35 U.S.C. §112 Rejections Not Based on Prior Art

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Purpose and Objectives

Purpose

The purpose of this topic is to teach new examiners the principles involved in making rejections under 35 U.S.C. 112, and how to treat special situations such as old combinations, Markush groups and res judicata. Concepts relating to claim interpretation are also included.

Objectives

After completion of this topic, the new examiner will be better able to:

1. Discuss the requirements of 35 U.S.C. 112
   - Description
   - Enablement
   - Best Mode
   - Claims defining applicant’s inventions
   - Definiteness
   - Further Limiting

2. Define new matter and know how to treat it whether it is in the specification, drawings or claims.

3. Recognize specialized situations such as aggregation, old combination, res judicata, multiplicity, prolixity, Markush groups, and nonstatutory (omnibus) claims and know how to properly treat them.

4. Interpret claim language in accordance with statutory provisions and case law.
   - Preamble
   - 35 U.S.C. 112, paragraph 6
   - Words and phrases
• Product-by-process claims
• Functional language
• Negative limitations
• Alternative expressions
• Claims containing multiple categories of invention
• Transitional phrases
• Open language (comprising)
• Closed language (consisting of)
• Intermediate language (consisting essentially of)
• Body of Claim

Outline

1. 35 U.S.C. 112
   • Background
   • General Approach
   • Paragraph 2—Applicant’s Invention
   • Paragraph 2—Definiteness
   • Paragraph 1—Enabling
   • Paragraph 1—Description
   • Paragraph 1—Best Mode
   • Paragraph 6—Means or Step for Performing a Specified Function


3. Specialized Situations
   • Aggregation
4. Claim Interpretation
   • Words and Phrases
   • Product-By-Process Claims
   • Functional Language
   • Preamble
   • Claims containing multiple categories of invention

35 U.S.C. 112

A. Background

35 U.S.C. 112, first paragraph, deals with the specification, and requires that it describe:

a. the invention (description)

b. the manner of making and using the invention (enablement), and

c. best mode.

These items must be described “in such full, clear, concise and exact terms as to enable any person skilled in the art” to understand them.

The second and sixth paragraphs of 35 U.S.C. 112 deal with the claims. The second paragraph sets forth the requirement that there be one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
The sixth paragraph deals with permissible forms of claiming and rules of construction pertaining to those forms.

B. **General Approach**

Any analysis under 35 U.S.C. 112 should begin with the determination of whether the claims satisfy the requirements of the second paragraph of §112 to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. Once having determined that the subject matter defined by the claims is definite and that the claims set forth what applicant regards as his invention, analysis turns to the first paragraph of §112 to determine whether the scope of protection sought is supported by the specification disclosure. The pertinent inquiries include determining (1) whether the subject matter defined in the claims is described in the specification, (2) whether the specification disclosure, as a whole, is such as to enable one skilled in the art to make and use the claimed invention and (3) whether the best mode contemplated by the inventor of carrying out that invention is set forth. The two requirements, (a) how to make and (b) how to use the claimed invention, are referred to as the enablement requirement of §112. The invention, for the purpose of 35 U.S.C. 112, paragraph one analysis, is defined by the claims.

C. **Rejection**


**Claiming the Subject Matter Which Applicant Regards as His Invention—MPEP 2172**

A. **Approach**

Any analysis of claims for compliance with 35 U.S.C. 112 must begin with an analysis of the claims 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. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

B. **Evidence to the Contrary**

Evidence that shows that a claim does not correspond in scope with what applicant regards as his invention may be found in contentions or admissions contained in briefs or remarks filed by applicant (*In re Prater*, 415 F.2d 1303, 162 USPQ 541, CCPA 1969) or in affidavits filed under 37 CFR 1.132 (*In re Cormany*, 476 F.2d 998, 177 USPQ 450, CCPA 1973), but probably not by statements or material contained in applicant’s specification (*In re Conley*, 490 F.2d 972, 180 USPQ 454, CCPA 1974); *In re Ehrreich*, 200 USPQ 504 (CCPA 1979). The concurring opinion (J. Baldwin) in *In re Mayhew*, 188 USPQ 356 (CCPA 1976) presents an argument that material contained in the specification can be relied
on to support a 35 U.S.C. 112, second paragraph rejection that claims do not point out “what applicant regards as his invention.”


If the specification discloses that a particular feature or element is critical or essential to the practice of the invention, failure to recite or include that particular feature or element in the claims would support a rejection that those claims are not supported by an enabling disclosure. *In re Mayhew*, 188 USPQ 356 (CCPA 1976). See also MPEP 2173.05(l).

D. **Shift Permitted**

The second paragraph of 35 U.S.C. 112 does not prohibit an applicant from changing what he regards as his invention during the pendency of his application. *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971) (Applicant was permitted to claim and submit comparative evidence with respect to claimed subject matter which was originally only the preferred class within much broader claims (method claims).

The fact that claims in a continuation application were directed to subject matter which applicants had not regarded as part of their invention when the parent application was filed was held not to prevent the continuation application from receiving benefit of the parent application’s filing date. *In re Brower*, 433 F.2d 813, 167 USPQ 684 (CCPA 1970).

**Claims Particularly Pointing Out and Distinctly Claiming the Subject Matter—Definiteness—MPEP 2173–2173.06**

A. **Essential Question**

The essential question under 35 U.S.C. 112, second paragraph, is whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. Definiteness of claim language is analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). See also MPEP 2173.02.

Likewise, reference to the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. *In re Cohen*, 438 F.2d 989, 169 USPQ 45 (CCPA 1971); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970); *In re Anderson*, 176 USPQ 331 (CCPA 1973). See also MPEP 2173.03.

If the scope of the invention sought to be patented cannot be determined from the language of the claims, a 35 U.S.C. 112, second paragraph rejection is appropriate. *In re Wiggins*, 179 USPQ 421 (CCPA 1973).
MPEP 2173.02: If the disclosure and claims are sufficient for one skilled in the art to understand, an examiner “should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirements.”

B. Pertinent Considerations

1. Claim Interpretation and Construction—MPEP 2111–2111.06

During patent examination, the pending claims must be “given the broadest reasonable interpretation consistent with the specification.” Reading a claim in light of the specification to interpret limitations explicitly recited in the claim is quite different than reading limitations of the specification into a claim to narrow the scope of a claim by implicitly adding disclosed limitations which have no express basis in the claim. In re Prater, 415 F.2d 1393, 162 USPQ 541, 550-551 (CCPA 1969). Applicant cannot rely on the specification to impart to the claims limitations not recited therein. Such reliance is ineffective to define over the prior art. In re Lundberg, 244 F.2d 543, 113 USPQ 530 (CCPA 1957); In re Winkhaus, 188 USPQ 129 (CCPA 1975).

The definiteness of claim language must also be analyzed in light of the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. W. L. Gore & Assoc., Inc. v. Garlock, Inc., 220 USPQ 303 (Fed. Cir. 1983) (Definiteness of claim language is determined as of the filing date, and it is error to rely on subsequent formula developments and publications to find uncertainty as to terms used in a patent.)

Though applicant has a right to claim what he regards as his invention under 35 U.S.C. 112, it is a function of the examiner to construe the claims presented. A refusal to construe the claims more broadly than is considered warranted by the claim language is not a rejection. In re Volk, 207 USPQ 1086 (CCPA 1980). Compare In re Priest, 199 USPQ 11 (CCPA 1978) (The Board erred in adding an inferential limitation to the claims in order to reach a particular decision; examination required by statute is of the subject matter defined by the claims submitted by applicant.)

2. Breadth Is Not Indefiniteness—MPEP 2173.04

If the scope of the subject matter embraced by the claim is clear (metes and bounds), and if the applicant has not otherwise indicated that he intends the invention to be of a different scope, then the claim complies with the second paragraph of 35 U.S.C. 112. If the enabling disclosure of the specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the second paragraph of 35 U.S.C. 112. In re Borkowski, 422 F.2d 904, 164 USPQ 642 (CCPA 1970).

A claim which referred to a chemical compound as a “polypeptide of at least 24 amino acids having the following sequence” and then recited 24 amino acids in a particular order had been rejected under the second paragraph of 35 U.S.C. 112 as failing to
“positively identify the entire chemical structure of the compound desired to be claimed.”
The examiner and the Board of Appeals had viewed the absence of a limitation as to amino
acids beyond the 24th position as rendering the claim indefinite. The court held that “While
the absence of such a limitation obviously broadens the claim and raises questions of
sufficiency of disclosure, it does not render the claim indefinite. The absence of the
limitation has a precise meaning. Regardless of the specification, the claimed subject matter
is in no way limited by the presence, absence or sequence of amino acids beyond the 24th
position.” In re Fisher, 427 F.2d 833, 166 USPQ 18, 23 (CCPA 1970) (emphasis in
original).

See also In re Morisi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) (Process claim
specifying that component be “essentially free of alkali metal” was not impermissibly
indefinite when (I) prior art required use of such metal, and (2) the claimed process
contained an undesired minute quantity of such metal. The specification provided adequate
guidance as to the level of the metal, and it would be unfair to require the applicant to
specify a cut-off number.)

3. Correspondence between Specification and Claims

The meaning of every term used in the claims should be apparent from the
descriptive portion of the specification, with clear disclosure of its import. MPEP 608.01(o);
2173.05(a). Remember that an original claim is part of the original disclosure.

4. New Terminology—MPEP 2173.05(a)

Courts have recognized that it is not only permissible, but often desirable, to use new
terms that are frequently more precise in describing and defining the new invention. This
issue was considered by the CCPA in a case in which the Board of Appeals had rejected
claims to medicinal compositions as indefinite because certain potency and purity
limitations there recited were inadequate to enable a decision to be made as to patentability
over the prior art. The court recognized that there might be a problem in determining
differences over the prior art where the claim uses language which is now accepted and
precise but which had not been used in the art. The court also recognized that, were it to
require that claims speak in the language of the prior art, it would be prohibiting the use of
the newer and frequently more precise language of the present art. The court’s solution is to
allow the use of new expressions when they are definite, and to allow the Office to call for
comparative evidence when there is reason to believe that the prior art discloses subject
matter which renders the claimed subject matter old or obvious. In re Fisher, 427 F.2d 833,
166 USPQ 18, 23 (CCPA 1970).

5. Special Definitions—MPEP 2173.05(a)

A term used in the claims may be given a special meaning in the description, but no
term may be given a meaning repugnant to the usual meaning of the term. MPEP 608.01(o);
2173.05(a). For example, where an applicant’s claims used the language “a carbamide” and
his specification defined the term “carbamide” (i.e., urea) as including “urea, thiourea,
melamine, and other urea derivatives and substituted ureas,” it was held that the claims did not accurately define his invention. *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). In a more recent case, applicants’ claim 24 referred to “a phenyl radical” and claim 25 was drawn to:

A photographic color coupler as described in claim 24 wherein the phenyl radical is a 3-octadecylcarbany1phenyl radical.

