Table of Contents

I. Introduction 5

A. The patent term 5

1. Patent term adjustment 6

II. Patent Claims 6

A. Introduction 6

1. Definition of a Patent Claim 6

B. Claim Definiteness Requirement (35 U.S.C. §112, ¶2) 7

1. Own Lexicographer Rule 7

2. Definiteness Standards 7

3. Antecedent Basis 9

C. Anatomy of a Patent Claim 10

2. Preamble 10

3. Transition 10

4. Body 11

D. Independent and Dependent Claims (35 U.S.C. §112 ¶3-4) 12

E. Specialized Claiming Formats 12

1. Means-plus-function claim elements (35 U.S.C. §112, ¶ 6) 12

2. Product-by-process claims 14

3. *Jepson* claims 15

III. Potentially Patentable Subject Matter (35 U.S.C. §101) 15

A. Introduction 15

1. The General Nature of §101 15

2. The Statutory Categories of §101 15

3. Claiming the Inventive Concept within Different Statutory Categories 16

B. Section 101 Processes 17

1. Basic Principles 17

2. Computer-Implemented Processes 17

3. Business Methods 17

C. Section 101 Machines 19

D. Section 101 Compositions of Matter 19

1. Structure versus Properties 19

2. Purified Forms of Natural Products 19

3. Life Forms 20

E. Section 101 Manufactures 20

F. Nonpatentable Subject Matter 20

IV. The Utility Requirement (35 U.S.C. §101) 20

A. Introduction 20

B. Beneficial Utility 21

C. Practical Utility 22

D. Supreme Court view: *Brenner v. Manson (1966)* 23

E. Federal Circuit View 23

1. *In re Brana*: Chemical Compounds 23

2. *In re Fisher*: Genetic Inventions 24

F. Inoperability 25

1. Examples of Inoperable Inventions 26

2. Inoperable Species within a Genus 26

G. Immoral or Deceptive Inventions 27

V. Disclosure Requirements 27

A. Introduction 27

1. Statutory Framework 27

2. Timing of Disclosure Compliance 28

3. Anatomy of §112 28

B. The Enablement Requirement 29

1. Undue Experimentation 29

2. Speculation and Prophesy 30

3. *Wands* Factor: Predictable v. Unpredictable Inventions 31

4. *Wands* Factor: Scope of the Claims 31

5. *Wands* Factor: Working Examples 32

6. Nascent and After-Arising Technology 32

C. The Best Mode Requirement 32

D. The Written Description of the Invention Requirement 33

1. Timing Mechanism 33

2. How an Application Conveys Possession of an Invention 34

3. Distinguishing Written Description from Enablement 34

4. Typical Fact Scenarios Invoking Written Description Scrutiny 35

VI. Novelty and Loss of Right (35 U.S.C. §102) 35

A. Section 102 Terminology and General Principles 35

1. Burden of Proof 35

2. The Meaning of Anticipation 35

3. Distinguishing Novelty from Loss of Right 36

4. What Is a Printed Publication? 36

5. The Strict Identity Rule of Anticipation 37

6. The Special Case of Species/Genus Anticipation 38

7. Geographic Distinctions in §102 38

8. Who Is the Actor? 38

9. Anticipation by Inherency 39

10. Enablement Standard for Anticipatory Prior Art 40

B. Known or Used within 35 U.S.C. §102(a) 41

C. The Statutory Bars of 35 U.S.C. §102(b) 42

1. Introduction 42

2. Grace Period 42

3. §102(b) Public Use 43

4. §102(b) On Sale Bar 44

5. Experimental Use Negation of the §102(b) Bars 46

D. Abandonment under 35 U.S.C. §102(c) 46

E. Foreign Patenting Bar of 35 U.S.C. §102(d) 46

F. Description in another’s Earlier-Filed Patent or Published Patent Application under 35 U.S.C. §102(e) 46

G. Prior Invention under 35 U.S.C. §102(g) 47

1. Interference Proceedings under §102(g)(1) 47

2. Anticipation under §102(g)(2) 48

3. Applying the Priority Rules of §102(g) 49

H. Antedating (or “Swearing Behind”) Prior Art (Rule 131) 50

VII. The Nonobviousness Requirement (35 U.S.C. §103) 51

A. Introduction 51

B. The *Graham v. John Deere* Framework for Analyzing Nonobviousness 51

1. *Graham*’s Analytical Framework for a §103 Analysis 51

C. *Graham* Factor: Level of Ordinary Skill in the Art 52

D. *Graham* Factor: Scope and Content of the Prior Art 52

1. Sources of Prior Art 52

2. §102/103 Overlap 53

3. Analogous Act 53

E. *Graham* Factor: Differences between Claimed Invention and Prior Art 54

F. *Graham* Factor: Secondary Considerations 54

1. The Weight to be Accorded Secondary Considerations Evidence 55

2. The Nexus Requirement for Evidence of Commercial Success 55

G. Combining the Disclosures of Prior Art References to Establish Obviousness 56

1. Teaching, Suggestion, or Motivation to Combine 56

2. KSR v. Teleflex: Combinations, Predictability, and “Common Sense” 56

3. Teaching Away 57

4. “Obvious to Try” 57

VIII. Patent Infringement 57

A. Introduction 57

1. Statutory Framework 57

2. Two-Step Analysis for Patent Infringement 60

B. Step One: Patent Claim Interpretation 60

1. The Central Role of Claims 60

2. Judge or Jury as Interpreter? The *Markman* Revolution 60

3. Evidentiary Sources for Claim Interpretation 61

4. The *Phillips* Debate: “Contextualist” versus “Literalist” Approaches 61

5. *Markman* Hearings 62

6. Claim Interpretation Canons 62

C. Step Two: Comparing the Properly Interpreted Claims 63

1. Literal infringement 63

2. Infringement under the Doctrine of Equivalents 63

D. Legal Limitations on the Doctrine of Equivalents 65

1. Overview 65

2. Prosecution history estoppel (PHE) 66

E. Inducing Infringement under §271(b) 69

1. Direct infringement 69

2. Requisite intent 69

F. Contributory Infringement under §271(c) 70

1. Permissible “repair” v. infringing “reconstruction” (i.e., a new making) 70

G. Component Imports/Exports – territorial issues 71

1. Exports 71

2. Imports 71

IX. Defenses to Patent Infringement 72

A. Laches 72

B. Inequitable Conduct 73

1. Materiality 73

2. Intent to deceive 74

*3.* Intent to deceive after *Therasense* 75

X. Remedies 75

A. Injunctions – 35 U.S.C. §283 75

1. Permanent injunctions 75

2. Preliminary injunctions 76

B. Damages for Past Infringements 79

1. Compensatory Damages 80

2. Enhanced Damages and Willful Infringement 84

# Introduction

## The patent term

The U.S. law on the term of patents underwent a major change effective June 8, 1995. This change harmonized U.S. law on patent terms with that of other countries, and also dramatically reduced incentives to obtain *submarine patents* (the colloquial term for patents that issue after secretly pending in the USPTO for many years.

|  |  |
| --- | --- |
| Year of patent | Validity (years) |
| 1790 – 1835 | 14 |
| 1836 – 1860  | 14 plus a potential 7 year extension |
| 1861 – 1994 | 17  |
| 1995 - *current* | Filed on or after June 8, 1995 | The patent expires 20 years after the earliest effect U.S. filing date |
| Patents in force on June 8, 1995 or pending patent applications | The patent expires the later of the two: 20 years from filing or 17 years from issuance. |

Note: the word “term” does not include the duration the patent was in the application process and although the patent expires 20 from the earliest effective filing date, the “term” is 20 years minus the time spent in the application process.

Note: a design patent is valid for 14 years from the date of issue.

### Patent term adjustment

Due to the potential pendency delays caused by the USPTO and not the applicants, the 1994 Uruguay Round Agreements Act added to the patent laws the concept of *patent term adjustment*. This is codified as 35 U.S.C. §154(b).

This provides that if the issue of a patent is delayed by certain failures of the USPTO to take time action during the application’s pendency, the term of the patent will be extended by one day for each day of such delay. Typically, the USPTO is given 3 years to complete the patent.

#### Provisional applications

#### Eighteen month publication of applications

# Patent Claims

## Introduction

### Definition of a Patent Claim

A patent claim is a single-sentence definition of the scope of the patent owner’s property right – that is, her right to exclude others from making, using, selling, offering to sell, or importing the invention, in this country, during the term of the patent.

A patent claim *does not* describe the invention; this is the role of the written description and drawings, parts of the patent document that are distinct from the claims.

Patent applications are typically filed with an array of claims of varying scope, ranging from very broad to very narrow.

## Claim Definiteness Requirement (35 U.S.C. §112, ¶2)

The specification shall conclude with one or more ***claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention***.

### Own Lexicographer Rule

35 U.S.C. §112, ¶2 of the Patent Act requires that each patent conclude with one or more claims that particularly point out and distinctly claim the subject matter which the applicant regards as his invention – the ***definiteness*** requirement.

Patent law permits the applicant to create new words with which to claim her novel technology. The applicant may make up and define terms to be used in her claims. In this manner, the written description portion of a patent operates as a sort of dictionary for terms found in the claims.

However, if the applicant chooses not to supply definitions for the terms in her claims, either expressly or implicitly, such terms will be given their ordinary and customary meaning to persons of ordinary skill in the art of the invention.

### Definiteness Standards

The Patent Act requires that claims “particularly point out and distinctly claims the subject matter which the applicant regards as his invention.” This is so because indefinite claims do not give clear warning about the patentee’s property rights.

In order to determine if the claim language is sufficiently “particular” and “distinct” to satisfy the Patent Act, the proper vantage point is that of the hypothetical ***person having ordinary skill in the art (PHOSITA)*** – e.g., scientist, engineer, technician, or other worker.

* *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*
	+ The patent in suit was directed to a portable folding wheelchair for children that could easily be installed on and removed from the seat of an automobile. The nature of the invention was such that the dimensions of the chair would need to be altered for a particular make of car.
	+ The claim recited “wherein said front leg portion is *so dimensioned* as to be insertable through the space between the doorframe of an automobile and one of the seats thereof.” The accused infringer alleged that this variability in dimensions rendered the claim indefinite under 35 U.S.C. §112, ¶2.
	+ The Federal Circuit disagreed and held that it was irrelevant that a particular chair, once constructed, might fit in some cars and not others. The phrase “so dimensioned” was “as accurate as the subject matter permits.” Patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.
	+ So long as the PHOSITA could make and use the invention without undue experimentation, the disclosure was enabling, and so long as the PHOSITA could reasonably determine if a particular chair infringed the claim, the claims were sufficiently definite.

The use of adjectives such as “substantially” or “about” to qualify as numerical or structural limitations in patent claims does not necessarily render the claims indefinite under 35 U.S.C. §112, ¶2.

#### Definite defined by field

The standard to use in drafting is to ask whether an expert witness could convincingly testify that the allegedly vague language in the claim means something definite to people in the field.

The principle dictates that the same language might be indefinite in a claim pertaining to one technology, but not indefinite in a claim arising from a different field.

#### Definiteness and means-plus-function claims

Means-plus-function claims must find adequate support in the written description portion of the specification.

Claim definiteness is to be determined from the perspective of one skilled in the art; material in the written description may thus be supplemented by general knowledge in the field for purposes of determining whether a means-plus-function claim is definite. However, information in a reference cited in the written description could not be incorporated by reference to establish definiteness.

* *Standard Oil Co. v. American Cyanamid Co.*
	+ The patent infringement action involved a catalytic process used primarily to manufacture acrylamide. The claim used the term “partially soluble,” but it was not defined in the patent, nor was a standard definition offered by the patentee. However, the term “slight soluble” did appear to have an established meaning at the relevant time.
	+ The inventor was aware of the meaning of “slightly soluble,” having used it in the specifications, and conceding that she was “skilled in the art” of chemistry, nevertheless elected to use another term, i.e., partially soluble when she stated the claim.
	+ Because “partially soluble” was not defined in the specification and no standard definition existed at the time, there is no realistic way that those skilled in the art could utilize the process as claimed in the patent.

This is one example of a situation that often arises during prosecution. The Patent office strictly enforces its rule that all phrases used in claims “must find clear support or antecedent basis in the description so that the meaning of the claims may be ascertainable by reference to the description.”

#### No antecedent basis, but not “insolubly ambiguous”

In recent cases, the Federal Circuit has held that a claim is indefinite only if it is “insolubly ambiguous,” and that a claim is not “insolubly ambiguous” if it can be construed, even with difficulty, in light of the specification and the perspective of one skilled in the relevant art.

The requirement of antecedent basis is a rule of patent drafting, administered during patent examination. The MPEP states that “obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite."

* *Enzo Biochem, Inc. v. Applera Corp.*
	+ The patentee’s claims covered a technique for detecting the presence of a target nucleotide sequence of interest. The specific claim wording is this: the linkage group must bind the probe to the signal while “not interfering substantially” with hybridization and/or detection.
	+ The court held that the claims were not indefinite. “Because the intrinsic evidence here provides a general guideline and examples sufficient to enable a person of ordinary skill in the art to deter the scope of the claims, the claims are not indefinite even though the construction of the term not interfering substantially defines the term without reference to a precise numerical measurement.”

#### Functional language in claims

Functional language speaks of what a device does, rather than what it is. Terms such as “a clamp,” “a screw,” or “a latch” describe a structural feature of an invention, i.e., what that feature is. But a phrase such as “holding device,” or “means of attaching” describe this same feature in terms of what it does. And these latter phrases are broader than the others; they include a nail, a Velcro closure, and anyway of attaching something to something else.

### Antecedent Basis

The first time a particular element is introduced in a patent claim, it should be preceded or introduced by the indefinite article “a.” Thereafter, each time the claims drafter intends to refer back to that same previously introduced element, it is referred to as “said” element or “the” element.

Example:

1. A foam football comprising
	1. A body having a longitudinal axis and an external surface;
	2. ***Said external surface*** comprising a plurality of grooves aligned with said longitudinal axis;
	3. Wherein ***each of said grooves*** has a minimum depth of about 0.5 inches.

Each time the terms “football,” body,” “longitudinal axis,” “external surface,” and “groves” are introduced, they are expressed as “a ….” Thereafter, these elements are referred to as “said…,” to indicate that the claims drafter is referring to the same element.

