upon which to base generic claim language.”

• “representative examples are not required by the statute and are not an end in themselves. Rather, they are a means by which certain requirements of the statute may be satisfied. Thus, inclusion of a number of representative examples in a specification is one way of demonstrating the operability of a broad chemical invention and hence, establishing that the utility requirement of § 101 has been met. It also is one way of teaching how to make and/or how to use the claimed invention, thus satisfying that aspect of § 112.”
Teaching Point: Robins

MPEP §2164.02 Working Example: “Compliance with the enablement requirement of 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be ‘working’ or ‘prophetic.’”
In re Bundy, 642 F.2d 430 (CCPA 1981): *Incorporation By Reference and Lack Of Example*

- **Specification incorporated by reference earlier patent specification.**
  - Includes disclosure relating to preparation of the compounds generally, and several specific examples, but none were compounds within the subgenus claimed in this application.
  - No example of a specific use of any of the disclosed prostaglandin analogs, i.e., setting forth a dosage to achieve a desired response.

- **Rejection for lack of written description support because “not a single example was directed to one of the claimed compounds.”**

- **Board upheld to the extent rejection was based on the how-to-use and best mode requirements of § 112.**
CCPA: Reversed.

- Specification: novel compounds are “useful for each of the above-described purposes for which the PGE compounds are used”

- “This can only reasonably be read as teaching that each compound can be used for each and every one of the aforesaid biological responses. Appellant’s further statements that the novel analogs are ‘substantially more selective with regard to potency’ or ‘more specific in its activity’ because of a ‘different and narrower spectrum of biological potency,’ does not negate the asserted usefulness for each purpose. There is no requirement that all have the same degree of activity for each use. What is necessary to satisfy the how-to-use requirement of s 112 is the disclosure of some activity coupled with knowledge as to the use of this activity.”

- “sufficient guidelines as to use are given in the disclosure here.”
  – Compounds claimed, not therapeutic use.
Teaching Point: Bundy

MPEP §2164.06(b)  Examples of Enablement Issues – Chemical Cases: Decisions Ruling That The Disclosure Was Enabling

MPEP §2164.07  Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101: “Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention’s asserted utility.”
In re Borkowski, 422 F.2d 904 (CCPA 1970): Guidance To POSITA For Enablement

Claimed invention: process for producing oxygenated hydrocarbons such as alcohols, glycols, aldehydes, and acids by reacting hydrocarbons with ferric chloride in vapor phase and hydrolyzing the resulting chlorohydrocarbon.

Examiner’s rejection: lack of enablement.

Board: Affirmed. “The disclosure, though, is ...deficient ... to illustrate the ‘mode of operation’ in which appellants believe their invention to lie....Desirably and necessarily, such illustration should provide an exemplary correlation of the times of reaction, rates of reactant, feed and material removal (chlorinated product, ferric oxide, HCl, etc.). This would inform a man skilled in the art of ... some sort of jumping off place[.]”
In re Borkowski (con’t): POSITA Can Practice Without Undue Experimentation

CCPA: Reversed.

• “The ‘exemplary correlation’ which the board considered necessary would appear to be nothing more nor less than a specific working example. However, as we have stated in a number of opinions, a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.”

• “[N]o basis for concluding that without such information the worker in the art would not be enabled by the specification to practice the invention, i.e., to ‘balance’ the several reactions involved in appellants' process. The ‘few hours' experimentation mentioned by the examiner certainly would not seem to be an undue amount of time considering the nature of the claimed invention.”
In re Brower, 433 F.2d 813 (CCPA 1970): Unique Application of a CIP

Did parent application satisfy the requirements of 35 U.S.C. § 120 for antedating a prior art reference?

Examiner and Board: No - parent case limited in its disclosure to the use in the process of a viscose containing both additives (polyalkylene glycol and a water soluble salt) and claims were ‘unduly broad’.

CCPA: Reversed.
• parent application contained “an enabling disclosure of the invention now claimed.... Section 120 of the statute requires nothing more in this respect.”
• Illustrates a difference between paragraphs (a) and (b) of § 112
Teaching Point: Brower

MPEP §2172 Subject Matter Which the Inventor or a Joint Inventor Regards as The Invention: shift in claims permitted in CIP.

CIP claim can nonetheless get §112(a) benefit even though §112(b) not satisfied in the parent.
In re Oda, 443 F.2d 1200 (CCPA 1971): Written Description When Posita’s Knowledge Of Error Also Provides Knowledge Of Correction

**Claims**

- 1. 5-nitro-3, 3-bis-(4-dimethylaminophenyl)-phthalide.
- 2. 5-acetylamino-3, 3-bis-(4-dimethylaminophenyl)-phthalide.
- 3. 5-benzoylamino-3, 3-bis-(4-dimethylaminophenyl)-phthalide.

