

EXHIBIT 16**Chapter 2100 Patentability**

2105	Patentable Subject Matter — Living Subject Matter	2126	Availability of a Document as a “Patent” for Purposes of Rejection Under 35 U.S.C. 102(a), (b), and (d)
2106	*>Patent< Subject Matter **>Eligibility<	2126.01	Date of Availability of a Patent As a Reference
2106.01	**>Computer-Related Nonstatutory Subject Matter<	2126.02	Scope of Reference's Disclosure Which Can Be Used to Reject Claims When the Reference Is a “Patent” but Not a “Publication”
2106.02	**>Mathematical Algorithms<	2127	Domestic and Foreign Patent Applications as Prior Art
2107	Guidelines for Examination of Applications for Compliance with the Utility Requirement	2128	“Printed Publications” as Prior Art
2107.01	General Principles Governing Utility Rejections	2128.01	Level of Public Accessibility Required
2107.02	Procedural Considerations Related to Rejections for Lack of Utility	2128.02	Date Publication Is Available as a Reference
2107.03	Special Considerations for Asserted Therapeutic or Pharmacological Utilities	2129	Admissions as Prior Art
2111	Claim Interpretation; Broadest Reasonable Interpretation	2131	Anticipation — Application of 35 U.S.C. 102(a), (b), and (e)
2111.01	Plain Meaning	2131.01	Multiple Reference 35 U.S.C. 102 Rejections
2111.02	Effect of Preamble	2131.02	Genus-Species Situations
2111.03	Transitional Phrases	2131.03	Anticipation of Ranges
2111.04	“Adapted to,” “Adapted for,” “Wherein,” and “Whereby” Clauses	2131.04	Secondary Considerations
2112	Requirements of Rejection Based on Inherency; Burden of Proof	2131.05	Nonanalogous >or Disparaging Prior< Art
2112.01	Composition, Product, and Apparatus Claims	2132	35 U.S.C. 102(a)
2112.02	Process Claims	2132.01	Publications as 35 U.S.C. 102(a) Prior Art
2113	Product-by-Process Claims	2133	35 U.S.C. 102(b)
2114	Apparatus and Article Claims — Functional Language	2133.01	Rejections of Continuation-In-Part (CIP) Applications
2115	Material or Article Worked Upon by Apparatus	2133.02	Rejections Based on Publications and Patents
2116	Material Manipulated in Process	2133.03	Rejections Based on “Public Use” or “On Sale”
2116.01	Novel, Unobvious Starting Material or End Product	2133.03(a)	“Public Use”
2121	Prior Art; General Level of Operability Required to Make a Prima Facie Case	2133.03(b)	“On Sale”
2121.01	Use of Prior Art in Rejections Where Operability Is in Question	2133.03(c)	The “Invention”
2121.02	Compounds and Compositions — What Constitutes Enabling Prior Art	2133.03(d)	“In This Country”
2121.03	Plant Genetics — What Constitutes Enabling Prior Art	2133.03(e)	Permitted Activity; Experimental Use
2121.04	Apparatus and Articles — What Constitutes Enabling Prior Art	2133.03(e)(1)	Commercial Exploitation
2122	Discussion of Utility in the Prior Art	2133.03(e)(2)	Intent
2123	Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments	2133.03(e)(3)	“Completeness” of the Invention
2124	Exception to the Rule That the Critical Reference Date Must Precede the Filing Date	2133.03(e)(4)	Factors Indicative of an Experimental Purpose
2125	Drawings as Prior Art	2133.03(e)(5)	Experimentation and Degree of Supervision and Control
		2133.03(e)(6)	Permitted Experimental Activity and Testing
		2133.03(e)(7)	Activity of an Independent Third Party Inventor
		2134	35 U.S.C. 102(c)
		2135	35 U.S.C. 102(d)
		2135.01	The Four Requirements of 35 U.S.C. 102(d)
		2136	35 U.S.C. 102(e)
		2136.01	Status of U.S. Patent as a Reference Before and After Issuance
		2136.02	Content of the Prior Art Available Against the Claims
		2136.03	Critical Reference Date

2173.05(d)

MANUAL OF PATENT EXAMINING PROCEDURE

In re Fredericksen 213 F.2d 547, 102 USPQ 35 (CCPA 1954). 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.

2173.05(d) Exemplary Claim Language (“for example,” “such as”) [R-1]

Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences >may< lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

(A) “R is halogen, for example, chlorine”;

(B) “material such as rock wool or asbestos” *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1949);

(C) “lighter hydrocarbons, such, for example, as the vapors or gas produced” *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949); and

(D) “normal operating conditions such as while in the container of a proportioner” *Ex parte Steigerwald*, 131 USPQ 74 (Bd. App. 1961).

>The above examples of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. See MPEP § 2173.02 for guidance regarding when it is appropriate to make a rejection under 35 U.S.C. 112, second paragraph.<

2173.05(e) Lack of Antecedent Basis [R-5]

A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to “said lever” or “the lever,” where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of “said lever” in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended. A claim which refers to “said aluminum lever,” but recites only “a lever” earlier in the claim, is indefinite because it is uncertain as to the lever to which reference is made. Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. >*Energizer Holdings Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006)(holding that “anode gel” provided by implication the antecedent basis for “zinc anode”);< *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) (“controlled stream of fluid” provided reasonable antecedent basis for “the controlled fluid”). Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. See *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir. 2001) (holding that recitation of “an ellipse” provided antecedent basis for “an ellipse having a major diameter” because “[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter”).

EXAMINER SHOULD SUGGEST CORRECTIONS TO ANTECEDENT PROBLEMS

Antecedent problems in the claims are typically drafting oversights that are easily corrected once they are brought to the attention of applicant. The examiner’s task of making sure the claim language complies with the requirements of the statute should be carried out in a positive and constructive way, so that minor problems can be identified and easily