## Anatomy of a Patent Claim

Every patent claim has three parts: a preamble, a transition, and a body. The example to be used below is:

1. A widget comprising:

Part A;

Part B; and

Part C, attaching said Part A to said Part B;

Wherein said Part A is made of copper and said Part B is made of lead and said Part C is made of gold.

### Preamble

A preamble is a short and plain expression of what the invention is. In the example, the words “[a] widget” are the preamble. The preamble need not include an express reference to one of the four statutory classifications of potentially patentable subject matter under 35 U.S.C. §101 (i.e., process, machine, manufacture, or composition of matter, so long as it is clear from the entirety of the claim that the invention fits within one or more of those classifications.

A preamble may be longer than just one or two words. In such cases, the qualifying language in the preamble is sometimes but not always, treated as a limitation of the claim. For example, a variation of the example above: “1. A widget for use in marine applications comprising: …” The preamble is the entire phrase and may be used as a limitation on the claim – i.e., would an identical widget used on land infringe?

The Federal Circuit rule is that, generally, preamble language is considered limiting only if the language is necessary to give “life, meaning and vitality” to the claim, or if it recites essential structure or steps. Typically, if the preamble terminology is repeated and referenced in the body, it is most likely limiting. However, when the body for the claim recites a structurally complete invention and the preamble language only states an intended purpose or use for that invention, the preamble language is generally not limiting.

### Transition

The transition in the example claim is the single word “comprising.” The transition is a key code word or term of art that affects the scope of the claim. The three primary claim transitions used in the U.S. are discussed below.

#### “Comprising” transition

A “comprising” transition means “including” or “containing” the elements listed following the transition. Inclusion is a patent claim of the comprising transition indicates that the claim is open in scope. ***An “open” claim*** encompasses or is literally infringed by another’s product that includes each of the explicitly recited elements of the claim, *plus anything else*. Infringement of a comprising claim cannot be avoided by copying the invention and merely adding on additional elements not recited in the claim.

Example: to claim “a widget comprising A, B, and C” would be literally infringed by a widget ABC, a widget ABCD, a widget ABCXYZ and so on.

#### “Consisting of” transition

Inclusion in a patent claim of the “consisting of” transition indicates that the claim is closed in scope. ***A “closed” claim*** encompasses or is literally infringed by another’s product that includes each of the explicitly recited elements of the claim, *but nothing else* (other than impurities normally associated with the recited elements). Thus, a claim that employs a “consisting of” transition is potentially much narrower in scope than a claim that uses a comprising transition.

Example: a claim to “a widget consisting of A, B, and C” would not be literally infringed by a widget ABC but not by a widget ABCD.

#### “Consisting essentially of” transition

A “consisting essentially of” transition means that the claim is closed, *except for the addition of any elements that do not change the essential function or properties of the composition*. These are most commonly used when claiming chemical compositions.

Example: a claim that recites “an adhesive consisting essentially of A, B and C” would be literally infringed by another’s adhesive ABC, as well as by an adhesive ABCD if D was merely a dye not impacting the adhesive’s stickiness. However, it would not be literally infringed by an adhesive ABCX if the inclusion of X changed the basic nature of the adhesive from a permanent one like SuperGlue to a repositionable one like Post-It Notes.

### Body

The body of a patent claim lists all elements of the invention and should specify how the elements are related to or interact with each other.

Example: for a claim reciting “the widget comprising A, B, and means for attaching A to B,” the body of the claim is all the words after the comprising transition. The body recites three elements: element A, element B, and a “means” element that functions to attach A to B.

There is no maximum or minimum number of elements that must be cited but a sufficient number must be included to recite an invention that is novel, nonobvious, and useful. The device as claim must be operable; that is, it must work. So long as these conditions are met, it is permissible to claim “subcombination” inventions that are some subset of a larger device. For example, automobile tires and headlights are subcombination inventions because they consist of major subassemblies of parts and have their own utility.

Its axiomatic: the more elements included in a claim, the narrower its scope; the fewer elements included, the broader its scope.

## Independent and Dependent Claims (35 U.S.C. §112 ¶3-4)

1. Dependent claim

A dependent claim is one that refers to (or depends from) some other, previously presented claim. A dependent claim includes all limitations of the claim from which it depends, and also adds some further limitation(s).

1. Independent claim

An independent claim stands alone without referring to any other claim.

The principle of ***claim differentiation*** provides that the existence of a dependent claim shows that the independent claim from which it depends is not so limited. For example, if claim 1 recites “a widget comprising A, B, and C,” and claim 2 recites “the widget of claim 1 wherein A is red,” this means that the widget of claim 2 must comprise a red A, a B (of any color) and a C (of any color). Furthermore, the existence of dependent claim 2 shows that the widget of independent claim 1 is *not* limited to having a red A; rather (barring some sort of limiting language in the written description), the A element in claim 1 can be on any color.

Claim 2 in the above example can be thought of as a subset of species of claim 1.

## Specialized Claiming Formats

### Means-plus-function claim elements (35 U.S.C. §112, ¶ 6)

#### Introduction

*Functional claiming* refers to the general notion of claiming an invention by what it does, rather than what it is in terms of physical structure. For example, one might functionally claim a “means for fastening part A to part B” rather than reciting a specific structure such as “a nail.”

§112, ¶ 6 provides that an element in a claim for a combination (of two or more elements) can be claimed in terms of what the element *does*, rather than what its structure is, by expressing the element as a generic “means” that performs a recited function, without reciting its structure.

##### Combination requirement

§112, ¶ 6 speaks of “an element in a claim *for a combination*,” the use of “single means claims” – that is, claims reciting only a single element expressed in means-plus-function terms – is prohibited.

Example: a claim to a “widget comprising a means for fastening A to B” is permitted, but a claim to a “widget comprising A, B, and means for fastening A to B” is.

Example: a claim reciting “a widget comprising a means for [performing function X] and a means for [performing function Y]” is permissible, because this claim includes more than one means-plus-function element.

##### Common usage

Drafters will often use the means-plus-function format to express those elements that can be performed by many different types of structures or devices. All such structures or devices need not be explicitly disclosed in the patent application, so long as at least one “corresponding structure” is clearly identified in the written description.

Example: a claim to an athletic shoe might recite:

An athletic shoe comprising:

* + 1. A left upper portion,
		2. A right upper portion,
		3. A sole portion integrally connected to said left upper portion and to said right upper portion, and
		4. Means for detachably fastening said left upper portion to said right portion.

Element (iv) is expressed in means-plus-function form, because it recites a generic “means” for performing a function, in this case the function of “detachably fastening said left upper portion to said right upper portion,” without reciting any structure that could be used to perform the fastening function.

#### Interpreting the scope of means-plus-function elements

The last clause of §112, ¶ 6 mandates that a means element in a patent claim “shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” This requires that in order to interpret the scope of a means-plus-function element in a claim, reference to the written description must be made. The written description must disclose the “corresponding structure” (or material or acts) for the means recited in the claim – failure to do so renders the claim indefinite under §112, ¶ 2.

As an example of a corresponding structure, assume that the written description of the athletic shoe patent stated that “a pair of shoe laces can be used to detachably fasten the left upper portion to the right upper portion,” and that the drawings depicted the use of shoe laces. This would be interpreted as reading on the disclosed structure, the shoe laces, as well as any “equivalents thereof.” The equivalents need not be explicitly disclosed in the patent and determination of what types of items would qualify as equivalents would be resolved in litigation – it is a question of fact.

Note: An equivalent structure or act under §112 for literal infringement must have been available at the time of patent issuance (*Al-Site Corp. v. VSI Int’l Inc.*). This rule seems correct from the standpoint of preserving the definiteness of the claim under 35 U.S.C. §112, ¶ 2; it is difficult to see how a claim encompassing a technology not yet in existence could satisfy the statutory requirement for definiteness.

#### Distinguishing §112, ¶ 6 statutory equivalents and the Doctrine of Equivalents

The doctrine of equivalents compares a patent claim with an accused product or process. §112, ¶ 6 entails a comparison of one structure, material or act (that in the specification) to another structure, material or act (that in a product or process alleged to be covered by the patent claim).

In order to have *literal infringement* of a means-plus-function claim, the function performed by the accused component must be *identical*, not merely insubstantially different, to the function recited in the claim.

### Product-by-process claims

This is used primarily in claiming chemical and biotechnological inventions. This was developed as a way of claiming a product, such as a composition of matter or an article of manufacture, that could not be adequately identified by its structure (e.g., the structure was unknown and could not be determined). Rather, the only way of identifying the product was through a recitation of the process by which it was made.

In examining claims for patentability (i.e., for novelty and nonobviousness), the USPTO interprets product-by-process claims as drawn to the product, and not limited by the process steps recited in the claim.

Example:

A composition of matter X, made by a process of comprising the steps of:

1. Obtaining Y,
2. Mixing Y and Z to form a mixture,
3. Heating the mixture to temperature 100° for 20 minutes,
4. Cooling the mixture to form a precipitate,
5. Recovering said precipitate, and
6. Isolating X from said precipitate.

The USPTO’s practice in examining this claim for patentability would be to interpret it as a claim to the product X, per se, not limited to X made by following the recited process steps (a) trough (f). Thus the USPTO will consider the claim anticipated (i.e., lacking novelty) if the prior art discloses the identical product X made by *any* process.

### *Jepson* claims

The *Jepson* claiming format is most frequently used in the claiming of mechanical inventions, but is not limited to that subject matter. A *Jepson* claim includes a preamble that begins with the word “in” and ends with the phrase, “an improvement comprising.”

*Jepson* claims are understood to impliedly admit that anything recited in the preamble of the claim is in the prior art. The *Jepson*’s claim’s preamble is generally considered to be limiting because the patentee’s choice of *Jepson* format is seen as an indication of intent to use the preamble to define the structural features of the claimed invention.

In order to find infringement of a *Jepson* claim, every limitation of the claim, including the preamble, must be met in the accused device either literally or equivalently.

# Potentially Patentable Subject Matter (35 U.S.C. §101)

## Introduction

### The General Nature of §101

Eligible types or categories of inventions for utility patents comprise ***statutory subject matter***, referring to the categories of subject matter recited in 35 U.S.C. §101.

**§101. Inventions patentable**

 Whoever invents of discovers any new and useful *process, machine, manufacture,* or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Along with the requirements of §101, an invention must still satisfy the remaining statutory criteria of utility, novelty, and nonobviousness before a patent will be granted. The legislative history of the 1952 Patent Act expansively states the U.S. patents are available for “anything under the sun that is made by man.” Although the courts have generally construed potentially patentable subject matter quite broadly, the case law interpreting §101 provides important limits on what can be patented.

### The Statutory Categories of §101

1. A ***process*** is synonymous with a method, and is merely a series of steps for carrying out a given task. Process patents have been granted for a method of making a “stuffed-crust” pizza, and to the Amazon for its method of “one-click” online ordering of merchandise.
2. A ***machine*** is synonymous with an apparatus, and generally has moving parts, such as an internal combustion engine.
3. A ***composition of matter*** includes chemical compositions and mixtures of substances such as metallic alloys.
4. A ***manufacture*** is the “catch-all” category for human-made subject matter without moving parts, such as a helically grooved foam football or the Java Jacket insulating sleeve for hot drink cups.

### Claiming the Inventive Concept within Different Statutory Categories

The claims of a patent need not explicitly recite the category of potentially patentable subject matter to which the invention belongs; the proper categorization is usually clear from the face of the claim. For example, a claim that recites “a programmed computer” is understood as directed to the machine category of §101.

So long as the claim is sufficiently definite under 35 U.S.C. §112, ¶2, such that the USPTO examiner can determine whether the recited subject matter falls within one or more categories of §101, nothing further is required.

The inventive concept to which a given patent is directed may encompass a number of different manifestations. That is to say, the “invention” may be claimed in many different ways – drawn to more than one statutory subject matter category.

Example: an inventor of a novel and nonobvious drug may file an application of matter, as well as a method of synthesizing the drug, as well as a method of treating patients from a certain disease, which method comprises administering an effective amount of the drug. All of these claims would be drawn to various aspects of the same “invention” or “inventive concept.”

Although claims that fall within different statutory categories are often filed in one application, in certain instances the USPTO will require “restriction” of certain groups of claims into separate patent applications. For example, the drug inventor in the above example might be required to restrict her original (parent) application to only those claims directed to the composition of matter, and to file one or more additional (divisional) applications to the remaining claims reciting the method of making and method of treatment.

* *Diamond v. Chakrabarty*
	+ The Court held that the genetically engineered, petroleum-consuming bacterium could be properly categorized as either a “composition of matter” or a “manufacture.”
	+ The patent was over transformed plasmids which resulted in an oil eating bacteria which were never naturally occurring and therefore patentable.

## Section 101 Processes

### Basic Principles

A process is synonymous with a method, or a series of steps for accomplishing some result. Often, the process is a novel and nonobvious method of making some end product. Importantly, the end result of the process *need not be patentable*; in other words, a process claim can be granted for a novel and nonobvious method of making an old product.

### Computer-Implemented Processes

Many patented processes or methods are implemented through the use of computers and software.

* *Diamond v. Diehr (1981)*
	+ The Court upheld the patentability of a computer-controlled process for curing synthetic rubber. The process contained the well-known Arrhenius equation, but the Court stated that the presence of such mathematical subject matter in a patent claim does not necessarily deprive the claim of potential patentability under 35 U.S.C. §101.
	+ The process did not seek to pre-empt the use of the equation but sought only to foreclose others from using the equation in conjunction with all of the other steps recited in the claimed process.

The Federal Circuit interpreted *Diehr* as simply standing for the proposition that a “physical transformation” is “not an invariable requirement, but merely one example of how a mathematical algorithm may bring about a useful application.”

* *Gottschalk v. Benson (1972)*
	+ The Court held unpatentable claims for an algorithm used to convert binary code decimal numbers to equivalent pure binary numbers. The sole practical application of the algorithm was in connection with the programming of a general purpose digital computer.
	+ The Court defined “algorithm” as a “procedure for solving a given type of mathematical problem,” and they concluded that such an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent.

### Business Methods

A process or method of doing business or operating a business is potentially patentable so long as the claimed method is not an unapplied, abstract idea or concept.

However, “the use of mental processes to resolve a dispute” is not patentable subject matter (*In re Comiskey*). That claim encompassed a “method for mandatory arbitration resolution regarding one or more unilateral documents.” None of the claims involved a computer or machine. Even though the process performed a useful, practical service, “mental processes – or processes or human thinking – standing alone are not patentable even if they have practical application.”

