# **Chapter 2100 Patentability**

2105	Patentable Subject Matter — Living Subject Matter
2106	Patentable Subject Matter - Computer-Related Inventions
2106.01	Computer Programming and 35 U.S.C. 112, First Paragraph
2106.02	Disclosure in Computer Programming Cases
2107	General Principles Governing Utility
	Rejections
2107.01	Procedural Considerations Related to Rejections for Lack of Utility
2107.02	
	Therapeutic or Pharmacological Utilities
2111	Claim Interpretation; Broadest Reasonable
	Interpretation
2111.01	-
2111.02	_
2111.03	-
2112	Requirements of Rejection Based on Inherency;
	Burden of Proof
2112.01	Composition, Product, and Apparatus Claims
2112.02	Process Claims
2113	Product-by-Process Claims
2114	Apparatus and Article Claims - Functional
	Language
2115	Material or Article Worked Upon by
	Apparatus
2116	Material Manipulated in Process
2116.01	Novel, Unobvious Starting Material or End
	Product
2121	Prior Art; General Level of Operability
	Required to Make a Prima Facie Case
2121.01	Use of Prior Art in Rejections Where Operability Is in Question
2121.02	
	Constitutes Enabling Prior Art
2121.03	Plant Genetics - What Constitutes Enabling
	Prior Art
2121.04	Apparatus and Articles - What Constitutes Enabling Prior Art
2122	Discussion of Utility in the Prior Art
2122	Rejection Over Prior Art's Broad Disclosure
4143	Instead of Preferred Embodiments
2124	Exception to the Rule That the Critical
	Reference Date Must Precede the Filing Date
2125	Drawings as Prior Art
2126	Availability of a Document as a "Patent" for
	Purposes of Rejection Under 35 U.S.C. 102(a),
	(b), and (d)

DOCKET

LARM

Α

	_
2126.01	Date of Availability of a Patent As a Reference
2126.02	Scope of Reference's Disclosure Which Can
	Be Used to Reject Claims When the Reference
	Is a "Patent" but Not a "Publication"
2127 De	omestic and Foreign Patent Applications as
Pı	ior Art
2128 "H	Printed Publications" as Prior Art
2128.01	Level of Public Accessibility Required
2128.02	Date Publication Is Available as a Reference
	dmissions as Prior Art
	nticipation - Application of 35 U.S.C. 102(a),
	), and (e)
2131.01	Multiple Reference 35 U.S.C. 102 Rejections
2131.02	Genus-Species Situations
2131.03	Anticipation of Ranges
2131.04	Secondary Considerations
2131.05	Nonanalogous Art
	5 U.S.C. 102(a)
2132.01	Publications as 35 U.S.C. 102(a) Prior Art
	5 U.S.C. 102(b)
2133.01	Rejections of Continuation-In-Part (CIP)
	Applications
2133.02	Rejections Based on Publications and Patents
2133.03	Rejections Based on "Public Use" or "On Sale"
. ,	"Public Use"
2133.03(b)	
2133.03(c)	
	"In This Country"
	Permitted Activity; Experimental Use
	(1) Commercial Exploitation
2133.03(e)	
	(3) "Completeness" of the Invention
2133.03(e)	· · · ·
0102 02(-)	Purpose (5) Europrimentation and Decrees of Supervision
2155.03(e)	(5) Experimentation and Degree of Supervision and Control
2133 03(a)	(6) Permitted Experimental Activity and
2133.03(0)	Testing
2133.03(e)	(7) Activity of an Independent Third Party
	Inventor
2134 35	5 U.S.C. 102(c)
2135 35	5 U.S.C. 102(d)
2135.01	The Four Requirements of 35 U.S.C. 102(d)
2136 35	5 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
2136.04	Different Inventive Entity; Meaning of "By Another"