The court referred to Hockh’s Chemical Dictionary which indicated that the term “phenyl” means “the monovalent radical C6H5—” and concluded that the meaning of the phrase “a phenyl radical” is “confined to a single definite radical,” and affirmed the rejection of claim 25 under the second paragraph of 35 U.S.C. 112. *In re Barr*, 170 USPQ 330, 339 (1971).

6. **Lack of Antecedent Basis in Claim—MPEP 2173.05(e)**

   a. Non sequitur—a claim is inferential and therefore indefinite when it recites “said lever” and there was no earlier reference in the claim to a lever.

   b. Indirect limitation—a claim which first recites “lever” and later recites “said aluminum lever” gives rise to a rejection based on the second paragraph of 35 U.S.C. 112.

7. **Trademark or Tradename—MPEP 2173.05(u)**

   Trademarks or tradenames identify sources of products and not the products themselves. Although the presence of a trademark or tradename in a claim is not per se improper, if the trademark or tradename is used in a claim as a limitation to identify or describe a particular product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). See also *In re Gebauer-Fuelnegg*, 50 USPQ 125 (CCPA 1941) (presence of tradename in a claim approved where accompanied by chemical description of material (. . . a rubber resin (pliolite), . . .)); *Ex parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931) (presence of trademark in a claim improper); and MPEP 608.01(v).

8. **Acceptable Language—MPEP 2173.01**

   A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims that they regard as their invention essentially in whatever terms they choose so long as the selected terminology is clear and terms are not used in ways that are contrary to accepted meanings in the art. See, for example, *In re Castaing*, 429 F.2d 461, 166 USPQ 550 (CCPA 1970) wherein claim terminology which was not conventional in the art was nonetheless determined to be definite.

   Generally, the scope of a claim will be considered definite where each recited limitation is definite. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). A claim
may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971). Accordingly, applicant may use functional language, alternative expressions, negative limitations or any style of expression which makes clear the metes and bounds of the subject matter for which patent protection is sought.

**C. Functional Language—MPEP 2173.05(g)**

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim—for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. See, for example, In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) wherein the Court held that in a claim directed to a kit of component parts capable of being assembled, limitations such as “members adapted to be positioned” and “portions . . . being resiliently dilatable whereby said housing may be slidably positioned” serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.

**D. Alternative Expressions—MPEP 2173.05(h)**

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression is commonly referred to as a Markush group which recites members as being “selected from the group consisting of A, B, and C.” Markush groups are discussed in detail near the end of the lecture. Alternative expressions using “or” are also acceptable, such as “wherein R is A, B, C, or D.” In In re Gaubert, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975), the following phrases were each held to be acceptable and not in violation of 35 U.S.C. 112, second paragraph: “made entirely or in part of;” “at least one piece;” and “iron, steel or any other magnetic material.”

An alternative format which requires some analysis before concluding whether or not the language is indefinite involves the use of the term optionally. In Ex parte Cordova, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language “containing A, B, and optionally C” was considered acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim. A similar holding was reached with regard to the term optionally in Ex parte Wu, 10 USPQ2d 2031 (Bd. Pat. App. & Inter. 1989). If the list of potential alternatives can vary and ambiguity arises, then it is proper to make a rejection under 35 U.S.C. 112, second paragraph and explain why there is confusion.
E. Negative Limitations—MPEP 2173.05(i)

Negative limitations define an invention in terms of what the invention is not, rather than what it is. There is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. In re Barr, 170 USPQ 330 (CCPA 1971) (the negative functional limitation “incapable of forming a dye with said oxidized developing agent” was definite because the boundaries of the patent protection sought were clear). See also In re Wakefield, 164 USPQ 636, 638, 640 (CCPA 1970) (A claim to synthetic polyisoprene which recited the limitation “being free from the proteins, soaps, resins and sugars present in natural Hevea rubber” in order to exclude the characteristics of the prior art product was considered definite because each recited limitation was definite).

F. Consideration of All Claim Limitations—MPEP 2143.03, 2173.06

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” In re Wilson, 424 F.2d 1382, 165 USPQ 494, 496 (CCPA 1970). The fact that terms may be indefinite does not make the claim obvious over the prior art.

If a claim is subject to more than one interpretation, and at least one interpretation would render the claim unpatentable over the prior art, the proper course of action is for the examiner to enter two rejections: (1) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph, and (2) a rejection over the prior art based on the interpretation of the claim which renders the prior art applicable. Ex parte Ionescu, 222 USPQ 537 (Bd. App. 1984). However, if there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a claim, a rejection under 35 U.S.C. 102 or 103 should not be made based on considerable speculation about the meaning of terms employed in a claim. In re Steele, 305 F.2d 859, 134 USPQ 292 (CCPA 1962).

G. Words of Degree

Words of degree in claims (relative terminology such as “substantially equal to”) are not indefinite if the specification provides a standard for measuring that degree. Seattle Box Co., Inc. v. Industrial Crating & Packing Inc. 731 F.2d 818, 221 USPQ 568, 574 (Fed. Cir. 1984). See also MPEP 2173.05(b).

Enablement Requirement—MPEP 2164–2164.08(c)

A. Essential Test

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The examiner must also consider whether the scope of enablement provided to one of ordinary skill in the art by the
disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

**B. Pertinent Considerations**

1. **Undue Experimentation—MPEP 2164.01**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. *United States v. Telelectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Stephens*, 188 USPQ 659 (CCPA 1976). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 USPQ 214 (CCPA 1976). An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. *In re Colianni*, 195 USPQ 150 (CCPA 1977) (Miller, J., concurring). The experimentation required, in addition to not being undue, must not require ingenuity beyond that expected of one of ordinary skill in the art. *In re Angstadt*, supra. For example, in one instance a “few hours” of experimentation to determine process parameters was not considered to be undue in view of the nature of the invention (preparation of oxygenated hydrocarbons). *In re Borkowski*, 164 USPQ 642 (CCPA 1970). In *Tabuchi v. Nubel*, 194 USPQ 521 (CCPA 1977) a screening procedure which took 15 calendar days was not considered undue experimentation because the test was both simple and straightforward and because of its demonstrated success in producing the desired result.

Specific factors which are to be considered in determining whether or not experimentation required is undue are (1) the quantity of experimentation necessary (time and expense); (2) the amount of direction or guidance presented; (3) presence of absence of a working example; (4) nature of the invention; (5) the state of the prior art; (6) the relative skills of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). Non-critical features of the invention may be supported by a more general disclosure than those at the heart of the invention. *In re Stephens*, 180 USPQ 659 (CCPA 1976).

2. **Burden on the Examiner—MPEP 2164.04**

The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. If an examiner can provide reasons sufficient to create a reasonable doubt as to the accuracy of a particular broad statement put forward by applicant as enabling support for a claim, a rejection under 35 U.S.C. 112, first paragraph can be made. 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 exists, a rejection
for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 169 USPQ 367 (CCPA 1971).

3. **Enablement Commensurate in Scope with the Claims—MPEP 2164.08**

   As concerns the breadth of a term in a claim, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, by specific example or broad terminology, is not important. In re Marzocchi, supra. A rejection of a claim under §112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as unduly broad under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. In re Skrivan, 166 USPQ 85 (CCPA 1970). It has been generally held that it is the function of the specification and not the claims to set forth practical limits of operation. In re Johnson, 194 USPQ 197 (CCPA 1977).

4. **Working Example—MPEP 2164.02**

   Compliance with the first paragraph of 35 U.S.C. 112 does not turn on whether a specific example or working example is disclosed. The 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. In re Borkowski, 164 USPQ 642 (CCPA 1970). Although there is no magical relationship between the number of representable examples and the breadth of the claims with respect to enablement, and compliance with §112 first paragraph does not turn on whether a specific example is disclosed, the lack of a working example is nonetheless a factor to be considered especially in a case involving an unpredictable and undeveloped art. In re Collianni (Miller, J., concurring), supra. See also MPEP 2164.03

5. **Evidence as a Whole—MPEP 2164.05**

   The specification as a whole must be considered in determining whether the scope of enablement provided by the specification is commensurate with the scope of the claims. In re Johnson, supra. The evidence as a whole, for example, including submitted factual affidavits, can negate a position that one of ordinary skill in a given art, even given its unpredictability, must engage in undue experimentation. In re Angstadt, supra.

6. **Specification Must be Enabling as of the Filing Date—MPEP 2164.05(a)**

   The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. In re Gunn, 537 F.2d 1123,
190 USPQ 402 (CCPA 1976). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. Gould v. Quigg, 822 F.2d 1074, 3 USPQ2d 1302 (Fed. Cir. 1987).

Likewise, the examiner can use later appearing art as evidence of the state of the art existing on the filing date of the application. In re Hogan, 559 F.2d 595, 194 USPQ 527 (CCPA 1977). In In re Wright, 27 USPQ2d 1510 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner’s position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled.

Neither an applicant nor the PTO can use a later publication disclosing a later existing state of the art to determine whether an earlier application complies with the requirements of 35 U.S.C. 112, first paragraph.

7. Inoperative Species—MPEP 2164.08(b)

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), claims reading on significant numbers of inoperative embodiments may not be enabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those embodiments that are operable. In re Cook, 439 F.2d 730, 169 USPQ 298 (CCPA 1971) (Claims are not broader than the enabling disclosure even if they read on a very large number of inoperative embodiments if “a person skilled in the relevant art could determine which conceived but not-yet-fabricated embodiments would be inoperative with expenditure of no more effort than is normally required” in the art. 169 USPQ at 302.)

Later cases follow this line of reasoning. In In re Anderson, 176 USPQ 331 (CCPA 1973), claims to a laminated dressing wherein the primary layer contains a medicament were rejected under 35 U.S.C. 112, first paragraph as broader than the enabling disclosure because the term “medicament” was not limited to operative or suitable medicaments. The court reversed the rejection, reasoning it was common knowledge that some medicaments would not work and applicant should not be limited to claiming to operative medicaments in operative quantities. The claims “are inherently limited—by common sense if nothing else—to such medication as would be useful in the particular application.” 176 USPQ at 334. Note also In re Geerdes, 180 USPQ 790, 793 (CCPA 1974) in which the court stated it was possible to argue that the claims encompass inoperative embodiments on the premise of unrealistic or vague assumptions, but such arguments are not a valid basis for a rejection under the first paragraph enablement provisions of 35 U.S.C. 112. See also In re Dinh-Nguyen, 181 USPQ 46, 48 (“It is not a function of the claims to specifically exclude either possible inoperative substances or ineffective reactant proportions.”) (emphasis in original); and In re Angstadt, 537 F.2d 498, 190 USPQ 214 (CCPA 1976) (A disclosure of a large
number of operable embodiments and the 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.) However, note In re Fisher, 166 USPQ 18, 20-21 (CCPA 1970) wherein the active ingredient in the claimed composition was an adrenocorticotropic hormone (ACTH) having at least 24 amino acids in a specified sequence. The court held the claims were not enabled by the specification which taught how to make ACTHs containing 39 amino acids because the specification did not enable one skilled in the art to make or obtain ACTHs with other than 39 amino acids, and there was no showing that one of ordinary skill in the art would have known how to make or obtain such other ACTHs without undue experimentation.