**Mistake in translating corresponding Japanese applications error - ‘nitric acid’ was mistranslated ‘nitrous acid.’**

**Reissue application filed.**

**Examiner rejected claims as drawn to new matter.**

**CCPA (Judge Rich): Reversed.**

“The reissue statute is based on fundamental principles of equity and fairness and that, as a remedial provision, intended to bail applicants out of difficult situations into which they get ‘without any deceptive intention,’ it should be liberally construed so as to carry out its purpose to the end that justice may be done to both patentees and the public. In re Willingham, 282 F.2d 353, 48 CCPA 727 (1960); In re Wesseler, 367 F.2d 838, 54 CCPA 735 (1966).”
In re Oda (con’t): POSITA’s Knowledge Of Error Also Provides Knowledge Of Correction

CCPA: Reversed (con’t)

• “There is no change proposed in the claims or in the description of the claimed compounds in the specification.”

• “The change from nitrous to nitric acid occurs only in description of how to make the claimed compounds, which is not the invention since no process is now claimed.”

• “a translation error, not a typographical error.”

• “one skilled in the art would appreciate not only the existence of error in the specification but what the error is. As a corollary, it follows that when the nature of this error is known it is also known how to correct it.”

• “There is not the slightest evidence to cast doubt on appellants' assertions or any suggestion they are trying to change the nature of the invention patented.”
MPEP §2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 1, “Written Description” Requirement: “An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.”
In re Marzocchi, 439 F.2d 220 (CCPA 1971): Presumptive Enablement

Claims recite the use of polyethyleneamine as the adhesion enhancer.

Examiner and Board rejected for lack of enablement.

- “The term is obviously generic to a considerable number of compounds varying in the number of ethylene groups, the number of amine groups and the relationship of the polyethylene groups to the amine groups, and accordingly does not provide a reasonable guide for those seeking to improve the adherence of vinyl resins to glass.”

CCPA: Reversed.

- “recitation must be taken as an assertion by appellants that all of the ‘considerable number of compounds’ which are included within the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics.”

- “The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.”
In re Marzocchi (con’t): Is There Sufficient Reason For Doubt? Can Overcome Doubt By Suitable Proofs

CCPA: Reversed (con’t)

• “As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling.”

• In this case, “it has not been asserted by the Patent Office that the chemical properties of known polyethyleneamines vary to such an extent that it would not be expected by one of ordinary skill in this art that any such compound would possess the necessary capability of enhancing adhesion. Additionally, we note that polyethyleneamine is listed in appellants’ specification as being only one of a much larger class of amine compounds possessing this necessary characteristic. … However, we see no basis to conclude that the ready avoidance of this result would not be within the level of ordinary skill in this art. Compare In re Skrivan, 427 F.2d 801, 57 CCPA 1201 (1970).”
Teaching Point: Marzocchi in MPEP

☐ MPEP §2163.04  Burden on the Examiner with Regard to the Written Description Requirement: “A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.”

☐ MPEP §2164.03  Relationship of Predictability of the Art and the Enablement Requirement: “what is known in the art provides evidence as to the question of predictability.”

☐ MPEP §2164.04  Burden on the Examiner Under the Enablement Requirement: “A specification disclosure ...must be taken as being in compliance with the enablement requirement ..., unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.”

☐ MPEP §2164.08  Enablement Commensurate in Scope With the Claims: “An enabling disclosure may be set forth by specific example or broad terminology; the exact form of disclosure is not dispositive.”
**In re Moore, 439 F.2d 1232 (CCPA 1971): Enablement For Broad Claim After One Figures Out What Is Being Claimed**

Claim 3. As a composition of matter, highly fluorinated 1-ethyladamantane containing at least 15 fluorine atoms per molecule.

Examiner and Board: “no evidence that any particular product within the scope of the claims can be prepared at will nor is there any disclosure of a single species. Thus there is no support for a claim generic to all conceivable species when only certain mixtures can be prepared.”
In re Moore (con’t)

CCPA: Reversed.

• “Any analysis in this regard should begin with the determination of whether the claims satisfy the requirements of the second paragraph. It may appear awkward at first to consider the two paragraphs in inverse order but it should be realized that when the first paragraph speaks of ‘the invention’, it can only be referring to that invention which the applicant wishes to have protected by the patent grant, i.e., the claimed invention. For this reason the claims must be analyzed first in order to determine exactly what subject matter they encompass. The subject matter there set out must be presumed, in the absence of evidence to the contrary, to be that ‘which the applicant regards as his invention.’”

• “As appellants’ disclosure makes clear ..., when the recited alkyl adamantanes are fluorinated by known processes to a degree short of complete substitution of all hydrogen atoms, there occur mixtures of compounds randomly florinated to the specified degree.”
In re Gardner, 475 F.2d 1389 (CCPA 1973):
Original Claim Can Constitute Written Description

Claim 2. A compound selected from the group consisting of a base of the formula: \(...\) and a nontoxic, pharmaceutically acceptable acid addition salt thereof, wherein \(R_1\) is a member of the group consisting of hydrogen, methyl, methoxy, chlorine and bromine.

Examiner: claim “too broad” in view of the lack of support in the specification for all the compounds encompassed by the substituent group \(R_1\) and the floating position thereof.

Only three of the five possible \(R_1\) substituents are specifically exemplified and substitution in these examples is always in the 7-position of the benzodioxan nucleus.
In re Gardner (con’t): Original Claim Can Constitute Written Description

□ CCPA: Reversed.