#### “Machine-or-transformation test”

A claimed process is patentable subject matter if:

* + - 1. It is tied to a particular machine or apparatus; or
			2. It transforms a particular article into a different state or thing.

The Federal Circuit explained that an article in the sense of its transformation test need not be limited to a tangible, physical substance such as the rubber cured in *Diehr*.

Examples: cured rubber and electronic signals and electronically manipulated data are forms of patentable subject matter

“Transformation of…raw data into a particular visual depiction of a physical object” will be patentable subject matter (e.g. an x-ray). However, the transformation of data into a visual depiction is insufficient (e.g., data into pie charts).

The transformation prong will be satisfied so long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances.

* *In re Bilski*
	+ The Supreme Court agreed with the lower court opinion that Bilski’s claim was not patentable subject matter but stated that the “Machine-or-transformation test” was not the sole test to be used for the analyses of process claims but was simply a test to consider.
	+ Bilski’s claimed invention involved a method of hedging risk in the field of commodities trading; the application was rejected by the USPTO because it was not implemented on a specific apparatus and merely manipulated an abstract idea and solved a purely mathematical problem without any limitation to a practical application. Bilski appealed.
	+ The key issues for the Federal Circuit were whether Bilski was seeking to claim a fundamental principle (such as an abstract idea) or a mental process, and if so, whether the claim would pre-empt substantially all uses of that fundamental principle if allowed.
	+ Bilski’s claimed process for hedging risk in commodities trading involved the purported transformations or manipulations simply of public or private legal obligations, relationships, business risks, or other abstractions. Such abstractions cannot satisfy the transformation test because they are not physical objects or substances and they are not representative of physical objections.

*Bilski* did not overrule the core holding of *State Street* that held business methods are potentially patentable subject matter. Nor did the court adopt a broad exclusion over software.

## Section 101 Machines

A machine (or apparatus) is a human-made device that has moving parts.

## Section 101 Compositions of Matter

A composition of matter is a mixture of substances such as a chemical composition or metallic alloy. This includes all compositions of two or more substances and all composite articles whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids.

### Structure versus Properties

If a composition of matter is claimed as such, it is the physical structure of the composition that must be novel, not merely its properties. The discovery or recognition of a composition’s previously unappreciated property (e.g., the ability of aspirin to lessen the risk of heart attacks) will not impart patentability to that composition if its structure is already known. Such a discovery might merit patentability if claimed as a process, nut not as a product.

This includes that the newly discovered property cannot be placed as a limitation in the claim and the claim be patentable.

### Purified Forms of Natural Products

The ***“product of nature” doctrine*** recognizes that potentially patentable subject matter must be created through human invention. Thus, a newly discovered mineral or a plant found in the wild is not patentable subject matter under 35 U.S.C. §101.

In contrast, so-called “purified forms” of natural products may be patentable if sufficiently different from the nonpurified (i.e., natural) forms so as to be novel and nonobvious.

* *Parke-Davis & Co. v. H.K. Mulford Co.*
	+ The patent was directed to a purified form of adrenaline, a naturally occurring hormone secreted by the suprarenal glands of animals.
	+ The inventor claimed “a substance possessing the herein-described physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form, and practically free from inert and associated gland-tissue.”
	+ The court upheld the validity of the patent stating that the inventor was the first to make it available for any use by removing it from the other gland-tissue in which it was found. Because it was available for practically every purpose as a purified form, it was essentially a new thing.
* *Ass’n for Molecular Pathology v. USPTO (The Myriad Case)*
	+ Isolated genes – found to be patentable still
	+ Diagnostic methods – unpatentable because a diagnosis is essentially an abstract idea

### Life Forms

In *Diamond v. Chakrabarty*, the Supreme Court confronted the question: whether living subject matter, such as a genetically engineered organism, is patentable subject matter under 35 U.S.C. §101.

* *Diamond v. Chakrabarty*
	+ The Court held that a micro-organism may constitute a “manufacture” or “composition of matter” within the meaning of §101. The micro-organism discovered by Chakrabarty qualified as patentable subject matter because it is a non-naturally occurring manufacture or composition of matter but a product of human ingenuity having a distinct name, character and use.
	+ Chakrabarty added four plasmids to non-oil eating bacteria which resulted in old-eating bacteria. The process of addition of the four plasmids was human ingenuity and the end-product, the oil-eating bacteria, did not occur naturally.
* *Funk Bros. Seed Co. v. Kalo Inoculant*
	+ Objects were combined but maintained their natural tendencies and this was unpatentable.

## Section 101 Manufactures

A manufacture in patent law is something of a catch-all category for those inventions that are human-made but do not fit into one of the previous categories. A manufacture is generally thought of as a human-made item without moving parts, in contrast to a machine.

## Nonpatentable Subject Matter

The following are not potentially patentable subject matter in the US:

* Laws of nature;
* Natural phenomena;
* Abstract ideas;
* Unapplied mathematical algorithms; and
* Products of nature

For example, the law of force (F=MA) is not patentable. *Applications* of these fundamental laws and principles may be.

# The Utility Requirement (35 U.S.C. §101)

## Introduction

United States patent law protects inventions that are novel, nonobvious and *useful*. A *useful* invention is one that possesses ***utility*** which has the goal of promoting the progress of the “useful arts” (U.S. Const., art. I, §8, cl. 8). The utility requirement is statutorily implemented through the mandate of 35 U.S.C. §101 (patentable inventions must be new and useful), the statute does not define what useful (or utility) means. This is filled in through case law.

The substantive threshold for satisfying the utility requirement is relatively low. The great majority of inventions are never challenged as lacking utility. Utility disputes tend to involve inventions in the chemical and biotechnological arts.

## Beneficial Utility

* *Lowell v. Lewis*
	+ A plaintiff must establish that the machine is a new and useful invention; the law will not allow a patent for an invention that is of a mischievous or injurious tendency.
	+ The invention does not have to be more beneficial than others on the market; all the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.
	+ Whether the invention be more or less useful than current products is a circumstance very material to the interests of the patentee, but of no importance to the public.

In *Bedford v. Hunt*, Judge Story reaffirmed that the law does not look to the degree of utility; it simply requires that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit.

* *Juicy Whip, Inc. v. Orange Bang, Inc.*
	+ Juicy Whip’s patent is on a post-mix dispenser that looks like a pre-mix dispenser. It had a reservoir bowl to create the visual impression that multiple servings of the dispensed beverage are stored within but the bowl actually contains a fluid with no connection to the outlet of the machine.
	+ The district court held the patent invalid because the invention’s purpose is deceptive – i.e., the purpose is to create an illusion, whereby customers believe that the fluid contained in the bowl is the actual beverage that they are receiving.
	+ The court stated that ***the threshold of utility is not high: an invention is “useful” under §101 if it is capable of providing some identifiable benefit.***
	+ The court then declined to follow *Lowell v. Lewis*. ***“The fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility.”***
	+ Much of the value of such products resides in the fact that they appear to be something they are not. Thus, the post-mix dispenser meets the utility requirement by embodying the features of a post-mix dispenser while imitating the visual appearance of a pre-mix dispenser. The fact that customers may believe they are receiving fluid directly from the display tank does not deprive the invention of utility.
	+ The requirement of utility in patent law is not a directive to the USPTO or the courts to serve as arbiters of deceptive trade practices.

## Practical Utility

To be patentable an invention must have some real-world use. “Practical” use does not necessarily mean “significant” or “extensive,” however. Even a chemical intermediate, which exists only for an instant of time when it is producing during the course of a chemical reaction, is useful because it is a tool that allows researchers to develop other chemicals have use therapeutic properties.

The Supreme Court characterized *Nelson* as the start of a trend toward a more liberal interpretation of patent utility in *Brenner v. Manson*. The court did not state that it was overruling *Manson*, the facts of which are distinguishable from *Nelson*.

* *In re Nelson*
	+ The court reversed the USPTO’s rejection of claimed steroid intermediates as lacking utility under §101. The court stated that a new group of steroid intermediates is *useful to chemists doing research* on steroids. Such intermediates are often placed on the market before much, if anything, is known as to what they are “good” for, other than experimentation and the making of other compounds in the important field of research.
	+ *Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys. This would tend to retard rather than promote progress*.
	+ The new steroids, being useful to research chemists for the purposes disclosed, are clearly useful to society and their invention contributes to the progress of an art.

Even novelty items, games or toys that may be considered trivial or frivolous can satisfy the utility requirement.

Example: A utility patent directed to a hat in the shape of a fried egg was issued; the written description stated the hat finds utility, for example, as an attention-getting item in connection with promotional activities at trade shows, conventions and the like.

The utility threshold is relatively low because if an invention does not offer much in the way of usefulness to society, the costs temporarily borne by the public because the invention is covered by a patent will not be excessive. Inventions that are only minimally useful will most likely be made or sold in very small quantities; therefore, the patentee’s right to exclude others from making, using, selling, offering to sell, and importing the claimed invention represents a minimal burden on society.

Thus, patent law does not attempt to evaluate the degree of utility of an invention, beyond some *de minimus* threshold level. Rather, the marketplace decides which inventions are the most useful, through the price the inventor can command for her patented product.

Lack of utility is rarely raised as a basis for challenging the validity of an issued patent.

Patentable utility does not require commercial success in the marketplace. Nor does it require that an invention work better than those that came before it. Rather, the utility requirement simply ensures that the invention *works* on some minimal level.

In *Bedford v. Hunt*, Judge Joseph Story rejected the notion that patent law is concerned with the *degree* of utility of an invention:

By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society…it is not necessary to establish, that the invention is of such general utility, as to supersede all other inventions now in practice to accomplish the same purpose. It is sufficient, that is has no obnoxious or mischievous tendency, that it may be applied to practical uses, and that so far as it is applied, it is helpful. ***This law does not look to degree of utility; it simply requires that it shall be capable of use****,* and that the use is such as sound morals and policy do not discountenance or prohibit.

## Supreme Court view: *Brenner v. Manson (1966)*

The controversial *Manson* decision arguably represents the high-water mark for what is required to satisfy 35 U.S.C. §101.

* *Brenner v. Manson*
	+ Manson claimed a new process for making a known steroid, a type of chemical compound. He asserted that his process had utility because the steroid it produced was being screened for tumor-inhibiting effects in mice, and the next adjacent homologue of the steroid had already been shown to work for that purpose.
	+ The Supreme Court held that the claimed process did not satisfy the utility requirement of 35 U.S.C. §101. It viewed Manson’s research in steroid chemistry, which it deemed an unpredictable art, as being too preliminary a stage to merit patent protection, noting that “a patent is not a hunting license” and “not a reward for the search, but compensation for its successful and conclusion.”
	+ What is required for patentability is “substantial utility.” This substantial utility standard could not be achieved until the process was defined and developed to the point that “specific benefit exists in currently available form.”
	+ The main issue was timing – what did the inventor now at the time of invention? From that knowledge, could the inventor disclose a specific, beneficial utility at that time?

The USPTO in 2001 issued examination guidelines that interpret the *Manson* decision as requiring utility that is “specific, substantial and credible.”

## Federal Circuit View

### *In re Brana*: Chemical Compounds

*In re Brana* appeared to lower the bar back toward the more lenient standards of utility espoused pre-*Mason*. *In re Brana* is an important utility case for several reasons. First, it clarified the procedural burdens borne by the patent applicant and the USPTO during a utility determination. It holds that the agency bears the initial burden of challenging an applicant’s presumptively correct assertion of utility (show a person having ordinary skill in the art would reasonably doubt the asserted utility); the burden then shifts to the applicant to prove the utility. Proof is typically made through submission of test data, experimental results, affidavits of experts and the like.

Second, *Brana* demonstrates that a biomedical invention may possess patentable utility even though it is not yet at the stage of development necessary for sales approval by the U.S. FDA.

* *In re Brana (1995)*
	+ Brana’s claims were directed to certain novel compounds intended for use in chemotherapy. He produced evidence before the USPTO showing that the compounds had cytotoxicity against human tumor cells, *in vitro*, and an efficacy that favorably compared to that of structurally similar prior art compounds tested in mice.
	+ The USPTO rejected the application but the Federal Circuit reversed and held that Brana’s evidence satisfied the utility standard and rejected the USPTO’s position.
	+ Patentable utility can be achieved well before FDA standards are satisfied: “*usefulness in patent law, and particularly in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans*.”

### *In re Fisher*: Genetic Inventions

*In re Fisher* was brought as a test case to clarify the standards for applying the §101 utility requirement to patent claims reciting ESTs (expressed sequence tags – fragments of cDNA).

* *In re Fisher (2005)*
	+ The Federal Circuit returned to the rigorous utility criteria announced by the Supreme Court in *Brenner v. Manson*. However, it remains to be seen whether this resurrection of *Manson* signals a heightened utility requirement for *all* inventions, or will instead be limited to those inventions involving genetic materials such as ESTs.
	+ The USPTO affirmed an examiner’s rejection of application claims to five ESTs encoding proteins and protein fragments in maize plants as lacking utility.
	+ According to the applicant, the ESTs provided at least one specific benefit to the public, for example the ability to identify the presence or absence of a polymorphism in a population of maize plants.
	+ While the USPTO admitted that using ESTs to determine whether populations share a common genetic heritage may be a “utility” it was not in the agency’s view a “substantial utility” as required by *Manson*, that is one that provides a specific benefit in currently available form.
	+ The Federal Circuit upheld the rejection in a split decision. They rejected the *de minimus* view of the utility requirement and instead hewed to the “specific” and “substantial” utility criteria espoused in *Manson*.

#### Test from In re Fisher

The Federal Circuit held that it order to show a “specific” utility, “an asserted use must…show that the claimed invention can be used to provide a well-defined and particular benefit to the public.”

In order to demonstrate a “substantial” utility, “an asserted use must show that the claimed invention has a significant and presently available benefit to the public.

#### Fisher’s claims

Fisher’s claimed ESTs failed to satisfy either one of these criteria. Each claimed EST uniquely corresponded to the single (or “underlying”) gene from which it was transcribed; yet as of the application’s filing date, no function was known for the underlying genes. The claimed ESTs were thus no more than “research intermediates” that were “unable to provide any information about the overall structure let alone the function of the underlying gene.”

Nothing about Fisher’s alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the application of indeed from any EST derived from any organism.

Fisher could not identify the function for the underlying protein-encoding genes. Absent such information, the majority concluded, “the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

#### Fisher dissent – Judge Radar

Radar dissented on the basis that the claimed ESTs were patentable research tools of cognizable benefit to society. Much like a microscope, the ESTs take a researcher “one step closer to identifying and understanding a previously unknown and invisible structure.”