8. **Block Diagrams—MPEP 2106.02, 2164.06**

Disclosure of apparatus with diagrams describing the function but not the structure of the apparatus is not, *per se*, fatal under the enablement requirement of 35 U.S.C. 112 as long as the structure is conventional or can be determined without undue experimentation. If the selection of the apparatus from the prior art is well within the purview of persons of ordinary skill in the art, “functional-type block diagrams may be acceptable, and, in fact, preferable if they serve in conjunction with the rest of the specification to enable a person skilled in the art to make such a selection and practice the claimed invention with only a reasonable degree of routine experimentation.” In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971) (emphasis in original).

For example, a disclosure of an electrical circuit apparatus, depicted in the drawings by block diagrams with functional labels, was held to be nonenabling in In re Gunn, 537 F.2d 1123, 190 USPQ 402 (CCPA 1976). There was no indication in the specification as to whether the parts represented by boxes were “off the shelf” or must be specifically constructed or modified for applicant’s system. Also there were no details in the specification of how the parts should be interconnected, timed and controlled so as to obtain the specific operations desired by the applicant. In In re Donohue, 550 F.2d 1269, 193 USPQ 136 (CCPA 1977), the lack of enablement was caused by lack of information in the specification about a single block labeled “LOGIC” in the drawings.

An applicant may refer to an element of a claimed invention which is held as a trade secret by name only and still satisfy the requirements of 35 U.S.C. 112 if equivalent elements are known, available to those skilled in the art and known to be equivalents. White Consolidated Industries v. Vega Servo-Control, 713 F.2d 788, 218 USPQ 961, 963 (Fed. Cir. 1983) The claimed control system required the use of a single pass translator such as SPLIT (held as a trade secret) for the practice of the invention. The claims where held invalid for failure to comply with the enablement requirement of 35 U.S.C. 112, first paragraph because the evidence did not show that suitable substitutes for SPLIT were known and widely available, however the evidence did show that it would take undue experimentation for one of ordinary skill in the art to develop a suitable single pass translator (about 1.5 person years of work).

9. **Critical Feature—MPEP 2164.08(c)**
If a feature which is taught as critical in the specification is not recited in the claims, the claims should be rejected for lack of enablement under 35 U.S.C. 112, first paragraph. In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Broad language in the disclosure (including the abstract) omitting an allegedly critical feature tends to rebut the argument of criticality. Features which are merely preferred are not to be considered critical. In re Goffe, 191 USPQ 429 (CCPA 1976). For example, in the Mayhew case the Court stated that since applicant’s disclosure was limited to “special cooling apparatus, specially located” as critical to obtaining the desired results, claims failing to recite such limitations were not supported by the enabling disclosure. In re Mayhew, 188 USPQ 356, 358 (CCPA 1976).

10. One Skilled in the Art—MPEP 2164.05(b)

The specification only needs to describe the invention in sufficient detail to enable a person skilled in the most relevant art to make and use the invention. When an invention, in its different aspects, involves distinct arts, the specification is adequate if it enables the adepts of each art, those who have the best chance of being enabled, to carry out the aspect related to their specialty. In re Naquin, 158 USPQ 317 (CCPA 1968); Ex parte Zechnall, 194 USPQ 461 (Bd. of App. 1973); Ex Parte Billotter, 192 USPQ 413 (Bd. of App. 1976). A factual basis must be set forth to demonstrate that it would be beyond the level of ordinary skill in a particular art to make and use the invention. Mere conclusionary statements as to the level of ordinary skill in the art are not a sufficient basis for a §112 first paragraph rejection. In re Brebner, 173 USPQ 169 (CCPA 1972).

11. Single Means Claim—MPEP 2164.08(a)

In re Hyatt, 708 F.2d 712, 218 USPQ 197 (Fed. Cir. 1983). The proper statutory rejection of a single means claims is the requirement of the first paragraph of 35 U.S.C. 112 that the enabling disclosure of the specification be commensurate in scope with the claim under consideration. The long recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor.

C. Burden of Proof—MPEP 2164.04

The Patent and Trademark Office has the initial burden of giving reasons, supported by the record as a whole, why the specification is not enabling. For example, showing that the disclosure entails undue experimentation is part of the initial burden. Also, concerning undue experimentation, the courts have held that merely demonstrating that some experimentation is necessary does not shift the burden to applicants to prove that such experimentation is not undue. In re Angstadt, supra. All assertions made that the enabling disclosure is not commensurate in scope with the protection sought by the claims must be supported by (1) evidence or (2) reasoning substantiating doubts so expressed. In re Dinh-Nguyen, 181 USPQ 46 (CCPA 1974). Reasons and evidence sufficient to create reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for
a claim can take any of the following forms: (1) statements on their face contrary to generally accepted scientific principles; (2) teachings in pertinent references; and (3) unpredictability of chemical reactions. *In re Marzocchi*, supra. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use the invention will be proper on that basis. Such rejection can be overcome by suitable evidence that the teaching contained in the specification is truly enabling. *In re Marzocchi*, supra. In any event, it is incumbent upon the Patent and Trademark Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, supra. Once the examiner has advanced a reasonable basis for questioning the adequacy of the disclosure, it is incumbent upon applicant to rebut that challenge. That is, the applicant has the burden of supplying adequate information from which the examiner could base a finding of whether the examiner’s challenge is correct, e.g. factual support as to what would be required or what was actually done in carrying out the invention. *In re Doyle*, 482 F.2d 1385, 179 USPQ 227 (CCPA 1973).

**D. Examples of Enablement**

The Patent and Trademark Office had rejected claims for lack of enablement in a “Hot-Dip Metal Coating Method and Apparatus” because the cooling means required by the invention was not claimed at the exit side of the treatment bath as described by the specification. The Court stated that the cooling means at the exit side of the treatment bath was merely a preferred embodiment and the PTO had failed to substantiate its rejection with evidence or reasoning that location of the cooling means elsewhere would not achieve the desired result. *In re Mayhew*, 179 USPQ 43 (CCPA 1973).

In a case involving the growth of linear crystals grown artificially from the vapor phase of crystal producing materials, the Court held that the general description in the specification of the temperature, pressure and vapor saturation requirements, without the disclosure of a specific example, was not sufficient to meet the requirements of the first paragraph of 35 U.S.C. 112. The court further held that the sufficiency of an application under 35 U.S.C. 112, first paragraph, must be judged as of its filing date, and therefore, later publications cannot be relied upon to supplement the disclosure. *In re Glass*, 181 USPQ 31 (CCPA 1974).

In *Dinh-Nguyen*, applicants were claiming a method of deuterating an organic compound. The Office alleged that because side reactions might occur, there was “at least a strong probability that the invention as broadly claimed encompasses significant areas wherein the process would be inoperative, or at the least, inadequately disclosed.” However, the Court found that since there was a general discussion of the claimed process, as well as three specific examples which demonstrated the general applicability of the process, the disclosure satisfied the enablement requirement of 35 U.S.C. 112, first paragraph. *In re Dinh-Nguyen*, 181 USPQ 46, 47 (CCPA 1974). In a case involving the making of sugar from starch, claims requiring an initial hydrolysis to a D.E. value of “less than about 15” units were rejected as broader than the enabling disclosure because the examples in the specification ranged between 5 and 15. In reversing the first paragraph, 35 U.S.C. 112
rejection, the Court stated that “less than 15” would merely inform one skilled in the art that anything “less than 15” would be operable, and the specification itself had demonstrated that values “between about 5 and about 15” would work. Furthermore, applicant submitted an affidavit to demonstrate that the teaching in the specification was truly enabling showing values of “1.4” to “6.7” as operable. The Court held the evidence clearly demonstrated that the lower limit of “about 5” specifically disclosed was not critical, and that values below “5” were operable. *In re Armbruster*, 185 USPQ 152 (CCPA 1975).

In the *Angstadt* decision, involving a method of oxidizing hydrocarbons employing improved catalysts, the issue was whether the claims were broader than the enabling disclosure in view of evidence in the specification itself which disclosed that not all of the complexes on which the claims read would produce the desired results. The Board of Appeals held that to determine which catalysts would work would require undue experimentation. The Court held, however, that applicants had disclosed 39 complexes which would work, and the amount of experimentation which would be required to determine other complexes which read on the claims but were not specifically disclosed as workable would not be undue. *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

However, in a case involving a method of using ultrasonic energy to mend broken bones, the Court held that the mere disclosure of “sufficient” ultrasonic energy to accomplish applicant’s purpose without a single specific example was not sufficient to meet the enablement requirements of 35 U.S.C. 112. The court noted that the specification did not provide any guidance in selecting suitable operating parameters, and that one skilled in the art would not be aware of any established criteria or techniques. *In re Colianni*, 195 USPQ 150 (CCPA 1977).

*In re Gunn*, 537 F.2d 1123, 190 USPQ 402 (CCPA 1976), discussed above with regard to block diagrams, involved a device for computing the amount of postage and for printing this amount and the zip code on the mail. The examiner rejected the claims under the first paragraph of §112 because the disclosure had only one figure of the apparatus which showed only *hollow rectangles*, and the specification described this apparatus only in terms of the function of the hollow rectangles, with no evidence of how the rectangles could be interconnected, timed or controlled. Applicant submitted patents and affidavit evidence to show the conventionality of the components. However, the patents issued after applicant’s filing date and the affidavits did not address what was known at the time the application was filed. Therefore, applicant had not overcome the *prima facie* case of non-enablement made out by the examiner. *In re Gunn*, 190 USPQ 402 (CCPA 1976).

*In re Howarth*—In responding to a rejection under 35 U.S.C. 112, first paragraph, for lack of enablement, applicant submitted copies of patent applications which had been opened for public inspection in Rhodesia, Panama and Luxembourg prior to the filing date and which disclosed the critical preparation of the starting material. In holding that the disclosure was non-enabling the court indicated that the public availability of a source of information may be controlling. When no guidance at all has been given, an applicant must show that anyone skilled in the art would have actually possessed the requisite knowledge or would reasonably be expected to check the source which the applicant relies upon to
complete his disclosure and would be able to locate the information with no more than reasonable diligence. *In re Howarth*, 210 USPQ 689 (CCPA 1931).

**E. Additional Considerations**

1. The abstract is part of the disclosure for enablement purposes. *In re Armbruster*, 185 USPQ 152 (CCPA 1975).

2. The scope of enablement varies inversely with the degree of unpredictability involved. *In re Angstadt*, supra. See also MPEP 2164.03.