2136.05	8 3
	102(e)
2137	35 U.S.C. 102(f)
2137.01	E E
2137.02	2 Applicability of 35 U.S.C. 103(c)
2138	35 U.S.C. 102(g)
2138.01	Interference Practice
2138.02	"The Invention Was Made in This Country"
2138.03	"By Another Who Has Not Abandoned,
	Suppressed, or Concealed It"
2138.04	"Conception"
2138.05	"Reduction to Practice"
2138.06	"Reasonable Diligence"
2141	35 U.S.C. 103; The Graham Factual Inquiries
2141.01	Scope and Content of the Prior Art
2141.01	(a) Analogous and Nonanalogous Art
2141.02	2 Differences Between Prior Art and Claimed
	Invention
2141.03	Level of Ordinary Skill in the Art
2142	Legal Concept of Prima Facie Obviousness
2143	Basic Requirements of a Prima Facie Case of
	Obviousness
2143.01	Suggestion or Motivation to Modify the
	References
2143.02	Reasonable Expectation of Success Is Required
2143.03	All Claim Limitations Must Be Taught or
	Suggested
2144	Sources of Rationale Supporting a Rejection
	Under 35 U.S.C. 103
2144.01	<b>F</b>
2144.02	· · · · · · · · · · · · · · · · · · ·
2144.03	8
	"Well Known" Prior Art
2144.04	6 11 6
	Rationale
2144.05	6
2144.06	0 1
0144.05	Purpose
2144.07	8
2144.00	Purpose
2144.08	B Obviousness of Species When Prior Art Teaches Genus
2144.00	
2144.09	5
2145	Compounds (Homologs, Analogues, Isomers) Consideration of Applicant's Rebuttal
2143	Arguments
2146	35 U.S.C. 103(c)
2140 2161	Three Separate Requirements for Specification
2101	Under 35 U.S.C. 112, First Paragraph
2162	Policy Underlying 35 U.S.C. 112, First
<b>#10#</b>	Paragraph

2163 The Written Description Requirement		
2163.01	Support for the Claimed Subject Matter in Disclosure	
2163.02	Standard for Determining Compliance With the Written Description Requirement	
2163.03	Typical Circumstances Where Adequate Written Description Issue Arises	
2163.04	Burden on the Examiner With Regard to the Written Description Requirement	
2163.05	Changes to the Scope of Claims	
2163.06	Relationship of Written Description	
	Requirement to New Matter	
2163.07	Amendments to Application Which Are	
	Supported in the Original Description	
2163.07(a)	Inherent Function, Theory, or Advantage	
2163.07(b)	Incorporation by Reference	
2164 Th	e Enablement Requirement	
2164.01	Test of Enablement	
2164.01(a)	Undue Experimentation Factors	
2164.01(b)	How to Make the Claimed Invention	
2164.01(c)	How to Use the Claimed Invention	
2164.02	Working Example	
2164.03	Relationship of Predictability of the Art and the	
	Enablement Requirement	
2164.04	Burden on the Examiner Under the Enablement Requirement	
2164.05	Determination of Enablement Based on Evidence As a Whole	
2164.05(a)	Specification Must Be Enabling as of the Filing Date	
2164.05(b)	Specification Must Be Enabling to Persons Skilled in the Art	
2164.06	Quantity of Experimentation	
2164.06(a)	Examples of Enablement Issues-Missing Information	
2164.06(b)	Examples of Enablement Issues - Chemical Cases	
2164.07	Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101	
2164.08	Enablement Commensurate in Scope With the Claims	
2164.08(a)	Single Means Claim	
2164.08(b)	Inoperative Subject Matter	
2164.08(c)	Critical Feature Not Claimed	
2165 Th	e Best Mode Requirement	
2165.01	Considerations Relevant to Best Mode	
2165.02	Best Mode Requirement Compared to Enablement Requirement	
2165.03	Requirements for Rejection for Lack of Best Mode	