In his view, the USPTO is not capable of knowing which “insubstantial” research step will contribute to a substantial breakthrough in genomic study. According to Judge Radar, the utility requirement of §101 is not the proper tool for rejecting inventions that do not advance the “useful arts” sufficiently to merit a patent; rather, that tool should be the nonobviousness requirement of §103.

## Inoperability

If the utility asserted for an invention contravenes generally accepted scientific principles, the USPTO will reject the inventor’s claims under 35 U.S.C. §101 as drawn to inoperable subject matter. Inoperability is a type of rejection for lack of utility. If an invention does not work as claimed, then it is not considered useful.

### Examples of Inoperable Inventions

* *Newman v. Quigg*
	+ The applicant claimed a device allegedly having higher energy output than input. The claim was rejected by the USPTO and affirmed by the Federal Circuit because the device lacks utility in that it does not operate to produce what he claims it does (the device having at most 77% efficiency).
* *In re Cortright*
	+ The operability of a hair loss treatment was issue. The patent applicant claimed a method of treating baldness by applying Bag Balm (a commercially available ointment normally used to moisturize the udders of cows) to the head of a human suffering from hair loss.
	+ The claim recited the particular way in which Cortright believed that her invention worked. However, the application lacked any information to substantiate that the method actually operated in this manner; that is, it did not demonstrate that the active ingredient actually offset the effects of lower male hormones as it recited.
	+ Therefore, the application did not provide a satisfactory description of how to use the invention of the claim in accordance with 35 U.S.C. §112.

### Inoperable Species within a Genus

Utility issues sometimes arise in the context of a generic claim that includes within it one or more species that are inoperable.

Example: consider a patent claim to a composition of matter comprising component X from 20 to 80 weight percent, for which the inventor asserts the utility of shrinking cancer tumors. If it is established that the embodiment of the invention in which X is present at 30 percent does not have any tumor-shrinking effect on cancer cells; therefore, the X equals 30 percent species does not possess the utility asserted for the genus. Is the claim in its entirety therefore invalid under 35 U.S.C. §101?

The answer depends on the facts of the particular case. Federal Circuit law holds that the presence of *some* inoperative embodiments does not necessarily render a claim invalid as lacking utility. Patent claims need not exclude all possibly inoperative species or embodiments. However, the presence of too many inoperative species or embodiments may give rise to enablement problems under 35 U.S.C. §112, ¶1. The patent’s written description must provide enough information that one of ordinary skill in the art could select or discern which embodiments are operable and which are not, and thus practice the invention, without undue experimentation.

## Immoral or Deceptive Inventions

Early U.S. judicial decisions recognized a morality component within the utility requirement.

In 1977, the USPTO issued a decision signaling that the agency would no longer reject inventions on the ground that they might be viewed by some segment of society as immoral.

* *Ex parte Murphy (1977)*
	+ The agency upheld the patentability of a “one-armed bandit” slot machine. The USPTO explained that “while some may consider gambling to be injurious to the public morals, we cannot find any basis in 35 U.S.C. §101 or related sections which justify a conclusion that inventions which are useful only for gambling *ipso facto* are void of patentable utility.”
	+ The USPTO stated they should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent on the game of chance if the requirements of the Patent Act otherwise have been met.
* *Juicy Whip, Inc. v. Orange Bang, Inc. (1999)*
	+ The Federal Circuit affirmed the rationale the *Murphy*. The patent suit was directed to a Slurpee-like beverage dispenser machine that included a transparent display chamber of the dispensed product, permitting consumers to see in advance the drink they believed they were buying.
	+ In actuality, the product (syrup and water) was mixed just before dispensing, so that the customer was not given what she had seen in the display chamber.

# Disclosure Requirements

## Introduction

### Statutory Framework

The three disclosure requirements for a U.S. patent application are found in the first paragraph of 35 U.S.C. §112 (titled “Specification”). These requirements are: (1) enablement, (2) best mode, and (3) written description of the invention. These disclosure requirements pertain to the informative quality of the patent *application* rather than the technical merits of the claimed invention.

Example: The inventor in *In re Glass* filed a patent application directed to methods and apparatuses for artificially growing high strength crystals. Although the USPTO did not challenge the novelty or utility of the claimed invention, the application’s disclosure was deficient under 35 U.S.C. §112, ¶1. The application did not disclose essential process parameters such as temperature, pressure, and vapor saturation conditions that the inventor had conceded were necessary to form the crystals.

### Timing of Disclosure Compliance

***The question whether a patent application satisfies each of the three disclosure requirements of 35 U.S.C. §112, ¶1 is analyzed as of the application’s filing date***.

The patent application’s teachings cannot be supplemented with new information (termed new matter) after the filing date in order to come into compliance with 35 U.S.C. §112, ¶1. Nor can the applicant rely on information provided by others, published after the application’s filing date, to argue that the application’s disclosure, supplemented by such publications, suffices to satisfy the statutory requirements by the time the application issues as a patent. If an applicant cannot supply enabling information at the time when she files her patent application, then she is not yet in a position to file.

The USPTO will allow patent applications to satisfy the disclosure requirements of 35 U.S.C. §112, ¶1 by incorporating by reference “essential material” from certain sources external to the patent application under examination, that is, either (1) a U.S. patent, or (2) a published U.S. patent application.

When an invention sought to be patented involved biological material (e.g., bacteria, DNA, plant tissue cultures, and seeds), it is customary for the applicant to deposit a sample of the material with a depository such as the American Type Culture Collection. Such a deposit is necessary if the biological material cannot be sufficiently described in words to satisfy the disclosure requirements.

Because the United States is a first-to-invent patent system, the novelty and nonobviousness of an invention are evaluated as of its “invention date.” Although the USPTO initially takes the applicant’s filing date as the presumptive invention date under a theory of *constructive reduction to practice*, an earlier actual invention date may be established by means of appropriate evidentiary submissions.

### Anatomy of §112

#### Enablement

This requires the inventor to describe her invention clearly enough so that one skilled in her art can understand it will enough to prevent the skilled artisan from having to undertake a great deal of experimentation to reproduce the claimed invention.

#### Written Description

The inventor must describe what he claims, and claims what he describes.

#### Claim Definiteness

In addition to disclosing his invention, an inventor must claim it in such a way that others can easily discern the boundaries of his legal right. He must demarcate clearly what he claims and what is left free to the public to use. Although the disclosure in the patent specification is often relied on to help interpret claim language, the definiteness requirement demands clarity in the claim language.

#### Best Mode

An inventor must disclose to the public the best mode he knows for practicing the claimed invention. Of all the embodiments encompassed within the claims, he must set forth the one, if any, that he believes is most effective.

The specification must disclose the ***best way*** the inventor knows how to practice the claimed invention and enable a person of skill in the art to do so.

## The Enablement Requirement

35 U.S.C. §112, ¶1 states:

“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same…”

Thus, the enablement provision specifies that an inventor must disclose both “how to make” the invention as well as “how to use” it. For example, if the claimed invention is a new chemical compound, the application must include an enabling disclosure of how to synthesize the compound, as well as reveal how the compound is used.

The goal of the enablement requirement is to put the public in effective “possession” of the invention, by providing to persons of ordinary skill in the art a detailed description of how to make and use the invention. The enabling disclosure thus provides a type of a blue-print that such persons can follow once the patent expires, and they are free to make and use the invention without liability.

The “how to use” requirement of 35 U.S.C. §112, ¶1 is closely tied to the utility agreement of 35 U.S.C. §101 – if an inventor does not know what the utility of her invention is, then logically she cannot describe how to use the invention.

### Undue Experimentation

Case law has engrafted an *undue experimentation* qualifier onto the enablement requirement as set forth in 35 U.S.C. §112, ¶1. ***A patent application will be considered enabling so long as the disclosure permits the hypothetical person skilled in the art to make and use the invention “without undue experimentation.”*** That the art worked might have to conduct *some* experimentation in order to make and use the invention as broadly as it is claimed is not fatal; only when the degree of experimentation becomes *undue* has the application failed to meet the enablement requirement. Note, a patent application need not disclose what is well known in the art.

* *The Incandescent Lamp Patent (1895)*
	+ Invention: filament in a light bulb. Two patents were at issue, Sawyer/Man and Edison’s patent. Edison asserts that S/M did not properly enable in their disclosure.
	+ Issue: S/M used carbonized paper in their invention, they are trying to assert that they have the right to exclude all carbonized fibrous textile materials. Had S/M discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials…and such quality or characteristic adapted them peculiarly to incandescent conductors, such a claim might not be too broad. However, most members for the genus did not work well; it took Edison a great effort to find a particular bamboo that was a good filament material.
	+ The S/M patent disclosure was deficient as it was not possible to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by painstaking experimentation.

Whether the degree of experimentation needed to reproduce the claimed invention has become undue, meaning that the enablement requirement has not been satisfied, turns on the application of a number of factors set forth in *In re Wands*, including:

1. The quantity of experimentation necessary;
2. The amount of direction or guidance presented;
3. The presence or absence of working examples;
4. The nature of the invention;
5. The state of the prior art;
6. The relative skill of those in the art;
7. The predictability or unpredictability of the art; and
8. The breadth of the claims.

Not everything *Wands* factor need be reviewed in every enablement determination; however, the factors are considered “illustrative, not mandatory.” Given the facts of a particular case, some factors may be more relevant than others.

### Speculation and Prophesy

* *Janssen Pharmaceutica v. Teva Pharms.*
	+ Janssen’s patent covered a method to treat Alzheimer’s disease with a chemical compound called galanthamine. The specification was slightly longer than one page and contained brief summaries of six scientific articles which discussed the use of galanthamine on humans or animals for various purposes. None of the six addressed the treatment of Alzheimer’s or dementia. Research on animal models was not completed by the time the patent issued and was not provided to the PTO.
	+ The court stated that “the utility requirement prevents mere ideas from being patented. The utility requirement also prevents the patenting of a mere research proposal or an invention that is simply an object of research (“a patent is not a hunting license” – *Brenner*).
	+ The court held that patent applications for methods of treating diseases usually include test results to satisfy the utility requirement. The test results need not be human trials, but rather may be from animal tests or *in vitro* research.
	+ There were no test results and the six scientific articles clearly did not provide evidence of utility because the inventor had stated during the prosecution of the patent that those references did not relate to the method of the invention and did not render it obvious.
	+ “Thus, at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient. If mere plausibility were the test for enablement under §112, applicants could obtain patent rights to “inventions” consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the “inventor” would be rewarded the spoils instead of the party who demonstrated that the method actually worked.”

### *Wands* Factor: Predictable v. Unpredictable Inventions

One *Wands* factor very often central to the inquiry is whether the invention is considered to be within a “predictable” or “unpredictable” technology. In general, inventions in the mechanical and electrical arts considered to be predictable. Based on the generally well-understood laws of physics, thermodynamics, and other basic scientific principles, if one embodiment of the invention is adequately described, then we can predict fairly easily how other embodiments within the scope of the claimed invention could be made and used.

Example: a mechanical invention claimed as “a widget comprising part A attached to part B by means of a fastener.” If the patent application discloses that A can be satisfactorily attached to B by means of a common nail, we can predict that other combinations employing a screw, glue, or Velcro as fasteners would also probably work.

This predictive assumption is not generally made about alternative embodiments in the case of inventions in the chemical and biotechnological arts – a minor change in the physical structure of a molecule or compound can result in major changes in properties and functions.

In order to be enabling, a patent application directed to complex inventions (e.g., chemical or biotechnological) must provide a correspondingly greater degree of how-to-make and how-to-use information, in contract with the disclosure of a simple mechanical device like the widget example.

Many inventions involve multiple components or factors, some mechanical, some chemical, some physiological, and so on. Certain components of such inventions may be considered within the predictable arts and others not; the inventions do not neatly fall within the mechanical or chemical category.

### *Wands* Factor: Scope of the Claims

Another *Wands* factor often of great importance in enablement determinations is the scope of the claims sought by the patent applicant. The degree of enabling disclosure provided by the written description and drawings must bear a “reasonable correlation” to the scope of the claims. The application must seek a right to exclude others from the claimed invention that is reasonably related in scope to the extent of her inventive contribution as disclosed in the patent application.

Rationale: If an inventor is awarded claims of scope significantly greater than the scope of his enabling disclosure, the public is harmed because subsequent improvers will be blocked unjustly by the original inventor’s patent and disinclined to conduct follow-on research. On the other hand, if the patent protection awarded is no broader in scope than the specific embodiments disclosed in the application, the resulting patent is of little economic value.

How many illustrative species must the application disclose in order to satisfy the enablement requirement? To what extent should we allow this inventor to exclude others from using embodiments that she has not in fact made or tested? There is no one-size-fits-all answer to these questions, but the Federal Circuit has instructed:

Patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. There must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and sure the invention as broadly as it is claimed…

### *Wands* Factor: Working Examples

The “working examples” referred to in *Wands* are commonly included in patent applications to help satisfy the enablement requirement, although examples are not required by statute.

Patent applications may contain two different types of examples:

1. “Working examples” – disclose the results of experiments or tests that were actually performed.
2. “Prophetic examples” – also referred to as paper examples, suggest how a person of ordinary skill in the art might go about experimenting with or testing the invention in the future.

### Nascent and After-Arising Technology

How should courts determine if a patent application’s disclosure is enabling when the patent claims are later asserted to cover embodiments of the invention that were not in existence when the patent application was filed?

## The Best Mode Requirement

* *Randomex, Inc., v. Scopus Corp.*
	+ The Federal Circuit determined that the indiscriminate listing of the best mode along with a number of other modes did not violate the best mode disclosure obligation.
	+ On the other hand, a scenario in which the best mode is indiscriminately listed among so many other possibilities as to result in “burial” or effective concealment might run afoul of the best mode requirement.

## The Written Description of the Invention Requirement

Patent law uses the phrase “written description” in two ways. In its more commonly used sense, written description refers to a physical part of the patent document. The written description portion of a patent encompasses all of the patent specification’s content other than the claims.

In its second use, the phrase “written description” is a reference to a *legal requirement* that the patent’s specification must satisfy in accordance with 35 U.S.C. §112, ¶1. The traditional view of this legal requirement was that the language of patent claims presented or amended after the filing date of the application must find adequate “support” in the written portion of the patent document. Recent Federal Circuit decisions have expanded the scope of the written description of the invention doctrine beyond this traditional purview.