3. To limit applicant to claiming “preferred” materials under the first paragraph of §112 in the absence of limiting prior art would not serve the constitutional purpose of promoting progress in the useful arts. *In re Johnson*, supra.

4. Each case must be determined on its own facts in determining the adequacy of the disclosure under 35 U.S.C. 112, first paragraph. *In re Angstadt*, supra.

5. When the specification disclosure as a whole would not enable one skilled in the art to make and use the claimed invention, the examiner may have reason to doubt the utility and operativeness of the claimed invention. This may result not only in a §112 first paragraph rejection, but also in a rejection under 35 U.S.C. 101. *In re Eltgroth*, 164 (CCPA 1970), *In re Knowlton*, 183 USPQ 33 (CCPA 1974). See also MPEP 2107, paragraph d, and MPEP 2164.07.


**Description Requirement—MPEP 2163–2163.07(b)**

The description requirement is separate and distinct from the enablement requirement. *In re Barker*, 194 USPQ 470 (CCPA 1977). The description requirement is simply that the claimed subject matter must be described in the specification. The function of the description requirement is to ensure that the applicant had in his possession, as of the filing date of the application relied on, the specific subject matter later claimed by him. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Blaser*, 194 USPQ 122 (CCPA 1977). It is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art would recognize from the disclosure that applicant’s invention included those limitations. *In re Smythe*, 480 F.2d 1376, 178 USPQ 179 (CCPA 1973). The description requirement is not met if the application does not expressly or inherently disclose the claimed invention. *In re Lukach*, 169 USPQ 795 (CCPA 1971). For example, see *In re Winkhaus*, 188 USPQ 129 (CCPA 1975) wherein the claims were amended to include a process step which was not specifically described in the application as originally filed. The applicant argued that the step would be apparent to a person of ordinary skill in the art. The court held “That a person skilled in the art might
realize from reading the disclosure that such a step is possible is not a sufficient indication to
that person that that step is part of appellants’ invention. Such an indication is the least that
is required for a description of the invention under the first paragraph of §112.” The
specification may disclose sufficient information to enable a person skilled in the art to
perform the process including the step in question and still not meet the description
requirement.

The written description consists of the specification and the claims as originally

The written description issue may be raised when the claims are amended or new
claims added during the prosecution of the application. A determination must be made of
whether the added subject matter is described in the original specification and claims. The
determination must also include a consideration of whether the added subject matter
constitutes new matter under 35 U.S.C. 132. Most of the applications which contain new
matter require both a written description and new matter rejection. The primary
consideration for both is factual. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA
1976). The issue may also be raised under 35 U.S.C. 119 or 120 as to whether the
application is entitled to the benefit of the filing date of a parent application or foreign
priority document. For example, in In re Risse, 378 F.2d 949, 154 USPQ 1 (CCPA 1967),
the application was rejected over a reference under 35 U.S.C. 102 or 35 U.S.C. 103. The
applicant attempted to remove that reference by obtaining the benefit of the filing date of the
parent application. The issue becomes whether the invention being claimed in the
continuation application is described in the parent application in the manner required by 35
U.S.C. 112. See also In re Lukach, 169 USPQ 795 (CCPA 1971).

A.  Burden of Proof—MPEP 2163.04

The inquiry into whether the description requirement is met must be determined on a
case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ
90, 96 (CCPA 1976). The examiner has the initial burden of presenting evidence or reasons
why persons skilled in the art would not recognize in an applicant’s disclosure a description
of the invention defined by the claims. In re Wertheim, 541 F.2d 257, 265, 191 USPQ 90, 98
(CCPA 1976); Ex parte Sorenson, 3 USPQ2d 1462, 1463 (Bd. Pat. App. & Inter. 1987).

In the Wertheim case, the issue was whether the foreign priority document complied
with the description requirement of 35 U.S.C. 112, first paragraph as to the claimed subject
matter so that the application would be entitled to the benefit of the foreign filing date under
35 U.S.C. 119. The examiner met the burden of proof with respect to some claims, but not
others. The foreign priority document disclosed a range of “25 to 60%” and specific
examples of “36%” and “50%.” A claim limitation of “at least 35%” did not meet the
description requirement because the phrase “at least” had no upper limit and caused the
claim to read literally on embodiments outside the “25% to 60%” range. However the court
held a limitation to “between 35% and 60%” did meet the description requirement because
“persons skilled in the art would consider processes employing a 35-60% solids content
range to be part of appellants’ invention. . . . The PTO has done nothing more than to argue
lack of literal support, which is not enough” to support a rejection under 35 U.S.C. 112, first paragraph. 191 USPQ at 98.

B. Statement of Rejection Requirements

Any time an examiner bases a rejection of a claim or the denial of the effect of a filing date of a previously filed application on the lack of a written description, the examiner should:

(1) identify the claim limitation not described; and

(2) provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed. A typical reason points out the differences between what is disclosed and what is claimed. A simple statement that “There does not appear to be a written description of the claim limitation ‘____________’ in the application as filed.” may be sufficient where the support is not apparent and the applicant has not pointed out where the limitation is supported.

C. Response to Amendments

If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Accordingly, the examiner should identify what portion(s) of the amendment lack support in the originally filed disclosure, and should fully explain the basis for the examiner’s finding. The examiner also should comment on the substance of applicant’s remarks. Any affidavits attesting to what one of ordinary skill in the art would consider disclosed by the application as originally filed must be thoroughly analyzed and discussed in the Office action.

D. Examples

In re Ahlbrecht, 435 F.2d 908, 168 USPQ 293 (CCPA 1971)—In order to comply with 35 U.S.C. 112, first paragraph, the recitation of a broad range must be described in full, clear concise and exact terms. The court held the description of a range “from 3–12” did not describe a claimed range of “from 2–12”.

In re Smith, 173 USPQ 679 (CCPA 1972)—Disclosure of a generic class of compounds and one example of a compound within a subgeneric class of compounds was not sufficient description to support claims to the subgeneric class of compounds.

In re Lukach, F.2d, 169 USPQ 795 (CCPA 1971)—Although there was no actual disclosure of molecular weight ratios in the specification, one example had an inherent
molecular weight ratio of 2.6. The claims contained a range of molecular weight ratios of 2.0 to 3.0. The inherent single embodiment was not sufficient description to support the claimed range.

_in re Welstead_, 463 F.2d 1110, 174 USPQ 449 (CCPA 1972)—The description did not support the claims because the specification did not contain a description of the claimed subgenus or descriptions of species thereof amounting, in the aggregate, to a description of the subgenus.

_in re Johnson_, 194 USPQ 187 (CCPA 1977)—Appellant lost an interference as to species within a generic claim, and thereafter filed an application directed to subgeneric claims which excluded the subject matter of the lost count. The court held that the appellant was entitled to the filing date of the grandparent application because “the specification, having described the whole, necessarily described the part remaining.” 194 USPQ at 196. The court distinguished _Welstead_ and _Lukach_ stating that “appellants’ grandparent application contains a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed” and the “grandparent application clearly describes the genus and the two classes of polymer materials excluded therefrom.” _Id._

_in re Blaser_, 194 USPQ 122 (CCPA 1977)—The parent specification disclosed that water in an amount up to 1.6 mols must be present to practice the invention, and exemplified the use of 1.2 and 1.5 mols of water. Claims setting forth a range of 0.6 to 1.6 mols of water were not entitled to the filing date of the parent application. “That a person skilled in the art . . . might proceed to run a series of experiments and derive a lower limit of 0.6 mols is not a sufficient indication to that person that 0.6 is described as a parameter of appellants’ process.” 194 USPQ at 125. However, the parent application did adequately describe claimed ranges of 1.2 to 1.5 and 1.2 to 1.6 mols of water. Furthermore, disclosure of a temperature range of 60° to 200° and specific disclosure of heating to 80° was sufficient description for a claim containing a range of 80° to 200°.

_in re Edwards_, 196 USPQ 465 (CCPA 1978)—Under circumstances of this case, the Court held that an adequate description of chemical reactions which will inherently produce, as the predominant component, the claimed compound is an adequate description of the compound.

_McLaughlin v. Roberts_, 197 USPQ 831, 835 (Bd. Pat. Int. 1978)—Roberts’ claims required 10–25% propellant. The disclosure specified that the propellant may be present from 10–79% of the product, preferably 40–79%, and more preferably 40–60%; the 25% upper limit of the claimed range was not specifically disclosed. The Board held that one of ordinary skill in the art, given appellant’s disclosure, would consider the use of the 10–25% range as a part of the invention (description requirement satisfied); likewise, the disclosure was considered enabling even though the 10–25% was not disclosed as the preferred part of the range and there were no examples of percentages within the lower range because one skilled in the art would be able to practice the invention using compositions having a propellant content within that range.
In re Wilder, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984)—The description requirement of 35 U.S.C. 112 is separate from the enablement requirement of that section. Inquiry into the description requirement is a question of fact. Because the specification and claims of the patent specified that a certain scanning function be in synchronism, generic claims added by a reissue application that eliminated the synchronism requirement did comply with the description requirement. The broadly worded title, customarily broad description of the drawing, and statement of objects of the invention did not indicate that appellants had possession of the generic invention as of the original filing date.

E. Notes

“Although [applicant’s] claims are rejected on references that teach no more than is disclosed in his earlier applications, that circumstance does not entitle him to claim his earlier filing date under Section 120 for claims not supported [paragraph 1, 35 U.S.C. 112] in those applications. In re Scheiber 199 USPQ 782, 784 (CCPA 1978).

There must be a continuous chain of copending applications each of which satisfies the requirements of 35 U.S.C. 112 with respect to the subject matter presently claimed in order to secure the benefit of the earliest filing date. In re Hogan, 194 USPQ 527 (CCPA 1977). This principle also applies to the use of a patent as prior art where the patent was a result of two or more applications. In re Wertheim, 209 USPQ 554 (CCPA 1981).

Best Mode—MPEP 2165.04

A third requirement of the first paragraph of 35 U.S.C. 112 is that: The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Policy

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, retaining the best for themselves. In re Nelson, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).

The failure to disclose a better method will not invalidate a patent if the inventor, at the time of filing the application, did not know of the better method OR did not appreciate that it is the best method. The applicant is required to disclose the best mode contemplated by the inventor even though applicant may not have been the discoverer of that mode. Benger Laboratories Ltd. v. R. K. Laros Co., 209 F Supp. 639, 135 USPQ 11 (E.D. Pa. 1962).

Failure to disclose the best mode need not rise to the level of active concealment or grossly inequitable conduct in order to support a rejection or invalidate a patent. Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad
categories, the best mode requirement has not been satisfied. *Union Carbide Corp. v. Borg-Warner*, 193 USPQ 1 (6th Cir., 1977).