“we see no need for either additional representative examples or more definite language to satisfy the description requirement. Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed. See In re Anderson, 471 F.2d 1237 (CCPA 1973). Nothing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. § 112.”
In re Gardner (con’t): Enablement Of A Broad Claim: No Basis For Doubting Activity

☐ CCPA: Reversed (con’t)

“The major question centers around the sufficiency of the disclosure with respect to the how-to-use requirement. The primary contention of the Patent Office is that reasonable basis exists for doubting that all of the compounds encompassed by claim 2 have the asserted utility, i.e. antihypertensive activity.

“no requirement in § 112 that all of the claimed compounds have the same degree of utility. Some antihypertensive activity coupled with knowledge as to the employment of this activity is all that is necessary to satisfy the how-to-use requirement.”

“no reasonable basis for concluding that the compounds encompassed by claim 2 would not have at least some antihypertensive activity.”
Teaching Point: Gardner-type Written Description Of Original Claim

MPEP §2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 1, “Written Description” Requirement: “It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification.”
In re Smythe, 480 F.2d 1376 (CCPA 1973): Creative Satisfaction Of Written Description

Limitations at issue: “inert fluid” and “inert gas”

Rejections:

- “failure to describe the invention insofar as the term ‘inert fluid’ encompasses liquids, since the specification and original claims refer only to ‘air or other gas which is inert to the liquids transmitted’ as the analysis samples.”
  - Board added:
    - “the term ‘fluid’ is ‘so broad as to include inoperative fluids.’”
    - “Insofar as the term ‘fluid’...encompasses liquids, there is no description thereof in appellants’ specification.”

- “specification does not enable one skilled in the art to use an ‘inert gas’ as a segmentizing medium in the invention.”
  - The specification “shows the segmentizing medium as air which is aspirated from the atmosphere surrounding the apparatus” but “inert gas” “covers the use of gases other than air as the segmentizing medium”
In re Smythe (con’t); Specification Conveyed “Inert Fluid” For Making Segmentizing Medium Work

CCPA: Reversed.

• “We cannot agree with the broad proposition...that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in section 112. Each case must be decided on its own facts. The question which must be answered is whether the application originally filed in the Patent Office clearly conveyed in any way to those skilled in the art, to whom it is addressed, the information that appellants invented the analysis system with an inert fluid as the segmentizing medium. See In re Ruschig, 379 F.2d 990, 54 CCPA 1551 (1967). If it did, then appellants have made a written description of their invention within the meaning of the first paragraph of 35 U.S.C. § 112.”

• “While fluid is a broader term, encompassing liquids, ...the specification clearly conveys to one skilled in the art that in this invention the characteristics of a fluid are what make the segmentizing medium work in this invention.
CCPA: Reversed.

“This is not a case where there is any unpredictability such that appellants' description of air or other inert gas would not convey to one skilled in the art knowledge that appellants invented an analysis system with a fluid segmentizing medium.”

“The disclosure of ‘air or other gas which is inert to the liquid’ sample by itself is not enough of a description of the use of all ‘inert fluid’ media. But the description of the properties and functions of the ‘air or other gas’ segmentizing medium described in appellants' specification suggest to a person skilled in the art that appellants' invention includes the use of ‘inert fluid’ broadly.”
“A hypothetical situation may make our point clear. If the original specification of a patent application on the scales of justice disclosed only a 1-pound ‘lead weight’ as a counterbalance to determine the weight of a pound of flesh, we do not believe the applicant should be prevented, by the so-called ‘description requirement’ of the first paragraph of § 112, ...from later claiming the counterbalance as a “metal weight” or simply as a 1-pound ‘weight,’ although both ‘metal weight’ and ‘weight’ would indeed be progressively broader than ‘lead weight,’ including even such an undisclosed, but obviously art-recognized equivalent, ‘weight’ as a pound of feathers. The broader claim language would be permitted because the description of the use and function of the lead weight as a scale counterbalance in the whole disclosure would immediately convey to any person skilled in the scale art the knowledge that the applicant invented a scale with a 1-pound counterbalance weight, regardless of its composition. Likewise, we find in the facts here a description of the use and function of the segmentizing medium which would convey to one skilled in the sample-analysis art the knowledge that applicants invented a sample analyzer with an inert fluid segmentizing medium.”
In re Smythe (con’t): Some Inoperative Fluids are Not a §112(a) Problem

☐ CCPA: Reversed (con’t)

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<td>“By disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory or advantage even though he says nothing concerning it.”</td>
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| Not a problem that “fluid” includes some “liquids” that might not work; any “inoperative” “liquids” “would be predictably inoperative in the invention and thus would never be selected by one skilled in the art.” |

| Regarding “inert gas” rejection, CCPA agreed with patent application that “it would not encompass undue experimentation to arrive at a satisfactory method and structure to employ liquid and gases other than air.” and cited In re Borkowski, 422 F.2d 904, 57 CCPA 946 (1970).” |
Teaching Point: Smythe Still Relevant!

MPEP §2163.07(a) Inherent Function, Theory, or Advantage: “By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.”
Amended claim “adheringly applying” one layer of tube to an adjacent earlier layer. Rasmussen's specification contained one example describing how adhesive applied.

- Disclosure only described one embodiment, and that was insufficient to support broadened scope of claim.