### Timing Mechanism

The written description of the invention requirement can best be understood as a timing or “priority policing” mechanism. It is quite common for patent applicants to submit amendments to a patent application after it has been filed, for the purpose of modifying the originally filed claims or adding one or more new claims.

Are these amended or new claims also entitled to the same *prima facie* invention date as the originally filed claims, or merely to the later date on which the new claims were actually presented? The answer is dependent on the written description of the requirement.

Satisfaction of the written description of the invention requirement ensures that such subject matter, claimed *after* an application’s filing date, was sufficiently disclosed in the application *at the time of its original filing* so that the *prima facie* date of invention for the later-claimed subject matter can fairly be held to be the filing fate of the application. Without written description of the invention scrutiny, a later-presented or amended claim not truly entitled to the earlier filing date of the application would be improperly examined against a smaller universe of prior art than is legally available, and the application would unfairly enjoy a windfall vis-à-vis the prior art.

Another way of understanding the written description of the invention requirement is that it functions to ensure that all claims amended or added after the filing date of the application find adequate “support” in the originally filed application.

The language added to the claims by amendment or introduced in newly presented claims must have previously appeared in the specification, either explicitly or implicitly.

The policy rationale behind the written description of the invention requirement is that it mandates the *inventor* be “in possession” of the claimed invention as of the filing date of the application (presumptive invention date by the USPTO). By ensuring that the later-claimed subject matter was in fact within the inventor’s original contribution, the written description of the invention requirement guards against unfair, overreaching inventors.

### How an Application Conveys Possession of an Invention

Compliance with the written description of the invention requirement should not be so burdensome as to prohibit an applicant from claiming “undisclosed, but obviously art-recognized equivalents” of expressly disclosed aspects of the invention; these “equivalents” are considered within the inventor’s possession.

A satisfactory written description of the invention need not even be in words.

* *Vas-Cath v. Mahurkar*
	+ “Under proper circumstances, drawings alone may provide a written description of an invention as required by §112.”
	+ The patent at issue claimed a catheter having double tubes of diameters within a specified range of ratios. Even though the design patent application drawings showed only one particular ratio of diameters falling within the range recited in the utility patent claims, the court concluded that the drawings provided an adequate written description of the invention.
	+ The fact the drawings did not show every possible embodiment within the recited range was not dispositive. The drawings were such that a PHOSITA would be aware that only certain ranges would produce acceptable results.
* *Enzo Biochem v. Gen-Probe*
	+ The court held that “proof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of §112, ¶1.”

### Distinguishing Written Description from Enablement

The written description of the invention requirement stands apart from the enablement requirement. The following example clarifies the difference:

Assume that a patent application as filed discloses and claims a red widget. No other color widget it mentioned, nor is any suggestion made in the application that the claimed widget could be any color other than red. Although a PHOSITA might arguably be *enabled* by this disclosure to make widgets of other colors, a generic claim later presented during the course of the prosecution that recited “a widget of a primary color” would not be valid under the written description of the invention requirement. This is because the as-filed patent application did not provide a written description of the invention as later claimed generically; the application showed only a red widget. The terminology used is that “the initial disclosure does not support the broader, later-presented claim to a ‘widget of a primary color.’”

### Typical Fact Scenarios Invoking Written Description Scrutiny

The procedural context of the above example, which involves the presentation of a new claim during ongoing prosecution after the patent application had been filed, is a typical one for written description issues. Written description of the invention issues usually arise in the “time gap” situations when (1) new claims are added to a pending patent application, (2) an originally filed claim is substantively amended during prosecution, (3) an applicant claims the benefit of the earlier filing date of a related domestic patent application or a corresponding foreign-origin patent application, or (4) an interference is declared in which the issue is support for a count in the specification of one or more of the parties.

# Novelty and Loss of Right (35 U.S.C. §102)

The notion that patents are available only for inventions that are truly novel is a bedrock concept for all patent systems. What is novel, however, is not uniformly defined around the world. The United States analyzes novelty quite differently than other countries, in view of our unique “first to invent” system.

## Section 102 Terminology and General Principles

### Burden of Proof

The preamble of 35 U.S.C. §102 places a burden of proof on the USPTO to negative a presumption of novelty. “A person *shall* be entitled to a patent *unless*...” The statute is drafted to indicate the initial burden of disproving novelty during examination of a patent application rests with the USPTO.

In order to reject an applicant’s claim(s) under 35 U.S.C. §102, the agency must accordingly show that at least one of the statute’s novelty-destroying or loss of right subsections (a) through (g) has been triggered.

Typical rejection is premised on citation of one of more prior art references. Claims may also be rejected under certain subsections of §102 based on events, such as a placing of the invention “on sale” or in “public use” within the meaning of §102.

For example, if a patent, journal article, other document, or event is stated by the USPTO to be prior art, it must qualify under some subsection of 35 U.S.C. §102. If it does not, then the document or event is not legally available for use as prior art to negate the presumed novelty of the applicant’s claimed invention.

### The Meaning of Anticipation

When one or more of the novelty provisions of §102 is triggered, patent attorneys say that the invention has been ***anticipated***. When an invention has been anticipated, it is old, and thus unpatentable.

### Distinguishing Novelty from Loss of Right

Section 102 is really two provisions:

* Novelty provisions: subsections (a), (e), (f) and (g)
* Loss of right provisions: subsections (b), (c), and (d)

One of the fundamental differences between the novelty and loss of right provisions lies in their respective triggering dates:

* Novelty provisions are triggered by events taking place before the invention – that is before the invention date
* Loss of right provisions key off of the date that is one year prior to the applicant’s filing date (referred to as the §102(b) critical date).

USPTO presumptively treats the applicant’s filing date as her invention date for purposes of lack of novelty unless and until the applicant proves an earlier actual invention date.

### What Is a Printed Publication?

A key policy concern of 35 U.S.C. §102 is that we not permit an applicant to withdraw technology already in the public’s possession by obtaining a patent.

The law is liberal when it comes to what constitutes public disclosure, even a drawing without words qualify (assuming it is sufficiently enabling). For example, a patent claim to a candle-shaped light bulb holder was found to be anticipated by a picture of the holder in a third party’s French-language catalog. In other words, ***the document or drawing will be considered a printed publication if it is sufficiently accessible to the public interested in this particular technology***.

#### How accessible is “sufficiently accessible”?

* *In re Hall*
	+ The court held that a single cataloged thesis in a foreign university’s library could constitute sufficient accessibility to those interested in the art exercising reasonable diligence.

In contrast,

* *In re Cronyn*
	+ Three students’ theses listed in alphabetically by the author’s names on index cards, kept among450 index cards in a shoebox in a college chemistry department’s library, not otherwise cataloged or indexed by subject, were held not sufficiently accessible to count as printed publications.
* *In re Klopfenstein*
	+ The court concluded that the inventors’ academic conference poster presentation, on display for three days but never reproduced or distributed to any of the conference participants, constituted a “printed publication” that resulted in a §102(b) loss of right to a patent.
	+ The court stated that they are not limited to finding something to be a “printed publication” only when there is distribution and/or indexing.

***The key inquiry for determining if there has been a printed publication is whether or not a reference has been made “publicly accessible.” That determination involves a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public***. The following factors were considered relevant:

* The length of time that the display was exhibited
* The expertise of the target audience
* The existence (or lack thereof) of reasonable expectations that the material displayed would not be copied
* The simplicity or ease with which the material displayed could have been copied

New and technology-specific questions of public accessibility arise with regularity today due to the Internet.

* *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*
	+ An inventor’s pre-critical date posting of an otherwise anticipatory paper on the patentee’s publicly available FTP server did not render the paper sufficiently accessible to trigger the §102(b) printed publication bar.
	+ The inventor had previously publicized the FTP server to other members of the cyber security community as a repository of his research on intrusion detection. However, the Federal Circuit viewed the FTP server posting as a prepublication communication for purposes of peer review; intent to publicize the paper was lacking.
	+ The court held the file name, “ndss98.ps,” of the paper to be relatively obscure and not reasonably likely to be found by a contemporaneous PHOSITA.
	+ Furthermore, the FTP server did not provide an index, catalogue, or other meaningful research tool to find the paper.
	+ Distinguishing *Klopfenstein*, the court analogized the paper on the FTP server to a poster at an unpublicized conference without a conference index of the location of the various poster presentations.

### The Strict Identity Rule of Anticipation

The strict identity rule states that in order to evidence anticipation of a claimed invention under 35 U.S.C. §102, ***a prior art reference must disclose every element of that invention, arranged as in the claim***.

For example, consider a patent claim that recites “a widget comprising part A attached to part B by means of part C.” The claim is *not* anticipated by a combination of two prior art references in which one reference shows a widget having part A attached to part B by means of part D, and a second reference shows that part D is equivalent to part C. However, this combination would likely give rise to an *obviousness* claim under 35 U.S.C. §103.

### The Special Case of Species/Genus Anticipation

A *genus* is a grouping or category made up of multiple *species* that share some common characteristic. Genus/species claiming is often, but not exclusively, encountered in chemical biotechnological patents.

Species anticipates a genus, but a genus does not necessarily anticipate species. Consider a mechanical patent application in which the inventor has claimed “a widget comprising a fastening mechanism.” The “fastening mechanism” can be viewed as a genus of all items that would perform a fastening function. The inventor is therefore claiming a genus of widgets; that is, every widget within the claimed genus of widgets having a fastening mechanism is part of his novel invention.

However, a prior art reference depicting a widget in which a nail operates as a fastening mechanism would refute the inventor’s claim that the entirety of his claimed genus of widgets is novel. ***The genus as a whole cannot be new if one or more of its constituent species is old***.

The converse is not always true. Consider a patent application in which the inventor has claimed “a widget comprising a nail” and a reference is cited describing a “widget fastening mechanism.” So long as the reference does not expressly or inherently disclose that “fastening mechanism” includes “a nail,” there is no anticipation – the strict identity rule is not met. However, it is likely the applicant would receive an obviousness rejection under 35 U.S.C. §103.

### Geographic Distinctions in §102

Under subsections 102(a) and 102(b), an invention is not patentable ***if it was “patented or described in a printed publication” anywhere in the world***, either

* before the invention date [per §102(a)], or
* more than a year before the filing date [per §102(b)].

On the other hand, the following count as anticipations or losses of right only if these events took place ***in the United States***:

* ***prior “knowledge or use by others”*** under §102(a); and
* ***“public use”*** or ***placing the invention “on sale”*** under §102(b)

The geographic distinctions in §102 may reflect a recognition that the search costs of discovering knowledge and use in a foreign country would be unfairly burdensome if placed on U.S. inventors.

### Who Is the Actor?

An important distinction between §102(a) and 102(b) is the identity of the persons who can trigger those subsections and by their actions destroy patentability.

***Anticipation*** under §102(a) must involve *someone other than the patent applicant*.

***Loss of right*** to patent under §102(b) can be the result of acts of *anyone*, including (and in the case of public uses and sales, most often because of) the applicant.

Note: an inventor’s own work can only be used against him as prior art if it constitutes a §102(b) bar.

### Anticipation by Inherency

The strict identity rule for anticipation provides that in order to anticipate a claimed invention, a single prior art reference must disclose *every* element of that invention, arranged as in the claim. A reference’s disclosure of individual elements is usually explicit, but case law makes clear that the disclosure can also be *inherent*.

Stated another way, if the practice of the prior art reference would *inevitably* have resulted in the claimed invention, a rejection of the claim as anticipated would be justified under these circumstances.

If, however, the extrinsic evidence presents a legitimate question as to whether the reference would have resulted in the applicant’s invention, then anticipated by inherency is not established.

Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, the disclosure is sufficient.

* *In re Robertson*
	+ The Federal Circuit sharply limited the use of “inherency” in showing that an existing product anticipates an invention. Robertson sought a patent on a diaper which had a fastener dedicated to keeping the diaper rolled up for disposal. A similar diaper (the Wilson diaper) was similar to Robertson’s diaper in most respects but lacked a dedicated fastener for disposal.
	+ The court allowed Robertson’s claim on the ground that Wilson’s design contemplated no special fastener for use during disposal. The court criticized the Board for concluding that Robertson’s design was “inherent” because the existing fasteners on Wilson’s diaper could be used to keep a diaper rolled up.
	+ The court stated that inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient

The doctrine of anticipation by inherency should be distinguished from situations in which the claimed invention was ***accidentally*** made or performed previously by others but not appreciated at the time.

* *Tilghman v. Proctor*
	+ Tilghman discovered a new process for breaking down animal fat where the process required merely for the fat to be mixed with water and then subjected to high temperature and pressure. One of the prior art references cited against Tilghman was a steam engine invented had been lubricated with animal fat.
	+ The court held Tilghman’s invention was not anticipated because of the accidental formation of fat acid in the steam cylinder. The process was never fully understood and those in the art never derived the least hint from this accidental phenomenon.
	+ If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting the attention and without its even being known what was done or how it had been done, it does not aniticpate.

Although older Supreme Court cases such a *Tilghman* might suggest that inherent anticipation requires *recognition* by prior art workers of the fact of the earlier making or performing of the invention, most judges of the Federal Circuit have rejected any contemporaneous recognition requirement. In *Schering Corp. v. Geneva Pharms., Inc.*, the court flatly rejected the contention that inherent anticipation requires recognition in the prior art.

### Enablement Standard for Anticipatory Prior Art

Anticipation requires the description in a single prior art reference of every element of a claimed invention. Another consideration is the *quality* of that description. In order to anticipatory, the prior art reference must describe the claimed invention in an enabling fashion, that is, with sufficient detail that a PHOSITA could make what it described in the prior art reference without undue experimentation.

For example, if an inventor files a patent application claiming a new chemical compound X, and a prior art reference describes merely the chemical formula of X but does not describe how to make X, the reference would not be adequate to anticipate because it is not enabling – this assumes that the method of making compound X would not otherwise have been obvious to a PHOSITA.

* *In re Hafner*
	+ A disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same not, entirely inadequate to support the allowance of such a claim.

## Known or Used within 35 U.S.C. §102(a)

Judge Learned Hand viewed anticipation under §102(a) as requiring that the anticipatory knowledge exist in a manner accessible to the public; that is, it must be “part of the stock of knowledge of the art in question.” The current majority rule clearly contemplates that “knowledge and use” under §102(a) must be that which is available to the public.