**B. Relevant Considerations—2165.01**

a) What is the invention? Determine what the invention is—the invention is defined in the claims. The specification need not set forth details not relating to the essence of the invention. *In re Bosy*, 360 F.2d 972, 149 USPQ 789 (CCPA 1966).

b) Specific example is not required. There is no statutory requirement for the disclosure of a specific example—a patent specification is not intended nor required to be a production specification. *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962). The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. Best mode may be represented by a preferred range of conditions or group of reactants. *In re Honn*, 364 F.2d 454, 150 USPQ 652 (CCPA 1966).

c) Compared to enablement requirement—MPEP 2165.02. Best mode is a separate and distinct requirement from the enablement requirement of paragraph 1 of 35 U.S.C. 112. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969). The best mode provision of Section 112 is not directed to a situation where the application fails to set forth any mode—such failure is equivalent to non-enablement. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

d) CCPA suggested, but did not hold, that the best mode requirement might necessitate the inclusion of a greater degree of specificity than that necessary to comply with the enablement requirement of 35 U.S.C. 112. *In re Boon*, 439 F.2d 724, 169 USPQ 231 (CCPA 1971).

e) New Matter—35 U.S.C. 132, 35 U.S.C. 251. If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the patent application was originally filed. *In re Hay*, 534 F.2d 917, 189 USPQ 790 (CCPA 1976). Any proposed amendment of this type should be treated as new matter.

**C. Examples**

*Thyssen Plastik Auger KG v. Induplas, Inc.*, 195 USPQ 534 (D. Puerto Rico, 1977)—When invention is in a process, and the inventors know of particular apparatus which forms the best means known to them for carrying out that process, such apparatus constitutes the best mode. Here, failure to disclose a specific second gear arrangement, instead describing a blank box described as conventional, was held to be a violation of the best mode requirement.

*Weil v. Fritz*, 202 PQ 447, 451 (CCPA 1979)—Under the circumstances of this case, the mere disclosure of a particular range of concentrations as *preferred* was sufficient to
satisfy the best mode requirement. Although the enumeration of possible problems is not
essential “unless such a nondisclosure strikes at the truthfulness of the presumption that the
‘mode’ described is indeed the ‘best’ contemplated.” (applicants did not disclose the pH
sensitivity of a compound used in a method for the inhibition of plant growth).

In re Sherwood, 204 USPQ 537, 544 (CCPA 1980)—In determining the adequacy
of a best mode disclosure, “only evidence of concealment (accidental or intentional) is to be
considered. That evidence, in order to result in affirmance of a best mode rejection, must
tend to show that the quality of an applicant’s best mode disclosure is so poor as to
effectively result in concealment.” Here, the evidence of concealment consisted of the
specification’s statement that use of a digital computer was the best mode even though only
an analog method was described in detail and evidence showing the existence of useable
digital computer programs. Even though the inventor had more information in his
possession concerning the contemplated best mode than was disclosed (a known computer
program), the specification was held to delineate the best mode in a manner sufficient to
require only the application of routine skill to produce a workable digital computer program.

Honeywell v. Diamond, 208 USPQ 452 (D.D.C. 1980)—Claimed subject matter was
a time controlled thermostat but the application did not disclose the specific quartzmatic
motor which was used in a commercial embodiment. The court concluded that failure to
disclose the commercial motor did not amount to concealment since similar clock motors
were widely available and widely advertised. There was no evidence that the specific
Quartzmatic motor was superior except possibly in price.

In re Bundy, 209 USPQ 48, 52 (CCPA 1981)—There was held to be no violation of
the best mode requirement where the Solicitor argued that concealment could be inferred
from disclosure in specification that each analog is “surprisingly and unexpectedly more
useful than one of the corresponding prostaglandins . . . for at least one of the
pharmacological purposes.” It was argued that appellant must have had test results to
substantiate this statement and this data should have been disclosed. The court concluded
that no withholding could be inferred from general statements of increased selectivity and
narrower spectrum of potency for these novel analogs, conclusions which could be drawn
from the elementary pharmacological testing of the analogs.

See MPEP 2165.04 for additional examples of evidence of concealment.

D. Additional Resources

MPEP 608.01(h)

McDougall, Dugald S., “The Courts Are Telling Us. Your Client’s Best Mode Must
Be Disclosed” with Editorial Epilogue by Gerald H. Bjorge, JPOS, Vol. 59, No. 5, pp. 321–
338 (May 1977)

JPOS, Vol. 60, No. 3, p. 171 (March 1978)
35 U.S.C. 112—Paragraph 6—Means or Step for Performing a Function—MPEP 2181–2186

A. Uses

The sixth paragraph of 35 U.S.C. 112 permits a form of claiming and specifies some of the parameters of the construction of such claims. If construction is not required, there is no warrant for bringing the sixth paragraph into play. The sixth paragraph does not provide a basis for rejecting claims. *In re Comstock*, 481 F.2d 905, 178 USPQ 616 (CCPA 1973).

B. Limitations

The sixth paragraph does not add any additional description requirement to that set forth in the first paragraph of 35 U.S.C. 112. BUT, while the sentence is permissive, it CANNOT be read as creating an exception to either the description requirement (first paragraph) or the definiteness requirement (second paragraph) of 35 U.S.C. 112. *In re Knowlton*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973).

Functional language, in and of itself, does not render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). See also MPEP 2173.05(g). The sixth paragraph of 35 U.S.C. 112 specifically allows the use of functional language to define claim limitations. *In re Roberts*, 470 F.2d 1399, 176 USPQ 313 (CCPA 1973).

C. Applicable To

An element in a claim for a combination . . .

Combination referred to in the sixth paragraph of 35 U.S.C. 112 includes not only a combination of mechanical elements, but also a combination of substances in a composition claim or steps in a process claim. *In re Fuetterer*, 319 F.2d 159, 138 USPQ 217 (CCPA 1963).

A radical constituting an element of a claimed chemical compound is an element in a claim for a combination within the meaning of the sixth paragraph of Section 112. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

The sixth paragraph of Section 112 clearly sanctions the use of means-plus-function limitations in claims drawn to a combination and does not distinguish between claims drawn to an apparatus or articles of manufacture. *In re Farrow*, 193 USPQ 689 (CCPA 1977)

D. Interpretation

When making a determination of patentability under 35 U.S.C. 102 or 103, a “means or step plus function” limitation is interpreted by giving it the “broadest reasonable interpretation.” Per the holding in *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845
(Fed. Cir. 1994), “the ‘broadest reasonable interpretation’ that an examiner may give means-plus-function language is that statutorily mandated in paragraph six [of 35 U.S.C. 112]. Accordingly, the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination.” 29 USPQ2d at 1850.

The application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim. However, if a prior art reference teaches identity of function to that specified in a claim, then under Donaldson an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.

The “means or step plus function” limitation should be interpreted in a manner consistent with the specification disclosure. If the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation.

NOTE:

Cases prior to 1975 will refer to the third paragraph of 35 U.S.C. 112. It became the sixth paragraph in an amendment dated November 14, 1975.

E. Single Means Claim

The provisions of the sixth paragraph of Section 112 do not apply to a claim drafted in a means-plus-function format which is not drawn to a combination. In other words, a single means claim drafted in a means-plus-function format does not comply with the enablement requirement of 35 U.S.C. 112, first paragraph. See In re Hyatt 218 USPQ 195 (Fed. Cir. 1983) and MPEP 2181.

New Matter—35 U.S.C. 112, 132 and 251

A. The Statute

35 U.S.C. 132—No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. 251—No new matter shall be introduced into the application for reissue.

B. The Rule—37 CFR 1.118 Amendment of Disclosure

(a) No amendment shall introduce new matter into the disclosure of an application after the filing date of the application (37 CFR 1.53(b)). All amendments to the
specification, including the claims, and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition to the original disclosure, cannot be added to the application after its filing date even though supported by an oath or declaration in accordance with 37 CFR 1.63 or 37 CFR 1.67 filed after the filing date of the application.

(b) If it is determined that an amendment filed after the filing date of the application introduces new matter, claims containing new matter will be rejected and deletion of the new matter in the specification and drawings will be required even if the amendment is accompanied by an oath or declaration in accordance with 37 CFR 1.63 or 37 CFR 1.67.

C.  The Manual—MPEP 608.04, 706.03(o) and 2163.06

Matter not in the original specification, drawing, or claims is usually new matter. By definition new matter is material added by amendment which does not have clear support in the original specification, claims, or drawings. It must be emphasized that the issue of new matter can arise by applicants either (1) adding material to the specification by amendment, or (2) deleting original material from the specification by amendment. For example, the addition of the term “PVC polymer” where the specification only contains the term “polyethylene” would be new matter. However, the deletion from the original specification of, for example, a lower limit (e.g., at least about 20) so that the specification no longer contains any lower limit would also be considered new matter.

The addition of new matter to the specification or claims or drawing most likely will occur in response to an Office action which rejects the claims or objects to the specification. However, the examiner should also be aware of the fact that new matter may also be added in a Preliminary Amendment. See MPEP 608.04(b). A Preliminary Amendment (even if filed concurrently with the application) does not enjoy the status as part of the original disclosure unless it is referred to in the oath. Accordingly, the amendment must be examined for new matter. A preliminary amendment filed with a continuation-in-part application filed under the file wrapper continuing procedure of 37 CFR 1.62(c) is considered to be an integral part of the C-I-P application as filed.

D. Procedure for Handling

Specification—If new matter is added to the specification, the examiner should object to the specification under 35 U.S.C. 132, and require applicant to cancel the material. Review of this objection is by way of petition.

The objection may be made using Form paragraph 7.28.

Claims—If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph and require cancellation of the new matter. Review of this rejection is by way of appeal. In re Rasmussen, 211 USPQ 323 (CCPA 1981).
The rejection may be made using form paragraph 7.31.01. If both the claims and specification contain new matter (either by direct amendment or by inference) and there has been both an objection and rejection by the examiner, the issue becomes appealable and should not be decided by petition.

E. **Rephrasing—MPEP 2163.07**

The examiner must realize that a mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. See *In re Anderson*, 176 USPQ 331 (CCPA 1973). The mere inclusion of dictionary or art recognized definitions known at the time of filing said application would not be considered new matter.

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes new terms are introduced which do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted. New claims and amendments to the claims already in the case should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature utilized in the application as filed, when by amendment of his claims he departs therefrom, he should generally make appropriate amendment of his specification so as to have therein clear support or antecedent basis for the new terms appearing in the claims. MPEP 608.01(o).