CCPA: §132 rejection reversed; §112 rejection inappropriate because claim supported by specification.
- “Disclosure is that which is taught, not that which is claimed. An applicant is entitled to claims as broad as the prior art and his disclosure will allow.”
- “that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment.”
CCPA (con’t).

• “one skilled in the art who read Rasmussen's specification would understand that it is unimportant how the layers are adhered, so long as they are adhered. Thus the phrase ‘adheringly applying’ is supported by the example found in the specification.”

• “FN7. The board seemed to realize that 35 U.S.C. s 112 requires disclosure of only one mode of practicing the invention, but nevertheless insisted upon a boilerplate recitation in the specification that the specific embodiment shown was not meant to limit the breadth of the claims, or that the example given was only one of several methods which could be employed. Such insistence is here an exaltation of form over substance.
**Teaching Point:**

Rasmussen and Smythe

MPEP §2163.01  Support for the Claimed Subject Matter in Disclosure: “If the examiner concludes that the claimed subject matter is not supported [described] in an application as filed, this would result in a rejection of the claim on the ground of a lack of written description under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, or denial of the benefit of the filing date of a previously filed application. The claim should not be rejected or objected to on the ground of new matter. As framed by the court in In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981), the concept of new matter is properly employed as a basis for objection to amendments to the abstract, specification or drawings attempting to add new disclosure to that originally presented. While the test or analysis of description requirement and new matter issues is the same, the examining procedure and statutory basis for addressing these issues differ. See MPEP § 2163.06.

MPEP §2163.05 Changes to the Scope of Claims (I)(B): “there may be situations where one species adequately supports a genus.”

MPEP § 2163.06  Relationship of Written Description Requirement to New Matter (I): New matter added to disclosure, the examiner should object to the introduction of new matter under 35 U.S.C. 132 or 251 as appropriate, and require applicant to cancel the new matter. New matter added to claims, examiner should reject the claims under 35 U.S.C. 112(a) - written description requirement.
In re Angstadt, 537 F.2d 498 (CCPA 1976): Enablement Even If Inoperative Embodiments

Claimed invention: a method of catalytically oxidizing secondary or tertiary alkylaromatic hydrocarbons to form a reaction mixture comprising the corresponding hydroperoxides, using an organometallic complex formed between hexaalkylphosphoramides and metal salts as the catalyst.

Rejection under §112 because “the specification states that not all of the complexes will produce hydroperoxides and neither discloses which of the complexes will not work nor gives any information as to how the operative catalysts might be determined, without undue experimentation.”

CCPA: Reversed.
- “many chemical processes, and catalytic processes particularly, are unpredictable..., and that the scope of enablement varies inversely with the degree of unpredictability involved[.]”
- the unpredictability of the claimed process “is demonstrated ...in [the] specification.”
  - Of 40 examples, only one yields no hydroperoxides in the final product.
  - disclosure in specification that some of these organometallic complex catalysts “yield *** no hydroperoxides in the final product.”
In re Angstadt (con’t): Testing Disclosed To Determine Which Work And Which Don’t

☐ CCPA: Reversed (con’t)
   ☐ In an unpredictable art, does §112 require disclosure of a test with every species covered by a claim? NO.
      ☐ “To require such a complete disclosure would apparently necessitate a patent application or applications with ‘thousands’ of examples or the disclosure of ‘thousands’ of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments.”

☐ Each case must be determined on its own facts.

☐ In this case, “we have no basis for concluding that persons skilled in this art, armed with the specification and its 40 working examples, would not easily be able to determine which catalyst complexes within the scope of the claims work to produce hydroperoxides and which do not....[A]ppellants have supplied the list of catalysts and have taught how to make and how to use them[.]”
Does the law allow for some experimentation? YES

“In this art the performance of trial runs using different catalysts is “reasonable,” even if the end result is uncertain, and we see no reason on this record why appellants should not be able to claim as their invention the broad range of processes which they have discovered.”

“The examples, both operative and inoperative, are the best guidance this art permits[.]”

“this court has never held that evidence of the necessity for any experimentation, however slight, is sufficient to require the applicant to prove that the type and amount of experimentation needed is not undue.”

“We hold that the evidence as a whole, including the inoperative as well as the operative examples, negates the PTO position that persons of ordinary skill in this art, given its unpredictability, must engage in undue experimentation to determine which complexes work. The key word is ‘undue,’ not ‘experimentation.’”
Teaching Point:
Angstadt Is Alive and Well

- MPEP §2164.01  Test of Enablement: “The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.”

- MPEP §2164.06  Quantity of Experimentation: “The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether “undue experimentation” is required to make and use the invention.”

- MPEP §2164.08(b) Inoperative Subject Matter: “identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable.”
Claim 1. An improved process for minimizing loss of volatiles during freeze-drying of coffee extract which comprises obtaining coffee extract, concentrating said extract to a higher solids level of at least 35%, ....

- Dependent claims: “between 35% and 60%”

- Were claims supported by priority application such that application was entitled to date benefit?

- Specification discloses “until a concentration of 25 to 60% solid matter is reached.”

- Examples disclose specific embodiments having solids contents of 36% and 50%.
In re Wertheim I (con’t): What Does The POSITA Recognize Was In Possession Of The Inventors?

CCPA: Some claims supported by priority application.