2165.04 Examples of Evidence of Concealment

**DOCKET A L A R M** Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

	Fwo Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph
2172 \$	Subject Matter Which Applicants Regard as
[	Their Invention
2172.01	Unclaimed Essential Matter
2173	Claims Must Particularly Point Out and
J	Distinctly Claim the Invention
2173.01	Claim Terminology
2173.02	Clarity and Precision
2173.03	Inconsistency Between Claim and
	Specification Disclosure or Prior Art
2173.04	Breadth Is Not Indefiniteness
2173.05	Specific Topics Related to Issues Under 35 U.S.C. 112, Second Paragraph
2173.05(a	a) New Terminology
2173.05(t	b) Relative Terminology
2173.05(c	c) Numerical Ranges and Amounts Limitations
2173.05(0	
2173.05(e	e) Lack of Antecedent Basis
2173.05(f	) Reference to Limitations in Another Claim
2173.05(g	g) Functional Limitations
2173.05(ł	n) Alternative Limitations
2173.05(i	) Negative Limitations
2173.05(j	) Old Combination
2173.05(k	x) Aggregation
2173.05(r	n) Prolix
2173.05(r	n) Multiplicity
2173.05(0	b) Double Inclusion
2173.05(p	b) Claim Directed to Product-By- Process or
	Product and Process
2173.05(c	) "Use" Claims
2173.05(r	) Omnibus Claim
2173.05(s	) Reference to Figures or Tables
2173.05(t	-
2173.05(u	1) Trademarks or Trade Names in a Claim
	) Mere Function of Machine
2173.06	Prior Art Rejection of Claim Rejected as
	Indefinite
2174 I	Relationship Between the Requirements of the
]	First and Second Paragraphs of 35 U.S.C. 112
2181 I	dentifying a 35 U.S.C. 112, Sixth Paragraph
	Limitation
2182	Scope of the Search and Identification of the
	Prior Art
<b>2183</b> I	Making a Prima Facie Case of Equivalence
	Determining Whether an Applicant Has Met
	he Burden of Proving Nonequivalence After a
	Prima Facie Case Is Made
2185 1	Related Issues Under 35 U.S.C. 112 First or

- 2185 Related Issues Under 35 U.S.C. 112, First or Second Paragraphs
- 2186 Relationship to the Doctrine of Equivalents

DOCKF

#### 2105 Patentable Subject Matter — Living Subject Matter [R-1]

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision, the Office has issued these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the *Chakrabarty* opinion:

1. "Guided by these canons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean `the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery."

2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."

3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' 5 Writings of Thomas Jefferson, at 75-76. See *Graham* v. John Deere Co., 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)."

4. "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."

5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity."

6. "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity 'having a distinctive name, character [and] use.' "

7. "Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here,

35 U.S.C. 102(a) or (b).); *In re Talbott*, 443 F.2d 1397, 170 USPQ 281 (CCPA 1971) (Applicant cannot avoid a 35 U.S.C. 102(d) rejection by exercising an option to keep the subject matter of a German Gebrauchsmuster (petty patent) in secrecy until time of U.S. filing.).

#### IV. THE SAME INVENTION MUST BE INVOLVED

#### "Same Invention" Means That the Application Claims Could Hsve Been Presented in the Foreign Patent

Under 35 U.S.C. 102(d), the "invention... patented" in the foreign country must be the same as the invention sought to be patented in the U.S. When the foreign patent contains the same claims as the U.S. application, there is no question that "the invention was first patented... in a foreign country." In re Kathawala, 9 F.3d 942, 945, 28 USPQ2d 1785, 1787 (Fed. Cir. 1993). However, the claims need not be identical or even within the same statutory class. If applicant is granted a foreign patent which fully discloses the invention and which gives applicant a number of different claiming options in the U.S., the reference in 35 U.S.C. 102(d) to "`invention... patented' necessarily includes all the disclosed aspects of the invention. Thus, the section 102(d) bar applies regardless whether the foreign patent contains claims to less than all aspects of the invention." 9 F.3d at 946, 28 USPQ2d at 1788. In essence, a 35 U.S.C. 102(d) rejection applies if applicant's foreign application supports the subject matter of the U.S. claims. In re Kathawala, 9 F.3d 942, 28 USPQ2d 1785 (Fed. Cir. 1993) (Applicant was granted a Spanish patent claiming a method of making a composition. The patent disclosed compounds, methods of use and processes of making the compounds. After the Spanish patent was granted, the applicant filed a U.S. application with claims directed to the compound but not the process of making it. The Federal Circuit held that it did not matter that the claims in the U.S. application were directed to the composition instead of the process because the foreign specification would have supported claims to the composition. It was immaterial that the formulations were unpatentable pharmaceutical compositions in Spain.).