F. **Obvious Errors—MPEP 2163.07**

An amendment to correct an obvious error does not constitute new matter where one skilled in the art would appreciate not only the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971) (change from nitrous to nitric acid in examples directed to methods of preparing a claimed compound was not new matter since error and correction would be apparent to one skilled in the art); *Ex parte Brodbeck*, 199 USPQ 230 (Bd. App. 1977) (An original claim limitation literally stated that a given percentage of the catalyst pores must be larger than 45A in radius, while the amended limitation stated that a given percentage of the catalyst pore volume is from pores larger than 45A radius. The former limitation implies a knowledge of the number of pores themselves, while the latter limitation implies only a knowledge of pore volume resulting from pores having the specified size. The Board was convinced by 2 declarations that one skilled in the art would recognize both the original limitation is in error, and what the erroneous expression should be.).

But, in *In re Nelson*, 126 USPQ 242 (CCPA 1960) a new matter rejection was affirmed where applicants had added a paragraph which indicated how, by well-known and obvious steps, applicants novel compounds could be converted into known useful compounds. The process steps, although well known and obvious in general, had never been applied to applicants’ novel compounds before. In *Ex parte Bondiou*, 132 USPQ 356 (Bd. App. 1961) a U.S. application claiming foreign priority had been mistranslated (i.e., 4 days
had been translated to 4 hours), but the error was not apparent upon reading the original U.S. application. The Board held that the amendment introduced prohibited new matter since the error was not apparent on its face. Even an affidavit showing that the priority document had been mistranslated was not sufficient to avoid the new matter holding.

G. **Inherent Function, Theory or Advantage—MPEP 2163.07**

By disclosing in a patent application a device that inherently performs a function, 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. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971) (relationships clearly depicted in the drawings provided sufficient disclosure to support claims). In *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973), the court found that the described properties and functions of the “air or other gas” set forth in the specification would suggest to a person skilled in the art that the invention included the use of “an inert fluid” broadly.

H. **Incorporation by Reference—MPEP 608.01(p), 2163.07(b)**

The actual text of material which was incorporated into the specification as originally filed by reference to another document may be inserted into the specification.

Essential material (i.e., material necessary to support the claims) may be incorporated by reference to:

1. A U.S. patent
2. A pending U.S. application

Essential material may not be incorporated by reference to:

1. Foreign patents
2. Non-patent publications
3. A patent or application which itself incorporates essential material by reference
4. A foreign application

*In re Fouche*, 169 USPQ 429 (CCPA 1971)—gives guidelines on when an applicant may fill in a Serial No. ____________ left blank in a specification as originally filed.

If improper reference is made (e.g., to a foreign patent), applicant is required to amend the specification to specifically include material improperly referenced AND the
amendment must be accompanied by an affidavit or declaration executed by the applicant, attorney or agent stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See the three Hawkins cases cited in MPEP 608.01(p), e.g. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1993).

Compare *Quaker City Gear Works Inc. v. Skil Corporation*, 223 USPQ 1161 (Fed. Cir. 1984) wherein reference to a helical wheel gear made according to “German Industrial Standard 45800 draft September 1963,” was held to be improper (does not comply with 35 U.S.C. 112, first paragraph, enablement requirement) because incorporation by reference is not permissible where material necessary for an adequate disclosure is unavailable to the public. Patentee was unable to produce a copy of the referenced document.

“[M]ere reference to another application, or patent or publication is not an incorporation of anything therein into the application containing such reference for the purposes of the disclosure required by 35 U.S.C. 112.” *In re de Seversky*, 474 F.2d 671 177 USPQ 144, 146 (CCPA 1973) (emphasis in original).

I. **Changes to the Scope of the Claims—MPEP 2163.05**

The issues of new matter and failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arise when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation.

J. **Broadening Claims**

In *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989), the benefit of foreign priority was denied because claims in the U.S. application were not supported in the foreign priority application. In the claims of the U.S. application, chemical compounds representing antibiotics were generically claimed via reference to a structure with varying moieties and were also claimed subgenerically in a Markush format. The foreign application disclosed only two of the species presented in the broad generic claim and in the 21 compounds listed in the Markush claims. The court concluded that the additional subject matter in the U.S. application was not adequately described in the foreign document.

K. **Narrowing or Subgeneric Claims**

The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. *Ex parte Ohshiro*, 14 USPQ2d 1750 (Bd. Pat. App. & Inter. 1989) (The Board affirmed the rejection under 35 U.S.C. 112, first paragraph, of claims to an internal combustion engine which recited “at least one of said piston and said cylinder (head) having a recessed channel” because the application which disclosed a cylinder head with a recessed channel and a piston without a recessed channel did not specifically disclose the “species” of a channeled piston.); *Ex parte Klager*, 132 USPQ 206 (Bd. App. 1959) (The Board held that a disclosure
of 1-halo-1-nitroethylene was not an adequate description of 1-chloro-1-nitroethylene because “an applicant cannot include and claim a specific thing not originally described, merely because it comes within the scope of the genus before disclosed.” 132 USPQ at 206.

Recitation of an undisclosed species may violate the description requirement, however a change involving subgeneric terminology may or may not be acceptable. See, e.g., In re Welstead, 463 F.2d, 174 USPQ 449 (CCPA 1972) (specification did not contain a description of the subgenus or descriptions of species thereof amounting, in the aggregate, to a description of the subgenus); In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (a generic disclosure and a single example which inherently disclosed a molecular weight ratio of 2.6 did not provide support for a subgeneric molecular weight ratio range of 2.0 to 3.0). Subgeneric language (intermediate scope) may be supported by broad generic language coupled with descriptions supportive of the limited genus claimed. In re Johnson, 194 USPQ 187 (CCPA 1977) (Appellant lost an interference as to species within a generic claim, and thereafter filed an application directed to subgeneric claims which excluded the subject matter of the lost count. The court held that the appellant was entitled to the filing date of the grandparent application because “the specification, having described the whole, necessarily described the part remaining.” 194 USPQ at 196. The court distinguished Welstead and Lukach stating that “appellants’ grandparent application contains a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed” and the “grandparent application clearly describes the genus and the two classes of polymer materials excluded therefrom.” Id.

Each case must be decided on its own facts in terms of what is reasonably communicated to those skilled in the art. In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

L. Range Limitations

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 the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%–60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

See also In re Blaser, 194 USPQ 122 (CCPA 1977) wherein the parent specification disclosed that water in an amount up to 1.6 mols must be present to practice the invention, and exemplified the use of 1.2 and 1.5 mols of water. Claims setting forth a range of 0.6 to 1.6 mols of water were not entitled to the filing date of the parent application. “That a person skilled in the art . . . might proceed to run a series of experiments and derive a lower limit of 0.6 mols is not a sufficient indication to that person that 0.6 is described as a parameter of
appellants’ process.” 194 USPQ at 125. However, the parent application did adequately describe claimed ranges of 1.2 to 1.5 and 1.2 to 1.6 mols of water. Furthermore, disclosure of a temperature range of 60°C to 200°C and specific disclosure of heating to 80°C was sufficient description for a claim containing a range of 80°C to 200°C.

M. Mechanisms Old in the Art

In re Chaplin, 168 F.2d 85, 77 USPQ 601 (CCPA 1948)—Amendment citing issued patent numbers to show “These mechanisms are not shown as they are well known in the art” would not be considered new matter provided the patents disclosed mechanisms old in the art.

Interrelationship with Description Requirement (35 U.S.C. 112, 1st Paragraph)—MPEP 2163.06

If new subject matter is added to the disclosure, whether it be in the abstract, the specification, or the drawings, 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. If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph—written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). In an instance in which the claims have not been amended, per se, but the specification has been amended to add new matter, a rejection of the claims under 35 U.S.C. 112, first paragraph should be made whenever any of the claim limitations are affected by the added material.

N. Claimed Subject Matter Not Disclosed in Remainder of the Specification

The claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. In re Benno, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Form paragraph 7.44 may be used where originally claimed subject matter lacks proper antecedent basis in the specification.

O. Burden of Proof

PTO has initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. In re Salem, 193 USPQ 513 (CCPA 1977). See the discussion of the burden of proof with regard to the description requirement, supra.

P. Prior Art Rejections—MPEP 2143.03

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” In re Wilson, 424 F.2d 1382, 165 USPQ 494, 496 (CCPA 1970). See also In re Miller, 169 USPQ 597 (CCPA 1971). New matter limitations must be anticipated
by or obvious over the prior art before a claim with new matter can be rejected as being unpatentable over the prior art.

Specialized Situations

A. **Aggregation**—MPEP 2173.05(k)

Definition: refers to a situation where there is no cooperation between the elements of a claim; e.g., washing machine associated with a dial telephone.

There is limited applicability today unless it amounts to noncompliance with the second paragraph of 35 U.S.C. 112. *In re Gustafson*, 141 USPQ 585, 589 (CCPA 1964) (aggregation rejection does not comply with spirit of 35 U.S.C. 132); *Ex Parte Holden*, 149 USPQ 378 (Bd. App. 1965) (comments that CCPA suggested in Gustafson that aggregation has no basis in 1952 Patent Act).

B. **Incomplete Claims**—MPEP 2173.05(l)

A claim can be rejected as incomplete if it omits essential elements, steps or necessary structural cooperative relationships of elements, such omission amounting to a gap between the elements, steps or necessary structural connections. See *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968) (Although the claim language recited intended uses, capabilities, and structure which would result upon the performance of future acts as indicated by the emphasized claim language, such claim language was not a positive structural limitation on the claim. Because appellant argued that the invention was not merely directed to a crimpable perforated ferrule and a ground wire, the court held that appellant failed to particularly point out and distinctly claim the subject matter which appellant regarded as his invention.). Compare *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) (In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as “members adapted to be positioned” and “portions . . . being resiliently dilatable whereby said housing may be slidably positioned” serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.).

An incomplete claim should also be rejected under the first paragraph of 35 U.S.C. 112 as based upon a disclosure which is not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See MPEP § 2164.08(c).

Greater latitude is permissible with respect to the definition in a claim of matters not essential to novelty or operability than with respect to matters essential thereto. Furthermore, the breadth of a claim is not to be equated with indefiniteness. See MPEP 2173.04.

C. **Old Combination**—MPEP 706.03(j)

A claim should not be rejected on the ground of old combination. See MPEP 2173.05(j) for a brief history of the principle of old combination.
D. Res Judicata—MPEP 706.03(w)

A. Definition: a thing adjudicated.

B. Policy: judicial policy designed to put an end to litigation once an issue has been decided.

C. Prerequisites

1. Identity of parties in two actions—In re Szwarc, 126 USPQ 404 (CCPA 1960).

2. Issues must be the same—new issues can be raised, e.g., by
   a. new affidavit evidence—In re Russell, 169 USPQ 426 (CCPA 1971); In re Herr, 153 USPQ 548 (CCPA 1967).
   b. different limitations in claims—In re Fisher, 166 USPQ 18 (CCPA 1970).

3. Earlier decision must have been by PTO Board of Patent Appeals and Interferences or any one of the reviewing courts. In re Hitchings, 144 USPQ 637 (CCPA 1965) held that a res judicata rejection is not applicable to an unappealed final rejection.