- “The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (Cust. & Pat.App.1973), and cases cited therein. It is not necessary that the application describe the claim limitations exactly, In re Lukach, supra, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 1382, 178 USPQ 279, 284 (Cust. & Pat.App.1973).”

- “The primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.”
In re Wertheim I (con’t): Changing the Invention During Prosecution

☐ CCPA: An applicant is allowed to change his view of what his invention is during the prosecution of his application:

- “That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.”

- “[i]t is not necessary that the application describe the claim limitations exactly, . . . but only so clearly that persons of ordinary skill in the art will recognize [it] from the disclosure . . . .”
In re Wertheim I (con’t): Claiming Less than the Whole But Not A Different Invention

CCPA: Claims supported by priority application (con’t)

• “Mere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims.”

• Claim 1 range, “at least 35%,” reads literally on embodiments employing solids contents outside the 25-60% range - applicant did not show that the upper limit, 60%, is inherent in “at least 35%.”

• Dependent claims’ range, “between 35% and 60%,” supported within the described broad range of 25% to 60% (and specific embodiments of 36% and 50%.
  
  – No evidence of difference between the broader and narrower range in terms of operability or of achieving any desired result.
  – “we are not creating a rule applicable to all description requirement cases involving ranges. Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. In re Baird, 348 F.2d 974, 52 CCPA 1747, 146 USPQ 579 (1965); In re Draeger, 150 F.2d 572, 32 CCPA 1217, 66 USPQ 247 (1945).”
In re Wertheim I (con’t): In ipsis verbis Support Is Not Always Required

CCPA:

• “The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under §112, then the statement ...that “the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of §112,” is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient.”
In re Wertheim I (con’t): Written Description Support For Values Not Specified

CCPA:

- Claim limitation “particle size of at least 0.25 mm,” supported by original application or is it new matter?

- Specification indicates that the 0.25 to 2.0 mm range is preferred, but also indicates that, as an alternative embodiment, “the foam may be dried in lumps or plates of undisclosed size, which are reduced to the obviously smaller preferred particle size by grinding only after being dried.”

- “the originally filed specification clearly conveys to those of ordinary skill in the art that appellants invented processes in which the frozen foam is ground to a particle size of “at least .025 mm[.]”
Teaching Point: Wertheim I

- MPEP §2163.03 Typical Circumstances Where Adequate Written Description Issue Arises: “...there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed.”

- MPEP §2163.04 Burden on the Examiner with Regard to the Written Description Requirement: “The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact.... The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims.”

- MPEP §2163.05 Changes to the Scope of Claims: (III) “With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure.”
In re Alton,
76 F.3d 1168 (Fed. Cir. 1996): Must Consider Expert Declaration on What POSITA Would Understand

☐ Board: upheld rejection for inadequate written description.

☐ Alton submitted expert declaration addressing the issue of whether a specific example in the specification described in a specific claim.

☐ FC: Vacate and remand.
  ☐ “We express no opinion on the factual question of whether the specification adequately describes the subject matter of claim 70. We do, however, hold that the examiner's final rejection and Answer contained two errors: (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's prima facie case of inadequate description.

  ☐ “the declaration is offering factual evidence in an attempt to explain why one of ordinary skill in the art would have understood the specification to describe the modification .... Dr. Wall's use of the words “it is my opinion” to preface what someone of ordinary skill in the art would have known does not transform the factual statements contained in the declaration into opinion testimony.”
In re Hogan, 559 F.2d 595 (C.C.P.A. 1977): Enablement For Embodiments Of The Future Based On What Know As Of Filing Date

☐ How to make and use the invention: judged as of filing date

☐ 1st application, 1953: solid polymers made from 1-olefin monomers and methods of making.
☐ 3rd CIP, 1971: crystalline form only.

☐ Other inventors later discovered could make polymers in amorphous form.

☐ PTO: Hogan could not claim both forms based on 1953 application and 1956 CIP because amorphous process discovered after the 1956 date.

☐ CCPA: PTO used other inventors’ work to show Hogan’s disclosure nonenabling. Post-filing art-related facts cannot be used to test compliance of 1953 application with §112.
Teaching Point: Not Quite Hogan?

MPEP §2164.05(a) Specification Must Be Enabling as of the Filing Date:
“Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application.”
In re Johnson, 558 F.2d 1008 (C.C.P.A. 1977): Provisos One Step Removed from Wertheim I

- Use of provisos allowed

- 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.”
Modern Litigation Application of Johnson

☐ 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 the step of administering to a subject suffering from said disorder a solid pharmaceutical composition comprising:

- (a) about 10mg to about 40mg 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, the acid-caused gastrointestinal disorder is selected from the group consisting of duodenal ulcer, gastric ulcer, gastroesophageal reflux disease, and erosive esophagitis, 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.
Modern Litigation Application of Johnson (con’t): Spec – A Reason To Exclude

☐ Santarus (con’t)
- Specification: “H2 antagonists, antacids, and sucralfate ... have certain disadvantages associated with their use.”

☐ DC: No support for “no sucralfate” limitation.
- specification does not “show why a person of ordinary skill in the art reading the application would believe that sucralfate was ‘contraindicated’ in the claimed composition.”