* *Gayler v. Wilder*
	+ Wilder owned a patent directed to a fireproof safe. The safe was constructed of inner and outer iron chests, between which was placed an inflammable material.
	+ Gayler, having been sued by Wilder for infringement, defended on the ground that the patent was invalid as anticipated by the prior knowledge or use of the safe by others. The invalidity defenses were based on the independent prior invention of the same safe by one Connor. Connor made the safe for his own business use and kept it where his employees passed by it on a daily basis.
	+ The Supreme Court held, because those persons were not aware of the safe’s internal construction, they did not possess “knowledge or use of the invention.”

Thus, to anticipate, prior knowledge or use of an invention by others in this country must have been knowledge or use that was accessible to the public. As between the earlier inventor who maintains his invention in secrecy, and a later inventor who is first to put the public in possession of the invention by entering into the patenting process, the patent law rewards the latter.

* *Nat’l Tractor Pullers Ass’n v. Watkins*
	+ The Ass’n contended that a device designed by three other men (the Huls device) anticipated Watkins’s patent on a tractor pulling sled. The Ass’n alleged that the Huls device was outlined in a diagram drawn on a tablecloth, but it could not produce the tablecloth itself.
	+ The court upheld Watkins’s patent because the tablecloth did not constitute public disclosure of the Huls device. The drawings were never available to the public as they were drawn on the underside of a table cloth and were never printed.
* *Rosaire v. National Lead Co.*
	+ Rosaire obtained methods patents for prospecting for oil. The patents were found invalid under §102(a) because a Gulf employee, Teplitz, had conceived and used the method previously.
	+ Teplitz’s use in one field was stopped but it was due to the poor quality of the field, not his desire to abandon the invention. The court held the plain use of the method, where no employees were held to secrecy, was sufficiently public use. ***Teplitz was under no obligation to publish his work as a prerequisite to invalidating the patents***.

## The Statutory Bars of 35 U.S.C. §102(b)

### Introduction

§102(b) lists four different ways in which, even though an invention may have been novel as of its invention date, the right to a patent on that invention nevertheless can be lost or forfeited. These four triggering events, also referred to as ***statutory bars***, are as follows: ***more than one year before the application’s filing fate, the invention was***:

1. Patented anywhere in the world;
2. Described in a printed publication anywhere in the world;
3. In public use in the United States; or
4. On sale in the United States

Patent attorneys refer to the date that is one year prior to the application filing date as the ***critical date*** for §102(b) purposes. Thus, in order to trigger the 35 U.S.C. §102(b), a statutory bar event must have occurred prior to the critical date.



Policies underlying the statutory bars include:

1. Minimize detrimental reliance by public on inventions not freely available for use
2. Encourage prompt dissemination
3. Prohibit undue commercial exploitation
4. Evaluate marketplace reaction

### Grace Period

A U.S. patent applicant enjoys a “grace period” or “safe harbor” under 35 U.S.C. §102(b) comprising the one year time period between the §102(b) critical date and his application filing date. During this one year pre-filing date grace period, an invention may be patented, described in a printed publication, in public use, or on sale, all without triggering a §102(b) loss of right.

Countries other than the US are generally “absolute novelty” systems that do not recognize any pre-filing date grace period. For example, under the European Patent Convention, any activity that makes an invention part of the “state of the art” at any time prior to the filing date of the European patent application will defeat novelty. Thus, when clients want to obtain patent protection in foreign countries as well as in the US, they should be advised not to make clients want to obtain patent protection in foreign countries as well as in the US, they should be advised not to make *any* public disclosure of their inventions at any time prior to filing their priority patent application.

### §102(b) Public Use

Because the Patent Act does not define what specific acts will trigger the “public use” or “on sale” statutory bars, we look to case law. Broadly speaking, a public use occurs when, prior to the 35 U.S.C. §102(b) critical date, the inventor “releases control” over her invention, effectively dedicating it to the public.

The key criterion of the public use bar is whether the inventor kept “control” over the use of the invention. Such “control” does not necessarily require that the inventor kept the invention locked away in secret. Patent rights are lost or forfeited when an inventor acted in such a way as to indicate an intent to abandon or otherwise dedicate the invention to the public.

*Egbert* teaches us (1) a single version, prototype, or person that uses satisfies public use, and (2) even if the invention is used within another product it may still constitute public use.

* *Egbert v. Lippmann (1881)*
	+ The inventor of an improved women’s corset gave his “intimate friend,” before the critical date, a pair of corset-steels that he had made without imposing on his friend any obligation of secrecy of restriction on her use of the steels.
	+ The Supreme Court held that the inventor’s acts amounted to a public use that invalidated the corset patent, noting that the inventor’s friend might have exhibited the steels to any person, or made other steels of the same kind, and used or sold them without violating any condition or restriction imposed on her by the inventor.
	+ ***The Court concluded that whether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known. If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person.***
		- Note this case decide under old regime when “grace period” was 2 years long.



* *Moleculon Research Corp. v. CBS, Inc. (1986)*
	+ Moleculon, assignee of a patent on a 3-D, rotating puzzle invented by Nichols, sued CBS (successor to a toy manufacturer) alleging patent infringement by certain of the well-known Rubik’s Cube puzzles. CBS answered by alleging that the Nichols patent was invalid for public use of the claimed invention more than a year before the patent application’s filing date.
	+ The evidence reflected that prior to the critical date, Nichols showed paper mockups of the puzzle to his friends. When he was later employed by Moleculon but still prior to the critical date, Nichols brought into his office a working wood-block prototype of the puzzle that he had built.
	+ Nichols showed the puzzle to the president of Moleculon and explained its workings. Moleculon thereafter undertook to patent and commercialize the puzzle.
	+ The court held, unlike the inventor in *Egbert*, ***Nichols had not given over the puzzle invention for free and unrestricted use by others. Rather, Nichols at all times retained control over the puzzle’s use and the distribution of information concerning the puzzle.***
	+ Nichol’s use was private and for his own enjoyment; he never used the puzzle or it to be used in a place or time when he did not have a legitimate expectation of privacy and confidentiality.
	+ ***Rule: if the inventor does not relinquish control of the invention and there is an expectation of secrecy, it does not constitute prior use.***

A patent can be invalidated for public use even though the claimed invention was used in secret. The common threat of the “non-informing public use” cases is the inventor’s secret commercialization of the invention outside of the statutory grace period.

* *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*
	+ The inventor Meduna obtained a patent on a process of conditioning metal surfaces, useful for building up worn metal machine parts. Prior to the critical date Meduna used his process on jobs for numerous commercial customers but without disclosing any details about the process, which also were not discernible from inspecting the finished metal surface.
	+ An inventor may continue for more than a year to use his invention for his private enjoyment and later patent it. But when he makes use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his monopoly.

### §102(b) On Sale Bar

Operations of the “on sale” bar results in a loss of right to a patent when an invention has been sold or offered for sale more than 1 year before the application filing date (i.e., outside of the one-year pre-filing date grace period).

The statutory phrase “on sale” is understood as meaning “placement on sale,” which encompasses offers to sell as well as completed sales. Moreover, a mere offer to sell even a single unit of the invention will trigger the §102(b) clock so long as the offer meets certain “commercial-ness” requirements established in the on sale bar case law.

Offers to sell or sales on an invention outside of the §102(b) grace period will result in a loss of right to patent (if known to the USPTO), or will invalidate an issued patent if the practical date activity does not come to light until the time of subsequent litigation challenging the patent’s validity.

A key issue in many on sale bar cases is what state of development the invention must be in before the inventor possesses an “invention” capable of being placed on sale within the meaning on §102(b). For example, an offer of a mere undeveloped “concept” cannot trigger the §102(b) clock. On the other hand, the invention need not necessarily have been actually reduced to practice in order to be capable of placement on sale.

***In order to be “on sale” within the meaning of 35 U.S.C. §102(b), two conditions must be satisfied before the critical date***:

1. The invention must be the subject of a commercial offer for sale; and
2. The invention must be ready for patenting.

A “commercial offer” is one definite enough to qualify as an “offer” in the general contract law sense, as exemplified by the definition of “offer” under the UCC – only an offer which rises to the level of a commercial offer for sale, one which the other party could make it into a binding contract by simple acceptance constitutes an offer for sale under §102(b).

The “ready for patenting” condition can be satisfied in “at least” two ways:

1. The invention may have already been actually reduced to practice; or
2. The invention may have at least been “reduced to drawings” in the sense that drawings or written descriptions of the invention exist that are sufficiently specific enough to enable a person having ordinary skill in the art to practice the invention.

The second condition was held satisfied in *Pfaff v. Wells Elec., Inc.*

* *Pfaff v. Wells Elec. Inc.*
	+ Prior to the critical date, the inventor had offered to sell thousands of units of his invention, a simple mechanical socket for holding computer chips during testing. Despite the fact that at the time of the offer, Pfaff had not actually constructed any of the sockets, the Supreme Court considered the invention ready for patenting such that the §102(b) bar was triggered.
	+ Detailed mechanical drawings and descriptions of the sockets existed as of the date that Pfaff accepted the purchase order (prior to the critical date), and the Court considered this information to have been enabling. The Court supported its conclusion by nothing that the purchaser was able to produce the sockets using Pfaff’s drawings and specifications, and that those sockets contained all the elements of the invention as later claimed in Pfaff’s patent.

### Experimental Use Negation of the §102(b) Bars

In *City of Elizabeth*, the Supreme Court clarified that “the use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as public use within §102(b).”

The Court characterized experimental use as use of an invention “only by way of experiment,” that is “pursued with a bona fide intent of testing the qualities” of the invention. So long as the inventor “does not voluntarily allow others to make the invention and use it, and so long as it is not on sale of general use, he keeps the invention under his own control, and does not lose his title to a patent.”

* *City of Elizabeth v. American Nicholson Pavement, Co. (1878)*
	+ The inventor/patentee Nicholson developed a method of paving streets using wooden blocks in a checker-board fashion, which he tested by paving a well-traveled section of public carriage road in Boston.
	+ Nicholson did not file a patent for 6 years after commencing the testing, he did not lose his right to patent due to the experimental use doctrine.
	+ Testing the roads extended durability while exposed to the elements was essential, Nicholson’s pavement invention was not of the type that could be satisfactorily tested anywhere other than a public road.
	+ Importantly, Nicholson’s intent to test his invention was bona fide, and the evidence proved he kept the invention under his control by checking it on a very regular basis.

## Abandonment under 35 U.S.C. §102(c)

This is referring to a waiver or forfeiture of the right to patent protection on the invention. This is rarely seen.

## Foreign Patenting Bar of 35 U.S.C. §102(d)

This is rare but this statutory bar is triggered when:

1. an inventor files a patent application in a foreign country,
2. files another application on the same invention in the US more than one year later, and
3. the inventor’s foreign patent has already issued before her U.S. filing.

## Description in another’s Earlier-Filed Patent or Published Patent Application under 35 U.S.C. §102(e)

Subsection (e) of §102 involves anticipation through the *description* (though not *claiming*) of the applicant’s invention in a patent or published patent application of another, where that “other” files her application in the US before the applicant’s invention date.

This subsection was made part of the Patent Act in order to statutorily codify the rule announced by the Supreme Court in *Alexander Milburn Co. v. Davis-Bournoville Co.*

* *Alexander Milburn Co. v. Davis-Bournoville Co.*
	+ Rule: A prior art U.S. patent is to be treated as constructively published as soon as it is filed. Thus, the effective date of the written description portion of a U.S. patent being used as §102(e) prior art is its U.S. filing date.

The policy rationale behind the rule in *Milburn* is that the presence of a description of the invention that the application is claiming in someone else’s earlier-filed patent application evidences that the applicant was *not* in fact the first to invent that subject matter. Based on the existence of the earlier-filed description, the law presumes that the first to invent is someone other than our patent applicant.

The §102(e) reference application need never issue as a patent, so long as the application is published.

An international application filed under the Patent Cooperation Treaty (PCT) also can be relied on by the USPTO as a §102(e)(1) reference if: (1) the international applicant designated the US; and (2) it was published under the PCT in the English language.

The effective date of a 35 U.S.C. §102(e) reference, whether it is an issued U.S. patent or a published patent application, remains the same in either case: the effective date is the U.S. application filing date of the reference patent or application.

## Prior Invention under 35 U.S.C. §102(g)

§102 comprises two prongs. ***The first prong, §102(g)(1), deals with priority contests called interferences between two or more parties who claim to have made the same invention at about the same time.*** There interference, an *inter partes* proceeding conducted within the USPTO, will determine which party was first to invent and hence entitled to the U.S. patent on the invention in question.

***The second prong, §102(g)(2), deals with anticipation of the claims of a patent (if Federal Circuit litigation challenging validity) by the act of someone other than the named inventor of the application or patent having made the invention in this country before the invention date of the application or patent***.

In both the interference and anticipation settings, the earlier invention must not have been abandoned, suppressed, or concealed.

### Interference Proceedings under §102(g)(1)

When two (or more) parties (i.e., inventive entities) apply for a U.S. patent on the same invention, each party having independently made the invention (i.e., not copied it), we cannot award both parties their own patent. Instead, the U.S. patent system has devised a procedure that awards the patent to the party who was the first to invent, regardless of the order in which the parties filed their respective patent applications.

***The competing claimants must participate in an interference proceeding, an inter partes adjudicatory proceeding within the USPTO to determine which party invented first***. The party who is the last to file her patent application (the junior party) bears the burden of overcoming a presumption that the first to file (the senior party) was also the first to invent. Thus, the party who was the first to file an application on the invention in question is presumptively entitled to the patent, *unless* the other party can successfully overcome this presumption.

***Evidence of earlier invention in an interference proceeding can be based on inventive activity outside the U.S. in accordance with the current version of 35 U.S.C. §104. This permits the use of evidence of inventive activity (e.g., conception, diligence, and reduction to practice) that (1) occurred on or after Dec. 8, 1993 in NAFTA countries; and (2) on or after Jan. 1, 1996 in WTO countries.***

* *Brown v. Barbacid*

### Anticipation under §102(g)(2)

The second subsection of §102(g) does not apply in the interference setting, but rather in either *ex parte* prosecution of a patent application or in Federal Circuit litigation challenging the validity of an issued patent. In this instance, a USPTO examiner is asserting under §102(g)(2) that some other inventor’s earlier making of the invention in this country is prior art that prevents the grant of a patent on the same invention to a patent applicant. If in the litigation setting, the challenger of validity (usually the accused infringer) is asserting that some other inventor’s earlier making of the invention in this country should invalidate the patent in suit.