4. No opportunity for further court review of the earlier decision.

D. Other Considerations

1. Should be accompanied by rejection on prior art or other appropriate grounds.

2. Timely filing of continuing case does not preclude res judicata rejection.

3. Doctrine should not be used to:
   a. refuse claims which are otherwise patentable—In re Craig, 162 USPQ 157 (CCPA 1969).
   b. force allowance of claims that do not comply with the statutes—In re Borkowski, 184 USPQ 29, 33 (CCPA 1975) (The Patent Office must have the flexibility to reconsider and correct prior decisions that it may find to have been in error.”); In re Riddle, 169 USPQ 45 (CCPA 1975) (Allowance of a claim by an examiner in a patent is not a bar
to the rejection of a pending claim to substantially the same invention on substantially the same art considered in the patent prosecution.)

E. Multiplicity—37 CFR 1.75(b); MPEP 2173.05(n)

A. Unreasonable number of claims in view of:

1. Nature and scope of invention
2. State of the art

B. Extremely Limited Applicability

1. The earlier views of the Court of Customs and Patent Appeals on multiplicity were set forth in In re Chandler, 45 CCPA 911, 117 USPQ 361 (1958) and In re Chandler, 50 CCPA 1422, 138 USPQ 138 (1963) (Applicants latitude in stating their claims in regard to number and phraseology employed “should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion.” 138 USPQ at 148.).

2. These views have been somewhat revised by its views in In re Flint, 411 F.2d 1353, 162 USPQ 228 (CCPA 1969) (“The [ 42 ] claims differed from one another and we have no difficulty in understanding the scope of protection. Nor is it clear, on this record, that the examiner or board was confused by the presentation of claims in this case or that the public will be.” 162 USPQ at 231) and In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970) (“Examination of forty claims in a single application may be tedious work, but this is no reason for saying that the invention is obscured by the large number of claims. We note that the claims were clear enough for the examiner to apply references against all of them in his first action.” 164 USPQ at 639.). The court in Wakefield also noted “there is no statutory authority for rejecting claims as being ‘unnecessary.’” Id.

C. If rejection is made:

1. basis is 35 U.S.C. 112, second paragraph or 37 CFR 1.75(b).
2. all claims should be included.
3. applicant should be required to select a reasonable number (examiner stipulates) for prosecution on merits.
4. SSP of two months if only rejection made in action.

F. **Prolix—MPEP 2173.05(m)**

A. Definition: long recitations of unimportant details which hide or obscure invention.

B. Test should be same as applied in metes and bounds requirement of 35 U.S.C. 112, second paragraph.

C. Picture claim, in itself, is insufficient justification for allowance of claim—MPEP 706.

G. **Nonstatutory or Omnibus Claim—MPEP 2173.05(r)**

A. Example: A device substantially as shown and described.


C. If case otherwise allowable, cancel by Examiner’s Amendment—MPEP 1302.04(b).

**Markush Practice—MPEP 2173.05(h)**

Markush Group—Definition—*Ex Parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1924)—The term “Markush” as applied to claims denotes a claim wherein a substance, substitute, agent, reactant, or material therein is recited as being selected from the group consisting of certain specified materials—e.g. “a material selected from the group consisting of A, B, C and D.” This type of expression was devised to meet the situation presented by chemical cases for conveniently expressing a broad claim involving of several chemical compounds which were not associated as a recognized group but yet had a common property that rendered them equivalent in the particular situation involved.

A Markush group often appears in a claim containing a structural formula—e.g. a 5-membered ring structure containing two heterocyclic radicals wherein one heterocyclic radical is N and the other is X wherein X is a bivalent radical selected from the group consisting of O, S and NH. In assessing the propriety of this grouping, the complete compounds presented in the structural formula rather than the substitutes per se must be considered. In other words, the question for consideration is not whether “O, S and NH” constitutes a proper group, but whether the “group consisting of oxazoles, thiazoles and imidazoles” is proper.

Application of prior art—Prior art which teaches or suggests all the limitations of a claim as to only one member of a Markush group is sufficient to render the claim unpatentable under 35 U.S.C. 102 or 103. If applicant limits the scope of a Markush group to avoid a reference, in order for the examiner to maintain an obviousness rejection over that
reference, the equivalency of the members of the Markush group must be recognized in the
prior art; the equivalency cannot be based on applicant’s disclosure or the mere fact that the
components at issue are functional equivalents. In re Ruff, 256 F.2d 560, 118 USPQ 340
(CCPA 1958). See also MPEP 2144.06.

Markush Group Containing Independent and Distinct Inventions—35 U.S.C. 121,
MPEP 802.01, 803.02—A claim containing a Markush group is considered to be directed to
independent and distinct inventions where two or more of the members of the Markush
group are so unrelated and diverse that a prior art reference anticipating the claim with
respect to the invention embracing one of the members would not render the claim obvious
under 35 U.S.C. 103 with regard to the invention embracing other member(s). MPEP
803.02.

A. History of Treatment of Markush Claims

At one time, claims written in Markush style were rejected under 35 U.S.C. 112,
paragraph one, if they contained non-elected species. Before that, Markush-type claims were
held withdrawn from consideration. The withdrawal was petitionable since there was no
rejection. Just a few years ago, a Markush claim with non-elected species was considered
“improper” and was rejected under 35 U.S.C. 121 for improper misjoinder of invention
because such a claim embraced more than one independent and distinct invention. However,
In re Weber, 198 USPQ 328 (CCPA 1978) and In re Haas, 198 USPQ 334 (CCPA 1978)
held that 35 U.S.C. 121 does not provide a basis for the rejection of claims.

B. Present Treatment of Markush Claims

In view of the decision in In re Harnisch, 206 USPQ 300 (CCPA 1980), a claim
should not be rejected as claiming an “improper” Markush group unless the examiner can
show that the subject matter of the claim lacks unity of invention. Broadly, unity of
invention exists where compounds included within a Markush group (1) share a common
utility and (2) share a substantial structural feature disclosed as being essential to that utility.

A claim having a Markush group which embraces compounds which do not have a
common utility (even in the generic sense) or do not possess a commonly patentable nucleus
or a single structural similarity would be subject to a rejection as being based on an
improper Markush group. For the great majority of cases which are not as extreme, the
examiner will obtain what guidance can be gleaned from decisions which have affirmed a
rejection of claims having improper Markush groups such as In re Swenson, 132 F.2d 336,
56 USPQ 180 (CCPA 1942); In re Ruzicka, 150 F.2d 550, 66 USPQ 226 (CCPA 1945); and
In re Winnek, 160 F.2d 572, 73 USPQ 225 (CCPA 1947), and those decisions where a
rejection of claims as being drawn to improper Markush groups have been reversed such as
In re Jones, 162 F.2d 479, 74 USPQ 149 (CCPA 1947); In re Schechter, 205 F.2d 185, 98
USPQ 144 (CCPA 1953); Ex parte Brouard, 201 USPQ 538 (Bd. Appeal 1976); and In re
Harnisch, supra, to determine whether such a rejection is appropriate in any particular case.

C. Practice
In each case where a claim is presented containing a Markush group, and where the subject matter of that claim is considered to contain independent and distinct inventions within the meaning of 35 U.S.C. 121, the examiner may make a requirement for restriction unless the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden on the examiner. In this requirement, the examiner will identify the inventions which are considered to be independent and distinct and require applicant to elect a single invention even though this requirement is traversed.

After applicant’s election, the examiner should search the generic claim to the extent of the elected species only, along with all specific claims directed to the elected species. If a prior art rejection can be made, the appropriate claims are rejected and the other species are held non-elected. Prosecution continues as in any other application. If, however, a prior art rejection cannot be made, the search is extended to the non-elected species to the extent necessary to determine patentability (the examiner may request non-examining time known as Markush time for the additional search time). If prior art is found to reject a non-elected species, a rejection is made while holding all non-examined species withdrawn from consideration.

If, after the rejection of an examined species, the applicant amends the generic claim to delete the elected species, the search must be extended to the extent that a non-elected species can be rejected over prior art. If prior art is found for any non-elected species after this amendment, a final rejection can be made. Amendments submitted after final rejection further restricting the scope of the claim may be denied entry as raising new issues which would require further consideration and/or search.

Claim Interpretation

A. Words and Phrases Broaderest Reasonable Interpretation and Plain Meaning—MPEP 2111–2111.01

Words in claims are to be given their broadest reasonable interpretation consistent with the specification where the patent has not yet issued and the applicant has an opportunity to change them. In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (1971). The interpretation must be reasonable, since words or terms have to be given the meaning called for by the specification of which they form a part. In re Rovka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). But, a specification may not distort a term to mean something that it does not mean. In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Words in a claim which have not been clearly defined in the specification must be given their plain meaning. In re Zletz 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

B. Transitional Phrases—MPEP 2111.03

The term comprising, which is synonymous with including, containing, or characterized by, is inclusive or open-ended and permits the inclusion of unrecited
additional steps, elements, or materials. *In re Baxter*, 656 F.2d 679, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

The term *consisting of* excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 225 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”).

The term *consisting essentially of* limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-552, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original). See also *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) (“consisting essentially of” may be used in the context of processes).

C. Relative Terminology—MPEP 2173.05(b)

*About* permits some tolerance. At least about 10% was held to be anticipated by a teaching of a content not to exceed about 8%. *In re Ayers*, 154 F.2d 182, 69 USPQ 109 (CCPA 1946). A pressure limitation of 2–15 pounds per square inch was held to be readable on a reference which taught a pressure “of the order of about 15 pounds to the square inch.” *In re Erickson*, 343 F.2d 778, 145 USPQ 207 (CCPA 1965).

Though the term *commercial scale* is proper under 35 U.S.C. 112, second paragraph, it is clear that the mere scaling up of a prior art process capable of being scaled up would not establish patentability in a claim to an old process so scaled. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)

While *generally* and other similar words are sometimes construed liberally to avoid unduly restricting a patent claim, the imprecision of such a term cannot be allowed to negate the meaning of the words it modifies. Thus, *generally planar* in a claim was intended to allow for irregular deviations from perfectly flat surface and not to broaden planar to encompass distinctly arcuate surfaces. *Arvin Industries v. Berns Air King Corp.*, 525 F.2d 182, 188 USPQ 49 (7th Cir. 1975).

The terms *thin* and *wide* are relative to the extent of being definitive only in regard to a particular object referred to. It is necessary to look to the specification in which such terms arise to determine their meaning. *In re Miles*, 463 F.2d 1401, 175 USPQ 33 (CCPA 1972).
The term “or like material” in the context of the limitation “coke, brick, or like material” was held to render the claim indefinite since it was not clear how the materials other than coke or brick had to resemble the two specified materials to satisfy the limitations of the claim. *Ex parte Caldwell*, 1906 C.D. 58 (Comm’r Pat. 1906).