☐ FC: Reversed
- “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.”
- Wertheim I can be read and applied more broadly
Support for Exclusion

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.
Support for Exclusion

In re Bimeda, (con’t)

• Bimeda
  – broad description of invention free from antiinfectives
  – Example 1 did not include acriflavine as an ingredient

• Examiner
  – “specific exclusion of acriflavine introduces new concept” not supported in original disclosure.

• 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.
Claim: immunoassay methods for detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of lgM isotype.

PTO: data presented by Wands to show products of antibodies unpredictable and/or unreliable. Of 143 hybridomas, only 4 of 9 tested fell within claims.

FC: “Wands’ Factors.” Routine nature of testing and high level of skill in the art. Claims enabled.
- Wands tried 3 times and each time made at least one antibody satisfying all the claim limitations.
- “The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”
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.
Teaching Point: Wands

- MPEP §2164.01 Test of Enablement: “is the experimentation needed to practice the invention undue or unreasonable?”

- MPEP §2164.01(a) Undue Experimentation Factors: *Wands* Factors listed.

- MPEP §2164.06 Quantity of Experimentation: “a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.”

- MPEP §2164.06(b) Examples of Enablement Issues — Chemical Cases
In re Breslow, 616 F.2d 516 (CCPA 1980): How To Make Even If Unstable

☐ Claimed nitrile imines.

☐ Rejection: fail to disclose how to prepare and isolate the claimed compounds.
  - “the claimed compounds are transitory intermediates which appellant has not been able to isolate and which apparently are not capable of existence, as such, in isolated form.”

☐ CCPA: Reversed.
  - Claims recite new chemical compounds.
  - Although unstable, they exist, are useful cross-linking agents, can be produced following the specification, and used for their intended purpose.
  - “a broad construction of s 101 was intended by Congress. Surely, appellant has made his nitrile imines, used them, and taught others how to do so. They can as well be considered ‘manufactures’ as ‘composition of matter.’”
Teaching Point: Apply Breslow

MPEP §2164.01(b)  How to Make the Claimed Invention: “Naturally, for unstable and transitory chemical intermediates, the ‘how to make’ requirement does not require that the applicant teach how to make the claimed product in stable, permanent or isolatable form.”
Claim 1. An emulsion blasting agent consisting essentially of:
- an aqueous solution of ammonium nitrate forming a discontinuous emulsion phase;
- a carbonaceous fuel forming a continuous emulsion phase;
- an occluded gas dispersed within said emulsion and comprising at least 4% by volume, thereof at 70°F. and atmospheric pressure; and
- a water-in-oil type emulsifying agent;
- said carbonaceous fuel having a consistency such that said occluded gas is held in said emulsion at a temperature of 70°F.

Du Pont: Claims invalid for lack of enablement.
- “disclosure...is nothing more than ‘a list of candidate ingredients’ from which one skilled in the art would have to select and experiment unduly to find an operable emulsion.”
- prophetic examples - no guarantee will actually work.
- Disclosure should be read to read only upon the two emulsifiers with which Atlas was able to produce suitable emulsions.
Atlas Powder (con’t): Limits Of Inoperability Of Species

☐ DC: Claims not invalid for lack of enablement.
   - “one skilled in the art would know how to select a salt and fuel and then apply ‘Bancroft's Rule’ to determine the proper emulsifier.”

☐ FC: Affirmed.
   - “Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid..... Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. ...That, however, has not been shown to be the case here.”
   - “Use of prophetic examples... does not automatically make a patent non-enabling. The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling. Du Pont did not meet that burden here.

   - Du Pont did not prove that the other disclosed emulsifiers were inoperable.
   - “one skilled in the art would know which emulsifiers would work in a given system.”
Teaching Point: Atlas Powder

MPEP §2164.08(b) Inoperative Subject Matter: “The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art.”
Cross v. Iizuka, 753 F.2d 1040 (Fed. Cir. 1985): Practical Utility For Compounds

- Both inventions directed to imidazole derivative compounds which inhibit the synthesis of thromboxane synthetase.

- Was Iizuka entitled to the benefit of his Japanese priority application?

- Board: Yes, “Japanese priority application contained an adequate how-to-use disclosure for the practical utility stated therein.”
Cross v. Iizuka (con’t): Pharmacological Activity Is Practical Utility

Issue on appeal: Did Iizuka’s Japanese priority application contain sufficient disclosure to meet the how-to-use requirement of § 112 with respect to the stated utility?

FC: Yes.

“a fair reading of the pertinent sections of the Japanese priority application...discloses utility for the imidazole derivative compounds of the phantom count both as an inhibiting agent for thromboxane synthetase in human or bovine platelet microsomes, as found by the Board, and as therapeutically active agents preventing the biosynthesis of thromboxane A2, thereby functioning as a medicine preventing deleterious conditions caused by thromboxane A2, as contended by Cross.”

“the in vitro utility disclosed in the Japanese priority application for the compounds of the count is sufficient to establish a practical utility.”

“adequate proof of any pharmacological activity constitutes a showing of practical utility.”

sufficient disclosure to enable one of ordinary skill in the art; at issue “is a pharmacological activity or practical utility, not a therapeutic use.”
Teaching Point: Cross v. Iizuka

MPEP §2164.02 Working Example: “Since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation for an in vitro or in vivo animal model example. A rigorous or an invariable exact correlation is not required[.]”
Specifications disclose brazing as the preferred method of attachment, and “TiCuSil” as the preferred brazing material.