#### 2136 35 U.S.C. 102(e)

DOCKE.

35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless-

\*\*\*\*

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4)of section 371(c) of this title before the invention thereof by the applicant for patent. \*\*\*\*

# ONLY U.S. PATENTS AND SIRS ARE ELIGIBLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

The reference must be a U.S. patent to be eligible for use in a 35 U.S.C. 102(e) rejection. *Ex parte Smolka*, 207 USPQ 232 (Bd. App. 1980) (A foreign patent document with priority back to an abandoned U.S. application cannot be the basis for a 35 U.S.C. 102(e) rejection. The foreign document cannot be prior art until it is patented or published.). Statutory Invention Registrations (SIRS) can also be used in 35 U.S.C. 102(e) rejections as of their filing dates.

# DEFENSIVE PUBLICATIONS ARE NOT PRIOR ART AS OF THEIR FILING DATE

A defensive publication is not a patent, it is a publication. Therefore, it is prior art only as of its publication date. Ex parte Osmond, 191 USPQ 334 (Bd. App. 1973) (Examiner rejected the claims over Defensive Publication T-858,018 issued by the PTO to Jacobson. The examiner made a 35 U.S.C. 102(a) rejection contending that a defensive publication can be used as a reference under 35 U.S.C. 102(a) as of its filing date. This position was authorized at that time by the MPEP and a Commissioner's Notice establishing the Defensive Publication Program. The Board found that in order for a 35 U.S.C. 102(a) rejection to apply, the reference must be of public knowledge and a Defensive Publication is not public knowledge at the time of its filing. Thus, the Board reversed the rejection. The Board also found that 35 U.S.C. 102(e) could not be used as a basis for rejection because the use of Defensive Publications as of their filing dates was not supported by section 102(e).) See MPEP § 711.06(a) for more information on Defensive Publications as references.

#### 2136.01 Status of U.S. Patent as a Reference Before and After Issuance

#### WHEN THERE IS NO COMMON ASSIGNEE OR INVENTOR, AN APPLICATION MUST ISSUE AS A PATENT BEFORE IT IS AVAILABLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

Generally, a U.S. patent must issue before it can be used as a reference in a 35 U.S.C. 102(e) rejection. *Ex parte Smolka*, 207 USPQ 232 (Bd. App. 1980) (An application to Smolka and Schwuger was rejected over 35 U.S.C. 102(e) based on a pending U.S. application to Corkill whose filing date antedated the Smolka *et al.* application. A German application corresponding to the Corkill application had been published, but did not antedate the effective filing date of the Smolka *et al.* application. The Board reversed the

rejection holding that a U.S. patent had to be issued to Corkill before it could become available as prior art under 35 U.S.C. 102(e). There was no common assignee nor any common inventor between the two applications.).

#### WHEN THERE IS A COMMON ASSIGNEE OR INVENTOR, A PROVISIONAL 35 U.S.C. 102(e) REJECTION OVER AN EARLIER FILED APPLICA-TION CAN BE MADE

Based on the assumption that an application will ripen into a U.S. patent, it is permissible to provisionally reject a later application over an earlier application under 35 U.S.C. 102(e). In re Irish, 433 F.2d 1342, 167 USPQ 764 (CCPA 1970). Such a provisional rejection "serves to put applicant on notice at the earliest possible time of the possible prior art relationship between copending applications" and gives applicant the fullest opportunity to overcome the rejection by amendment or submission of evidence. In addition, since both applications are pending and usually have the same assignee, more options are available to applicant for overcoming the provisional rejection than if the other application were already issued. Ex parte Bartfeld, 16 USPQ2d 1714 (Bd. Pat. App. & Int. 1990) aff'd on other grounds, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). Note that provisional rejections over 35 U.S.C. 102(e) are only authorized when there is a common inventor or assignee, otherwise the copending application must remain confidential. MPEP § 706.02(f) and § 706.02(k) discuss the procedures to be used in provisional rejections over 35 U.S.C. 102(e) and 103.