**D. Numerical Ranges and Amounts Limitations—MPEP 2173.05(c)**

The common phrase “an effective amount” may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase “an effective amount . . . for growth stimulation” was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase “an effective amount” has been held to be indefinite when the claim fails to state the function which is to be achieved. *In re Fredericksen*, 213 F.2d 547, 102 USPQ 35 (CCPA 1954); *In re Watson*, 517 F.2d 465, 186 USPQ 11, 20 (CCPA 1975) (“an effective amount of a germicide suitable for use in oral hygiene” complied with 35 U.S.C. 112, second paragraph). The more recent cases have tended to accept a limitation such as “an effective amount” as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an “effective amount of a compound of claim 1” without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

*Predominantly* means at least 50%. *In re Thomas*, 178 F.2d 412, 84 USPQ 132 (CCPA 1949). *Up to* includes 0 as a lower limit. *In re Mochel*, 470 F.2d 638, 176 USPQ 194 (CCPA 1974). The recitation of “a moisture content of not more than 70% by weight” reads on dry material or material containing no more moisture than is normally taken up from the atmosphere. *Ex parte Khusid*, 174 USPQ 59 (Bd. App. 1971).

**E. Other Terms**

The term *integral* was held not to be limited to a fabrication of the parts from a single piece of metal, but was inclusive of other means for maintaining the parts fixed together as a single unit. *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965). “Integral” is sufficiently broad to embrace constructions united by such means as fastening and welding. *In re Hotte*, 475 F.2d 644, 177 USPQ 326 (CCPA 1973).

The term *separate* does not necessarily proscribe all connection between parts. *In re Ruegg*, 165 USPQ 711 (CCPA 1970).
**Invention**—This term is used without any implication of patentability and only to refer to the thing invented regardless of its patentability. *In re Borah*, 354 F.2d 1009, 148 USPQ 213 (CCPA 1966).

The recitation of “means requiring no other input” than specific means does not mean that no other input can exist, but only that no other input is needed or required. *Stansbury v. Bond*, 482 F.2d 968, 179 USPQ 88 (CCPA 1973).

Statement in patent that extraction is preferentially carried out in successive stages implies that process may be carried out without separating the stages. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

### Product-by-Process

**Relevant MPEP Sections: MPEP 2113, 2173.05(p)**

Product claims may include process steps to wholly or partially define the claimed product. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973). The fact that it is necessary for an applicant to describe his product in product-by-process terms does not prevent the applicant from presenting claims of varying scope. *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972).

**A. Limitations**

Product-by-process type of claims do not inherently conflict with the second paragraph of 35 U.S.C. 112, *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967), but these claims must particularly point out and distinctly claim the product or genus of products for which protection is sought. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972).

**B. Patentability**

The invention defined in a product-by-process claim is a product, not a process. *In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966).

It is the patentability of the product claimed and NOT of the recited process steps which must be established. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 541 F.2d, 191 USPQ (CCPA 1976).

A comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning the patentability of the product. *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. *In re Rlug*, 333 F.2d 905, 142 USPQ 161 (CCPA 1964). In an *ex parte* case, product-by-process claims are NOT construed as being limited to the product formed by the specific process recited. *In re Hirao*, 535 F.2d 67, 190 USPQ 15, f.n.3 (CCPA 1976).
However, to the extent that the process limitations distinguish the product over the prior art, they must be given the same consideration and weight in assessing the differences between the claimed subject matter and the prior art *Graham v. John Deere Co.*, 383 US 1, 148 USPQ 523 (1973).

That some of the products covered by applicant’s claims may not be disclosed or suggested by the prior art is NOT relevant to patentability, where the claims embrace other subject matter completely disclosed by the prior art. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

**C. Burden of Proof**

PTO “bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature” than would be the case when a product is claimed in the more conventional fashion. *In re Fessman*, 489 F.2d 742, 180 USPQ 324, 326 (CCPA 1974).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, the burden is on the applicant to present evidence from which the examiner could reasonably conclude that the claimed product is patentably distinct from the product of the prior art. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972); *In re Fessman*, 489 F.2d 742, 180 USPQ 323 (CCPA 1974). *In re Marosi*, 710 F.2d 799, 218 USPQ 195 (Fed. Cir. 1983). This burden is NOT discharged solely because the product was derived from a process not known to the prior art. *In re Fessman*, 489 F.2d 742, 180 USPQ 324 (CCPA 1974).

*In re Marosi*, 710 F.2d 799, 218 USPQ 195 (Fed. Cir. 1983)—Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.

*In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985)—The practice and law related to product-by-process claims has developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made. For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. Once the PTO establishes a *prima facie* case that the claimed product and prior art product are identical or not patentably distinct, the burden shifts to applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product.

**D. Statutory Basis for Rejection**
When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either 35 U.S.C. 102 or 35 U.S.C. 103 is eminently fair and acceptable. PTO is not equipped to make and then compare products. In re Brown, 459 F.2d 531, 173 USPQ 685 (CCPA 1972).

**Functional Limitations—MPEP 2114, 2173.05(g) and 2181**

A. Definition: an attempt to define something by what it does rather than by what it is (as evidenced by specific structure or material, e.g.)

B. Permitted—specifically authorized by paragraph 6 of 35 U.S.C. 112 in defining an element of a combination

C. Burden of Proof—Inherency

Where applicant claims subject matter in terms of a function, property or characteristic and the subject matter of the prior art appears to be the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 35 U.S.C. 102 / 103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” In re Best, 195 USPQ 430, 433 (CCPA 1977).

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (The Board reversed the examiner’s rejection because the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Once the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. “[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. 102, on ‘prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same.” The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Brown, 173 USPQ 685, 688 (CCPA 1972); In re Swinehart, 439 F.2d 210, 169 USPQ 226, 229 (CCPA 1971) (“[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.”); In re Fisher, 166 USPQ 18, 23 (CCPA 1970) (where claims contain new terminology, the PTO may require comparative evidence when there is reason to believe that the prior art anticipates or renders obvious the claimed subject matter). See also In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971)
(applicant failed to show that the prior art parachute did not inherently possess the claimed functional limitations of sequentially opening and gradually decelerating); In re Echerd, 176 USPQ 321 (CCPA 1973) (evidence showed that prior art material did not possess the claimed flexibility, wet strength, and latent adhesive characteristics).

See MPEP 2112–2112.02 for a general discussion of the requirements of rejections based on inherency. See MPEP 2183–2184 for a discussion of the burden of proof with regard to proving or disproving the equivalence of prior art elements with claimed means plus function limitations.

PREAMBLE—MPEP 2111.02

A. Definition: An introductory part of the claim which appears before a recitation of the steps in a process, the elements of a machine or manufacture, or the ingredients of a composition.

B. Significance is determined on basis of the facts in each case—In re Van Lint, 148 USPQ 285 (CCPA 1966)

C. Weight of Preamble

1. General Rule

The preamble is not given the effect of a limitation unless it breathes life and meaning into the claim. In order to limit the claim, the preamble must be “essential to point out the invention defined by the claim.” Kropa v. Robie, 88 USPQ 478, 481 (CCPA 1951) (discussed below). In claims directed to articles and apparatus, any phraseology in the preamble that limits the structure of that article or apparatus must be given weight. In re Stencel, 4 USPQ2d 1071 (Fed. Cir. 1987). On the other hand, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976); Kropa v. Robie, 88 USPQ 478, 481 (CCPA 1951).

In In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976), the claim preamble set forth “A process for preparing foods and drinks sweetened mildly, and protected against discoloration, Strecker’s reaction, and moisture absorption.” The body of the claim recited two steps directed to the formation of high purity maltose and a third step of adding the maltose to foods and drinks as a sweetener. The court held that the preamble was only directed to the purpose of the process, and the steps could stand alone and did not depend on the preamble for completeness.
In *Kropa v. Robie*, 88 USPQ 478, 481 (CCPA 1951), a preamble reciting “An abrasive article” was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court said that “it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an ‘abrasive article.’” *Id.* at 481. Therefore, the preamble served to further define the structure of the article produced.

2. **Composition claims**

When the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. *Kropa v. Robie*, 88 USPQ 478, 480–81 (CCPA 1951) (discussed above). See also *In re Duva*, 156 USPQ 90 (CCPA 1967) (preamble “As a composition for chemically depositing gold” given patentable weight); *In re Hack*, 114 USPQ 161 (CCPA 1957) (preamble “a brazing alloy” not given patentable weight).

3. **Intended use resulting in structural or manipulative difference**

The intended use set forth in the preamble may further limit the claim if it does more than merely state the purpose or intended use.

In apparatus, article, and composition claims, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See, e.g., *In re Casey*, 152 USPQ 235 (CCPA 1967) (the manner or method in which a machine is used is not germane to the issue of the patentability of the machine itself); *In re Wertheim*, 191 USPQ 90, 102 (CCPA 1976) (process limitations in the preamble may serve to distinguish the subject matter of apparatus claims from the prior art; in this case claims directed to apparatus “for carrying out the process in claim 6” were not held to be limited by the process); *In re Finsterwalder*, 168 USPQ 530 (CCPA 1971) (Appellant claimed apparatus “which may be used in any method of construction to which it is reasonably adaptable. Thus, the fact that appellant discloses the apparatus as advantageous in the ‘free cantilever’ method of construction will not save the claims if the apparatus defined thereby would have been obvious to a person of ordinary skill in the bridge-construction art intending to use it in a somewhat different construction method.” 168 USPQ at 534.).
In a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. In re Otto, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making the structure.).

D. Jepson Claims—37 CFR 1.75(e)

1. Elements set forth in preamble are part of the claimed combination—MPEP 608.01(m)


3. Preamble elements in Jepson-type claim are impliedly admitted to be old in the art—but only an implied admission—In re Ehrreich, 200 USPQ 504, 510 (CCPA 1979). Here none of art relied on by examiner showed combination in preamble. See also MPEP 2129.

Claims Containing Multiple Categories of Invention

A. Product-by-Process Claims—MPEP 2173.05(p)

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention. A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. In re Moeller, 117 F.2d 565, 48 USPQ 542 (CCPA 1941); In re Luck, 177 USPQ 523 (CCPA 1973); In re Steppan, 156 USPQ 143 (CCPA 1967); and In re Pilkington, 162 USPQ 145 (CCPA 1969). A claim to a device, apparatus, manufacture or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

B. Reference to Limitations in Another Claim—MPEP 2173.05(f)

A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph. For example, claims which read: “The product produced by the method of claim 1.” or “A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions . . . .” are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim. See also Ex parte Porter, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to “the nozzle of claim 7” in a method claim was held to comply with 35 U.S.C. 112, second paragraph. However, where the format of making reference to
limitations recited in another claim results in confusion, then a rejection would be proper under 35 U.S.C. 112, second paragraph.

C. **Product and Process in the Same Claim—MPEP 2173.05(p)**

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990)*, a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a “process” nor a “machine,” but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.