DC: Claims invalid for lack of enablement.
   - Failed to disclose the six-stage braze cycle used for brazing TiCuSil.

FC: Reversed (but held invalid for failure to disclose best mode).
   - TiCuSil brazing was just one of the ways described to make and use the claimed inventions.

“If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment, ... and is not invalid for lack of enablement simply because it reads on another embodiment of the invention which is inadequately disclosed, ...Thus, it is sufficient here with respect to enablement that the patents disclose at least one attachment means which would enable a person of ordinary skill in the art to make and use the claimed inventions.”
“A patent need not teach, and preferably omits, what is well known in the art.”

- moly-manganese brazing not described in the patent specifications, but “was an old and well-known technique when the applications were filed.”

“Nonenablement is the failure to disclose any mode, In re Glass, 492 F.2d 1228, 1233, 181 USPQ 31, 35 (CCPA 1974), and does not depend on the applicant advocating a particular embodiment or method for making the invention.”
Teaching Point: SpectraPhysics

MPEP §2164.01(b)  How to Make the Claimed Invention: “As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. ...Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112.”
Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991): Written Description And Enablement Are Separate Requirements

☐ DC: No claims entitled to benefit of the filing date of Mahurkar’s earlier-filed United States design patent application, because design application (specifically, the drawings) did not provide sufficient written description support for the invention.

☐ FC: Reversed and remanded.
  ☐ “35 U.S.C. § 112, first paragraph, requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement. The purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.”
Vas-Cath (con’t): Written Description Conveys With Reasonable Clarity To POSITA That Inventors Possessed The Claimed Invention

FC: Reversed and remanded (con’t)

- Drawings alone may be sufficient for written description.

- The district court's requirement that the drawings “describe what is novel or important” was an error; no “gist” or “heart” of invention test.

- “The invention” is defined by the claims …. That combination invention is what the … drawings show.”

- “Mahurkar's later patenting of inventions involving different range limitations is irrelevant to the issue at hand. Application sufficiency under § 112, first paragraph, must be judged as of the filing date.”

- District court “erred in applying a legal standard that essentially required the drawings of the '081 design application to necessarily exclude all diameters other than those within the claimed range....the proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in those claims[.]

- Mahurkar expert declaration, Vas-Cath submitted no technical evidence to refute -> a genuine issue of material fact inappropriate for summary disposition.
Teaching Point: Vas-Cath


MPEP §163.02 Standard for Determining Compliance With the Written Description Requirement: “to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. ...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.”
In re Brana, 51 F.2d 1560 (Fed. Cir. 1995): How To Use Satisfied

- Rejection: lack of utility of the claimed compounds and the amount of experimentation necessary to use the compounds.
  - failed to describe any specific disease against which the claimed compounds were active and prior art tests/disclosed tests insufficient to establish a reasonable expectation that the claimed compounds had a practical utility (i.e. antitumor activity in humans).
    - in vitro data insufficient for in vivo utility.

- FC: Reversed.
**Brana (con’t) Presumptive Enablement and Evidence To Convince POSITA Of How To Use**

- **FC:**
  - Specification “states that the claimed compounds have ‘a better action and a better action spectrum as antitumor substances’ than known compounds” against specific type of cancer.
  - PTO did not meet burden of challenging a presumptively correct assertion of utility in the disclosure and “the nature of applicants' invention alone would [not] cause one of skill in the art to reasonably doubt the asserted usefulness.”
  - Even if burden shifted, “applicants proffered sufficient evidence to convince one of skill in the art of the asserted utility.”
    - “proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility.”
    - “FDA approval... is not a prerequisite for finding a compound useful within the meaning of the patent laws.”
Teaching Point: Brana

- MPEP §2164.01(c) How to Use the Claimed Invention: “If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied.”

- MPEP §2164.02 Working Example (II) CORRELATION: IN VITRO/IN VIVO: “Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition.”

- MPEP 2164.07 Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101: “The examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention’s asserted utility.”
Gore v. Garlock, 721 F.2d 1540 (Fed. Cir. 1983): Enablement to POSITA of Gore-Tex

- Claimed method for treating unsintered polytetrafluorethylene ("PTFE") and also the products that were produced by the method.

- DC: Claims invalid for, inter alia, lack of enablement.

- FC: Reversed.
  - "The district court considered whether certain terms would have been enabling to the public and looked to formula developments and publications occurring well after Dr. Gore's filing date in reaching its conclusions under § 112. Patents, however, are written to enable those skilled in the art to practice the invention, not the public, ..., and § 112 speaks as of the application filing date, not as of the time of trial."

- "[N]o evidence and no finding that those skilled in the art would have found the specification non-enabling ...on May 21, 1970, when the application which resulted in issuance of Dr. Gore's patents was filed."
Teaching Point: Gore v. Garlock

MPEP §2164.08  Enablement Commensurate in Scope With the Claims: “One does not look to the claims but to the specification to find out how to practice the claimed invention.”
In re Marosi, 710 F.2d 799 (CCPA 1983) sufficiently enabled; “appellants’ invention does not reside in such a number”

- Invention: process for making zeolitic compounds that did not require the use of alkali metals.