#### 2136.02 Content of the Prior Art Available Against the Claims

#### A 35 U.S.C. 102(e) REJECTION MAY RELY ON ANY PART OF THE PATENT DISCLOSURE

Under 35 U.S.C. 102(e), the entire disclosure of a U.S. patent having an earlier filing date can be relied on to reject the claims. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 983, 10 USPQ2d 1338, 1342 (Fed. Cir. 1989).

#### U.S. PATENT REFERENCE MUST ITSELF CON-TAIN THE SUBJECT MATTER RELIED ON IN THE REJECTION

When a U.S. patent is used to reject claims under 35 U.S.C. 102(e), the disclosure relied on in the rejection must be present in the issued patent. It is the filing date of the U.S. patent being relied on as the critical reference date and subject matter not included in the patent itself can only be used when that subject matter becomes public. Portions of the patent application which were canceled are not part of the patent and thus cannot be relied on in a 35 U.S.C.

DOCKET

102(e) rejection over the issued patent. *Ex Parte Stalego*, 154 USPQ 52 (Bd. App. 1966). Likewise, subject matter which is disclosed in a parent application, but not included in the child continuation-in-part (CIP) cannot be relied on in a 35 U.S.C. 102(e) rejection over the issued CIP. *In re Lund*, 376 F.2d 982, 153 USPQ 625 (CCPA 1967) (The examiner made a 35 U.S.C. 102(e) rejection over an issued U.S. patent which was a continuation-in-part (CIP). The parent application of the U.S. patent reference contained an example II which was not carried over to the CIP. The court held that the subject matter embodied in the canceled example II could not be relied on as of either parent or child filing date. Thus, the use of example II subject matter to reject the claims under 35 U.S.C. 102(e) was improper.).

#### THE SUPREME COURT HAS AUTHORIZED 35 U.S.C. 103 REJECTIONS BASED ON 35 U.S.C. 102(e)

U.S. patents may be used as of their filing dates to show that the claimed subject matter is anticipated or obvious. Obviousness can be shown by combining other prior art with the U.S. patent reference in a 35 U.S.C. 103 rejection. *Hazeltine Research v. Brenner*, 382 U.S. 252, 147 USPQ 429 (1965).

#### **2136.03** Critical Reference Date [R-1]

#### I. FOREIGN PRIORITY DATE

#### Reference's Foreign Priority Date Under 35 U.S.C. 119(a)-(d) Cannot Be Used as the 35 U.S.C. 102(e) Reference Date

A U.S. patent reference is effective prior art as of its U.S. filing date. 35 U.S.C. 119(a)-(d) does not modify section 102(e) which is explicitly limited to patent references "filed in the United States before the invention thereof by the applicant" (emphasis added). Therefore, the foreign priority date of the reference under 35 U.S.C. 119(a)-(d) cannot be used to antedate the application filing date. In contrast, applicant may be able to overcome the 35 U.S.C. 102(e) rejection by proving he or she is entitled to his or her own 35 U.S.C. 119 priority date which is earlier than the reference's U.S. filing date. In re Hilmer, 359 F.2d 859, 149 USPQ 480 (CCPA 1966) (Hilmer I) (Applicant filed an application with a right of priority to a German application. The examiner rejected the claims over a U.S. patent to Habicht based on its Swiss priority date. The U.S. filing date of Habicht was later than the application's German priority date. The court held that the reference's Swiss priority date could not be relied on in a 35 U.S.C. 102(e) rejection. Because the U.S. filing date of Habicht was later than the earli est effective filing date (German priority date) of the application, the rejection was reversed.). See MPEP

# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

#### E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.