An invention is anticipated under 35 U.S.C. §102(g)(2) if it was “made in this country by another inventor” before the applicant’s invention date and the prior inventor has not subsequently “abandoned, suppressed, or concealed” her invention.

Thus, ***§102(g)(2) is triggered by an earlier “making” of the invention in this country by another inventor, coupled with some sort of introduction of that invention to the U.S. public within a reasonable time period thereafter, whether by patenting, publication, sales, or the like.*** The prior inventor need not file a patent application on her invention, but she must take other action within a reasonable time after her actual reduction to practice to ensure that the public has obtained knowledge of the invention.

***In contrast with interferences under 35 U.S.C. §102(g)(1), the earlier invention that is relied on to anticipate (i.e., destroy novelty) under 35 U.S.C. §102(g)(2) must have been made in the U.S.*** In other words, the prior making of an invention relied on to anticipate or invalidate only “counts” under §102(g)(2) if it occurred in the U.S.

* *Dow Chemical Company v. Astro-Valcour, Inc.*
	+ An existing product may act as prior art even if the inventor of that product did not realize that it constituted a patentable invention.
	+ Astor-Valcour (AVI) manufactured plastic foam products. Although CFCs had traditionally been used as the “blowing agents” for inflating the foam, environmental concerns motivated AVI to find alternatives. AVI learned that a Japanese company used isobutane (a non-CFC gas) to turn polystyrene into Styrofoam. After finding that isobutane could be adapted for producing plastic foam, AVI obtained a license to use the isobutane-based inflation process.
	+ Dow subsequently obtained a patent covering the sort of foam that AVI was producing. When Dow sought to enforce its patent against AVI, the court invalidated Dow’s patent because the claimed invention was already being practiced by AVI when Dow applied for the patent.
	+ The court said: “Whether AVI understood that it had produced a legally patentable invention is immaterial for [the] purposes of § 102(g)(2). It is enough that the AVI employees appreciated the fact of their invention.”

### Applying the Priority Rules of §102(g)

The last sentence of §102(g) can be restated and thought of as:

*Generally*, the first to reduce to practice (who thereafter does not abandon, suppress, or conceal) is the first to invent, *unless* the last to reduce to practice is also the first to conceive and sufficiently diligent.

The date of conception is the date at which there is the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”

A reduction to practice is either actual or constructive. An *actual* reduction to practice occurs when a physical embodiment of the invention has been constructed that works for its intended purpose. A *constructive* reduction to practice occurs upon the filing of a patent application that satisfies the disclosure requirements of 35 U.S.C. §112, ¶1.

Reasonable diligence is proved by evidence that the inventor was continuously active in working toward a reduction to practice of the invention she conceived, or that a legitimate excuse exists for any inactivity during the relevant time period.

Examples:



## Antedating (or “Swearing Behind”) Prior Art (Rule 131)

The USPTO will assume that an application’s filing date is the applicant’s invention date, based on the theory that filing an application that satisfies the disclosure requirements of §112 for the subject matter claimed therein represents a constructive reduction to practice of that subject matter.

If the USPTO examiner locates a §102(a) or §102(e) reference that describes that identical invention in an enabling manner and has an effective date earlier than the applicant’s filing date, such reference is presumptively anticipatory.

In order to eliminate the cited reference as prior art, the patent applicant must show that she invented the subject matter of the rejected claim(s) prior to that effective date of the reference. In other words, the applicant must show that she, rather than the author of the reference, was the first to invent the claimed subject matter.

A patent applicant antedates a §102(a) or §102(e) reference by filing an appropriate affidavit or declaration to establish that she invented the subject matter of her rejected claim(s) prior to the effective filing date of the reference cited by the USPTO examiner. The showing of facts in the affidavit or declaration must establish either (1) an actual reduction to practice of the invention prior to the effective date of the reference, or (2) conception of the invention prior to the effective date of the reference coupled with due diligence from just prior to the effective date until a subsequent actual reduction to practice date or to the filing date of the patent application.

The antedating procedure of Rule 131 cannot be used to overcome a statutory bar reference, such as a printed publication under 35 U.S.C. §102(b). This reflects the policy of encouraging prompt filing of patent applications on novel inventions. Nor can antedating be used where the prior art reference is a U.S. patent or published patent application of another that *claims* the same patentable invention. In such a case the basis of the rejection would be 35 U.S.C. §102(g)(1), and the applicant may suggest an interference.

Lastly, a §102(g)(2) rejection cannot be overcome by the Rule 131 antedating procedure.

# The Nonobviousness Requirement (35 U.S.C. §103)

## Introduction

Patentability requires “something more” than novelty. An invention may be technically novel, such that none of the novelty-destroying or loss of right provisions of 35 U.S.C. §102 are triggered. But to be patentable, the invention also must represent enough of a qualitative advance over earlier technology to justify a patent.

35 U.S.C. §103(a) states that “a patent may not be obtained though the invention is not identically disclosed or described as set forth in §102.” This qualifying language indicates that nonobviousness is an additional condition that must be satisfied for patentability, even if the invention is not anticipated under one or more subsections of §102.

* *Graham v. John Deere (1966)*
	+ Graham invented a device designed to absorb shock from the shanks of plows and prevent damage to the plow as they plowed through rocky soil. Graham solved the problem by attaching the plow shanks to spring clamps, to allow them to flex freely underneath the frame of the plow. Graham obtained patent ‘811 and then ‘798 on improvements. Graham filed suit against John Deere claiming infringement of ‘798.
	+ The test for obviousness is whether the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.
	+ The Court held there were no nonobvious facets of ‘798 and declared the patent invalid.

## The *Graham v. John Deere* Framework for Analyzing Nonobviousness

### *Graham*’s Analytical Framework for a §103 Analysis

Turning to the details of applying the 35 U.S.C. §103 standard, the Supreme Court in *Graham v. John Deere* explained that nonobviousness is ultimately a question of law, the answer to which depends on several underlying factual inquiries. These factual inquiries, referred to as the *Graham* factors, must be answered in any determination of nonobviousness, whether made in the USPTO or by the courts.

Four factors that are essential to every nonobviousness analysis:

1. Level of ordinary skill in the art;
2. Scope and content of the prior art;
3. Differences between the claimed invention and the prior art; and
4. Secondary considerations (i.e., objective indicia of nonobviousness)

## *Graham* Factor: Level of Ordinary Skill in the Art

The level of ordinary skill in the technology of the invention is the perspective and skill set, possessed by the hypothetical PHOSITA, that the question of nonobviousness must be resolved. The proponent of validity usually will attempt to establish as law a level of ordinary skill as possible, such that the invention would have been considered nonobvious by the largest possible number of persons, while the challenger of validity typically will seek to raise that level.

In making a finding on the level of ordinary skill in the art, courts or juries will take into consideration some or all of the following types of evidence:

* Education level of the inventor;
* Education level of a typical work in the field (e.g., whether a PHOSITA would have a high school degree, college undergraduate or graduate degree – master’s or Ph.D.);
* Type of problems encountered in the technology and previous solutions to such problems;
* How quickly new innovation occurs in the technology; and
* Sophistication of the technology (e.g., is the invention a fishing lure or a method of cloning a gene?).

The educational level and expertise of the *inventor* do not necessarily equate to the level of ordinary skill of a hypothetical PHOSITA for the inventor may be a person of extraordinary skill.

## *Graham* Factor: Scope and Content of the Prior Art

### Sources of Prior Art

In evaluating the “scope and content of the prior art” *Graham* factor, the USPTO and the courts may obtain the prior art from several different sources. In a typical USPTO *ex parte* patent prosecution, the patent applicant will submit relevant prior art of which it is aware in the form of “Information Disclosure Statement.” In addition, the examiner will conduct her own independent research of the prior art accessible to the USPTO.

If an issued patent’s validity is being challenged in Federal Circuit, the accused infringer (i.e., the challenger of the validity) will introduce into evidence the prior art it seeks to have considered. Typically this prior art will include newly discovered prior art, that is, prior art documents or events that were not known to or considered by the USPTO during the initial examination of the patent application but that have been unearthed through the litigation discovery process. Introduction of such “new” prior art, which may be more pertinent than that considered by the USPTO, does not weaken the patent’s presumption of validity. Such introduction can nevertheless facilitate the validity challenger’s carrying of its burden to prove invalidity by clear and convincing evidence, for it would require the patentee to come forward with countervailing evidence.

### §102/103 Overlap

35 U.S.C. §102, the statutory provision that governs novelty and loss of right, is key to determining the scope of the prior art properly available in a *Graham* analysis under §103. §102 can be conceptualized as a catalog of the universe of information that may potentially qualify as prior art for purposes of a §103 nonobviousness analysis. This means, any reference relied on in determining nonobviousness must qualify as prior art under one or more subsections of §102.

***For example***, consider a third party’s sale of a product more than one year before the applicant’s filing date, which product was similar to but not anticipatory of (i.e., strictly identical to) the claimed invention. The third party’s sale of that product would not result in a loss of right to a patent on the claimed invention under §102(b), because the strict identity rule of anticipation would not be satisfied. However, if the PHOSITA would have been motivated to make the claimed invention by modifying the features of the sold products, in accordance with other knowledge available at that time to the PHOSITA (qualifying under §102), then the invention would have been unpatentable as obvious under §103.

### Analogous Act

Although 35 U.S.C. §102 provides a catalog of prior art that may be available for a 35 U.S.C. §103 obviousness rejection, *not all* prior art that otherwise qualifies under some subsection of §102 is properly used in a §103 analysis. In order to be considered in a nonobviousness analysis, prior art references also must be analogous art.

Analogous art is prior art that a PHOSITA would reasonably have consulted in solving the problem addressed by the claimed invention. The law recognizes that the PHOSITA cannot know all prior art in every field, and thus “attempts to more closely approximate the reality of the circumstances surrounding the making of an invention by only presuming knowledge by the PHOSITA of prior art in the field of his endeavor and in analogous arts.” This is known as the *Wood* formulation.

***When faced with a particular problem, it is reasonable to assume that that person would have consulted the following two categories of information:***

1. Prior art within the same field of endeavor as the invention; and
2. Prior art from a different field of endeavor, but reasonably pertinent to the same problem as that addressed by the invention.

Analogous art is the §102 prior art that is legally permissible to use in a §103 analysis, and it must arise from the same technological field as the claimed invention or be directed to the same problem even if in a different technological field.

Applying prong 1 of the *Wood* formulation necessarily requires determining the “same field of endeavor” for a given invention.

* *In re Bigio*
	+ The USPTO rejected Bigio’s claims for an ergonomically designed hair brush as obvious in view of two patents for tooth brushes.
	+ First, the court applied “the broadest reasonable interpretation” rule to approve USPTO’s interpretation of the claim term “hair brush” as encompassing “not only brushes that may be used for human hair on a scalp, but also brushes that may be used for hairs on other parts of animal bodies.”
	+ Second, in view of the broad claim interpretation, toothbrushes fell within the field of endeavor of Bigio’s invention; namely, the “field of hand-held brushes having a handle segment and a bristle substrate segment.”

Notably, in contrast with nonobviousness under §103, there is no analogousness requirement for prior art to qualify as *anticipatory* under §102. All references that qualify as prior art under some subsection of §102, regardless of their relationship to the field of the claimed invention or the problem addressed thereby, are available for an anticipation rejection, so long as the strict identity rule of anticipation is satisfied.

## *Graham* Factor: Differences between Claimed Invention and Prior Art

There must be some identifiable difference(s) between the prior art and the claimed invention; otherwise, the invention would be anticipated under §102.

For example, the identifiable differences between the claimed plow shank of the ‘798 patent at issue in *Graham v. John Deere* and the prior art plow shank (the ‘811 patent) included moving the hinge plate from below to above the shank, in order to provide the shank with greater flexing ability.

The question to be answered under §35 U.S.C. §103 is not whether *the differences* themselves would have been obvious to the PHOSITA. Rather, §103 asks whether the *subject matter as a whole* (i.e., the claimed invention as a whole) would have been obvious, in view of those differences plus the other factors required by the *Graham* analysis.

## *Graham* Factor: Secondary Considerations

Secondary considerations is evidence that focuses on the impact of the claimed invention on the marketplace rather than its technical merits. Thus, the final *Graham* factor is based on economic and motivational facts and data that underlie the making and marketing of the invention.

Common types of secondary considerations evidence include evidence showing the failure of others to solve the problem addressed by the invention, the commercial success of the invention, the existence of a long-felt need for the invention, the licensing and acquiescence of others to the patent at issue, and copying of the invention.

### The Weight to be Accorded Secondary Considerations Evidence

The Federal Circuit has held that where secondary considerations evidence is present in the record, it must be considered in determining nonobviousness.

When a patentee relies on secondary considerations evidence in the form of commercial success in attempting to establish nonobviousness, a court must consider marketplace realities in determining what weight that evidence should be given.

* *Merck & Co. v. Teva Pharms.*
	+ Even though commercial success was successfully proven by the patentee, the Federal Circuit held, due to the particular facts of the case, it was only minimally probative of nonobviousness.
	+ The court instructed that commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.
	+ The court concluded that because market entry by others was precluded on the basis of a separate Merck-owned patent and Merck’s statutory right to sell the drug at any dosage for 5 years, the inference of nonobviousness of weekly dosing, from evidence of commercial success, is weak.

### The Nexus Requirement for Evidence of Commercial Success

Evidence of commercial success may be sales volumes and market share. Such evidence is only probative of the nonobviousness of the invention if a sufficient *nexus*, or causal relationship, exists between the commercial success and features recited in the claims.

For example, suppose that the patentee in *Graham v. John Deere* had introduced evidence showing that the commercial embodiment of his patented invention had captured 50% of the U.S. market for plow shanks in each year since the product was introduced. This hypothetical evidence would be probative of nonobviousness only if the patentee could show that his sales success was due to consumer desire for the claimed features of the patented plow shank (i.e., its shock-absorbing design). If farmers bought the patented plow shank only because it was painted purple and became a novelty for that reason, or because the inventor drastically cut its price to a point far below that of competitors’ plow shanks, the alleged commercial success evidence would be rejected as nonprobative of nonobviousness *of the claimed invention*.

In *Iron Grip Barbell Co. v. USA Sports, Inc.*, the Federal Circuit held that a nexus could not be inferred from the mere existence of licenses. In *Iron Grip*, 3 out of 6 retail competitors had taken licenses under the patent but the Federal Circuit stated that is it often cheaper to take a license that to defend a patent infringement suit.