- Claim limitation: “essentially free of alkali metal.”

- Specification: “Free from alkali metal, for the purposes of the invention, means essentially free from sodium ions. The residual alkali metal content of such zeolites is in principle only attributable to impurities of the chemicals used as starting materials. . . . Thus, commercial pyrogenic silica (Aerosil), which is a particularly suitable starting material, contains about 4 ppm of Na2O.”

- Board: Indefinite; no teaching or disclosure to define an upper limit to the claim limitation even when the claims were read in light of the specification.
In re Marosi (con’t)

• CCPA: USPTO's position was impractical to the extent that the USPTO was requiring Marosi to specify a particular number as the cut-off between his invention and the prior art.

• Marosi's invention did not reside in such a number. The term "essentially free of alkali metal" had to be read in light of the specification to give it its broadest reasonable interpretation:

  “[Marosi has] provided a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine whether a process uses a [starting material] "essentially free of alkali metal" to make a reaction mixture ‘essentially free of alkali metal" to produce a zeolitic compound "essentially free of alkali metal.’ We are persuaded that such a person would draw the line between unavoidable impurities in starting materials and essential ingredients.”
Federal Circuit §112 Cases
§112 Requires More Than “Hope” Or “Plan”


  • "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.

  • 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.”
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.”
Lack Of Written Description Support From Inconsistent Use Of Terms

Rivera v. ITC, 857 F.3d 1315(Fed. Cir. May 23, 2017)

• Specification: “As used herein, the term ‘pod’ is a broad term and shall have its ordinary meaning and shall include, but not be limited to, a package formed of a water permeable material and containing an amount of ground coffee or other beverage therein.”

• Background of the Invention: The invention “more particularly relates to an adaptor assembly configured to effect operative compatibility between a single serve beverage brewer and beverage pods.”

• Abstract: “[t]he assembly is especially designed for brewing pods in brewers configured for cup-shaped beverage extract cartridges

• Claim 5. A beverage brewer, comprising:
  – a brewing chamber;
  – a container, disposed within the brewing chamber and adapted to hold brewing material while brewed by a beverage brewer, the container comprising:...
“parties agree that nothing in the ’320 patent explicitly describes a pod adaptor assembly with a filter integrated into the cartridge.”

But Rivera argued “that the integrated filter cartridge is simply a configuration of the generic disclosure of a ‘pod.’”

ITC: Claims invalid for lack of written description support.
   – “the specification was entirely focused on a ‘pod adaptor assembly’ or ‘brewing chamber,’ and did not disclose a container that was itself a pod or that contained an integrated filter.”

FC: Affirmed.
   – “The distinction between ‘pods’ and cartridges permeates the entire patent. There is no hint or discussion of a cartridge or pod adaptor assembly or receptacle that also serves as the ‘pod.’ Instead, the specification explains how the cartridge may be adapted to accept a separate ‘pod’ to be used inside the cartridge.”
Lack Of Written Description Support From Inconsistent Use Of Terms

Rivera (con’t)

• Expert testimony that a POSITA would understand the patent was “limited to embodiments that require use of a separate ‘pod.’”

• No WD support even if adopted broad definition because “[w]hatever a ‘pod’ is, the specification indicates that it is distinct from the receptacle[.]”

  “the question is whether a pod adaptor assembly, intended to allow compatibility between distinct brewing systems, also supports an undisclosed configuration that eliminates a fundamental component of one of those systems (i.e., the ‘pod’) through integration. It does not.”

  Rejected Rivera’s argument that POSITA knowledge could provide the WD support:
  “The knowledge of ordinary artisans may be used to inform what is actually in the specification, ..., but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification.”

  “That ordinary artisans may have understood that the filter could be incorporated into the cartridge does not save the claims—ordinary artisans would not have understood that Rivera had possession of an integrated filter system.”
Other Teachings

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.”
Protecting Your Innovation

• Develop validity/patentability positions during prosecution of U.S. patents.
  – Broad claims and narrow claims.
    – Every term is necessary, clearly defined, and consistently used.
    – Keep continuation pending while sorting out rights.

• Use declarations to strengthen patents to withstand court and PTAB challenges.
  – Requires careful thought and planning; avoiding inequitable conduct always.
  – Expert declarations to remove prior art.
  – Expert declarations to develop written description support and enablement throughout scope of claims.
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.
Expert Declarations

☐ Use facts as a 1-2 punch
  1. showing no prima facie case
  2. rebutting an assumed arguendo prima facie case

☐ Provides litigation or post-grant proceeding counsel the opportunity to use the same evidence, but of course, it better be good.

☐ *But be very careful with the declarations: K40 PTAB case - Instituted based on defective declaration submitted during prosecution.*

☐ *Intellect Wireless v. HTC Corp.*, 732 F.3d 1339 (Fed. Cir. 2013) and *Apotex, Inc. v. UCB, Inc.*, 763 F.3d 1354 (Fed. Cir. 2014)
  - Inequitable conduct for submitting false declarations.
  - Don’t do it!
Thank You!

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