## Combining the Disclosures of Prior Art References to Establish Obviousness

Frequently, a §103-based rejection of pending application claims in the USPTO (or a §103 challenge to the validity of an issued patent) will be founded on the argument that the respective disclosure of two or more prior art references, in combination, would have rendered the claimed invention obvious. This argument contends that the PHOSITA would have been motivated to combine their teachings and that theses combined teachings would have rendered the claimed invention obvious to the PHOSITA.

### Teaching, Suggestion, or Motivation to Combine

In order for a “combination of references” types of obviousness argument to be legitimate, there must exist some teaching, suggestion, or motivation (TSM) that would have suggested making the claimed combination.

For example, suppose that a patent claim recites “a widget comprising a lever arm A, a pulley B, and a spring C.” Suppose further that the USPTO examiner has rejected the claim as obvious, based on the combine teachings of prior art Reference 1, which shows a widget having a lever arm A; Reference 2, which shows a gizmo having a pulley B, and Reference 3, which shows a whatzit having a spring C. by extracting the relevant parts, the examiner has effectively re-created the patented invention by using the claim as a blueprint. If the references themselves or other prior art do not suggest the viability of making the combination, it is not available for a basis for rejection.

The law is clear that the record must contain adequate evidence of a suggestion to combine the references.

The Federal Circuit has held that such motivation may be found in the nature of the problem to be solved; the prior art references themselves need not provide an express, written motivation to combine. The motivation to combine may be found in two pertinent prior art references which address precisely that same problem as the claimed invention.

### KSR v. Teleflex: Combinations, Predictability, and “Common Sense”

The Court’s decision also stressed the role of “common sense” and “predictability” in determining whether an invention would have been obvious, but did not define those terms or clearly explain how they inform the statutory standard of §103.

* *KSR Int’l Co. v. Teleflex, Inc.*
	+ The Court examined what constitutes an adequate TSM to combine prior art disclosures.
	+ The patent in suit, owned by Teleflex, was directed to a “vehicle control pedal apparatus” incorporating an electronic sensor in a vehicle’s accelerator pedal. The sensor was capable of changing the pedal’s position depending on the height of the vehicle’s driver. More specifically, the apparatus combined the electronic sensor with an adjustable automobile pedal so that the pedal’s position could be transmitted to a computer controlling the throttle in the car’s engine.
	+ The primary prior reference relied on by validity challenger KSR was a U.S. patent to Asano. The Asano patent disclosed an adjustable pedal such that even when adjusted relative to a driver’s height, one of the pedal’s pivot points would remain fixed. The problem addressed by the Asano invention was a “constant ratio” problem – ensuring that the force required to depress the pedal always remain the same, no matter how the pedal was adjusted.
	+ Teleflex argued before the Federal Circuit that the problem its own invention solved was different – to design a smaller, less complex, and cheaper electronic pedal assembly. Teleflex contended Asano’s mechanical linkage-based device was complex, expensive to make and difficult to package.
	+ Asano provided an “obvious example” of an adjustable pedal with a fixed pivot point, and other prior art indicated that a fixed pivot point was the ideal location to mount a sensor.

### Teaching Away

Whether motivation to combine exists also must take into consideration whether any of the references to be combined actually teach away from the claimed invention. To teach away means that a prior art reference’s disclosure would discourage or dissuade the PHOSITA from doing what the inventor actually and successfully did.

Such a “teaching away” argument is not pertinent to the question of novelty under §102. A strict identity test controls anticipation. If a single prior art reference identically discloses every limitation of a claimed invention, arranged as in the claim, then it anticipates, even if the reference criticizes the invention or would otherwise discourage a PHOSITA from making the invention.

### “Obvious to Try”

The Court in *KSR* breathed new life into obvious to try arguments by redefining obvious to try situations. The Court stated that when determining whether a claimed invention would have been obvious two conditions must be met:

1. Does the prior art identify “predictable” solutions? and
2. Are such solutions “finite”?

# Patent Infringement

## Introduction

### Statutory Framework

U.S. courts recognize two basic forms of infringement: (1) ***literal infringement***, and (2) infringement under the judicially created ***doctrine of equivalents***.

Literal infringement means that an accused product or process comes precisely within the terms of an asserted patent claim.

Infringement under the doctrine of equivalent recognizes that, in order to adequately protect a patentee, we may sometimes extend the scope of her rights to exclude beyond the literal boundaries of the claim.

§271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

#### Direct versus Indirect Infringement under 35 U.S.C. §271

The act of “making” the claimed invention under §271(a) requires that an accused infringer has manufactured a device that meets each and every limitation of the asserted claim. Generally speaking, this means that if the claimed invention is a combination of elements, the accused device must be fully assembled and ready for use.

The act of merely making the claimed invention without authority creates infringement liability, even if the accused infringer thereafter does not sell the infringing device. Likewise, a mere “using” of the claimed invention without authority creates liability even where the accused infringer did not make the infringing device.

Example: Consider the scenario in which Accused Infringer 1 manufactures an infringing machine for sowing seeds and sells it to Accused Infringer 2, a farmer who merely uses the infringing machine to plant his crop. Both Accused Infringer 1 and Accused Infringer 2 are considered jointly and severally liable for patent infringement.

Indirect infringement concerns activity involving *less than a* making of the entire invention, such as assisting one who does or supplying certain required components of the invention. The direct infringer and the indirect infringer are both considered jointly and severally liability for the infringement under a theory of joint tortfeasance.

#### Joint Direct Infringement by Multiple Parties under §271(a)

* *BMC Resources, Inc. v. Paymentch, L.P.*
	+ BMC claimed a method for processing debit or credit card transactions without having to enter a personal identification number (PIN) but instead pay bills with a touch-tone phone and a debit or credit card network.
	+ Performance of the method as claimed required four different entities, each participating in the transaction: the merchant the customer sought to pay, an agent of the merchant such as BMC Resources), a remote payment network (such as an ATM network), and the financial institution that issued the card.
	+ Issue: *Must “whoever” in §271(a) be limited to a single entity that performs each and every method step, or can a single entity (i.e., Paymentech) be liable for direct infringement based on its participation in the combined acts of multiple entities under a theory of “joint infringement”?*
	+ The Federal Circuit rejected a mere “participation and combined action” standard, holding instead that direct liability exists in a joint infringement scenario only when the accused infringer is the effective “mastermind” who “controls or directs” all the other entities performing the method steps.
	+ In this case, the various entities involved in carrying out the multiple steps of the claimed invention were only related at “arm’s length.” Paymentech did not control or direct the activity of the other entities. The district court’s grant of summary judgment was affirmed.

##### *BMC Resources* Standard of Joint Direct Infringement

Where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises “control or direction” over the entire process such that every step is attributable to the controlling party, i.e., the “mastermind.” At the other end of this multi-party spectrum, mere “arm’s length cooperation” will not give rise to direct infringement by any party.

* *Muniauction, Inc. v. Thomson Corp.*
	+ Muniauction’s patent covered methods for conducting original issuer bond auctions over an electronic network such as the Internet. The court applied *BMC Resources* and held that even though accused infringer Thomson “controlled access to its system and instructed bidders on its use,” these acts were not sufficient to incur liability for direct infringement.
	+ ***The relationship must be such that the law would hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method.***
	+ Here, Thomson did not perform all the claim steps when it conducted its accused system, nor did others (e.g., bidders) perform those steps on Thomson’s behalf.

### Two-Step Analysis for Patent Infringement

***Analyzing patent infringement is a two-step process comprising:***

1. ***Interpretation of the patent claims; and***
2. ***Comparison of the properly interpreted claims with the accused device***

Interpreting the claims is sometimes also referred to as claim construction or as the task of constructing claims.

Comparing properly interpreted claims with the accused device is sometimes referred to as “reading the claims onto the accused device.” Patent claims are said to “read on” an accused device when the device would literally infringe the claimed invention (likewise, patent claims are said to “read on” the prior art when that subject matter would anticipate the claimed invention). It is improper to say that a device “reads on” a patent claim, however. Claims “read on” accused or prior art devices, not the other way around.

## Step One: Patent Claim Interpretation

Three key questions pertaining to patent claim interpretation: (1) Who interprets patent claims? (2) What evidentiary sources are used to interpret patent claims? and (3) What are the primary rules (or “canons”) of claim interpretation?

### The Central Role of Claims

A patent claim is a single-sentence definition of the literal boundary of the patent owner’s right to exclude. A patent claim does not describe the invention to which the patent is directed. Rather it defines the extent of the patent owner’s right to prevent others from exploiting that invention. The claims are found at the end of each patent’s specification; a patent must conclude with at least one claim.

The role of describing the patented invention is played not by the patent’s claims, but rather by its written description and drawings. These parts of the patent specification must provide an enabling disclosure of how to make and uses the best mode of carrying out the invention if such a mode was known to the inventor on the application filing date.

### Judge or Jury as Interpreter? The *Markman* Revolution

* *Markman v. Westview Instruments*
	+ The Court held that the 7th Amendment does not provide a right to a jury trial for the interpretation of patent claims. Rather, policy concerns dictate that the role of claim interpretation is to be performed by the judge instead of the jury in a jury trial.
	+ Here, the key claim interpretation dispute concerned the meaning of “inventory.”
	+ Defendant’s accused system tracked only cash invoices in a dry-cleaning process. Markman introduced expert testimony to support his position that “inventory” meant cash invoices.
	+ The jury found for Markman but the court granted defendant’s motion for judgment of noninfringement as a matter of law. They held that the intrinsic evidence (patent and prosecution history) made clear that “inventory” as used in Markman’s patent had to include “items of clothing”; therefore, no infringement by cash invoices.

The Court’s decision in *Markman* turned on function (i.e., public policy) considerations. The Court concluded that judges are simply better equipped than jurors to construe the meaning of claim terms based on documentary evidence, because the bread-and-butter work of the judiciary is to construe the meaning of language in legal documents upon reception of evidence.

The Court in *Markman* also cited the importance of uniform interpretation of a given patent as another policy reason why judges are better suited than juries to interpret patent claims.

### Evidentiary Sources for Claim Interpretation

*Intrinsic evidence* is that which is part of the public record associated with a patent’s issuance: the patent itself and its prosecution history, including the prior art cited therein. Competitors have access to this information as soon as the patent issues, if not before, and it is not considered “litigation-influenced.”

*Extrinsic evidence* is evidence outside the official administrative record of the patent’s procurement, such as expert testimony. Dictionaries are extrinsic evidence.

The Federal Circuit has held that, in most cases, the intrinsic evidence alone will be sufficient to resolve any claim interpretation issues. Only when the disputed patent claim terminology is still genuinely ambiguous following review of the public record of the patent may a district court rely on the extrinsic evidence. Although a district may always admit and use extrinsic evidence for the purpose of *understanding the invention*, it may not rely on the extrinsic evidence to arrive at a claim interpretation that is contrary to that provides by the intrinsic evidence.

### The *Phillips* Debate: “Contextualist” versus “Literalist” Approaches

There are two schools of thought on the issue of patent claim interpretation:

#### Contextualist approach (Federal Circuit majority)

The Contextualist approach seeks to find the meaning of patent claim terms in the context of the invention described in the patent specification. They view the written description and drawings of the patent as the primary tool for discerning what terms in the patent’s claims mean. Here, the ordinary meaning of a term in a claim must be considered in view of the intrinsic evidence: the claims, the specification, and the prosecution history.

#### Literalist approach

The literalist approach engages in a “heavy presumption” that claim terms carry the “ordinary and customary” meaning that a PHOSITA would attribute to them. To discern this meaning the literalist judges typically consult definitions in dictionaries, technical treatises, and other evidentiary sources extrinsic to the patent itself.

* *Phillips v. AWH Corp.*
	+ The *Phillips* panel majority affirmed the district court’s reading of “baffle” as limited by the patent’s specification to baffles that are oriented at acute or obtuse angles other than 90 degrees from the wall face. Such angles were necessary to the invention’s purpose of providing impact or projectile-resistant panels and constituted the only embodiment of the invention depicted in the patent’s figures.
	+ Because the accused infringer used only 90-degree-angled baffles in its panels, the *Phillips* majority affirmed the district court’s grant of summary judgment of noninfringement. One year later, an *en banc* panel reaffirmed that a patent’s specification rather than extrinsic evidence in the primary basis for construing claims. However, the *en banc* panel disagreed with the district court on the merit’s and reversed the decision.

The *Phillips en banc* decision also held that the appropriate temporal perspective for assessing the words in a patent claim is their ordinary and customary meaning to a PHOSITA at the time of the invention, i.e., as of the effective filing fate of the patent application.

### *Markman* Hearings

Claim interpretation responsibilities in the context of a separate pre-trial hearing variously referred to as a claim interpretation hearing or a *Markman* hearing.

Following a claim interpretation hearing, a district court will typically issue an order setting forth the manner in which the claims will be construed in the remainder of the case.

Absent the district court granting a summary judgment, claim interpretations generally will not be reviewed by the Federal Circuit until appeal is taken from a final judgment rendered after the completion of trial.

### Claim Interpretation Canons

* The claim should be construed narrowly in order to save validity
* Claim terms are interpreted from the perspective of a PHOSITA
* When attempting to find the meaning of a claim term, the contextual meaning of the term may trump the ordinary meaning
* Language in the specification may bind the patentee
* A patentee may choose to redefine a claim term away from its common, ordinary meaning. Typically, this is accomplished through an *express* redefinition. Less typically, a patentee may redefine a term *implicitly*, by a consistent use of a term in a particular way throughout the written description, even without an express definitional statement of what the term means.
* Courts generally should not adopt a claim interpretation that would exclude the preferred embodiment of an invention, although rare exceptions have been recognized in which a patentee amended the claims during prosecution in such a manner as to exclude the preferred embodiment.
* ***The principle of claim differentiation provides that the existence of a narrower dependent claim shows that the broader claim from it depends is not so limited.***
	+ For example, if a patent’s written description expressly defines “primary color” as red, blue or yellow”:
		- Claim 1. A widget of a primary color.
		- Claim 2. The widget of claim 1 wherein said primary color is blue.
	+ The existence of dependent claim 2 shows that independent claim 1 includes blue widgets but is not limited to blue widgets – claim 1 also literally reads on red widgets and yellow widgets.

## Step Two: Comparing the Properly Interpreted Claims

The second step of the patent infringement analysis requires that each limitation of the properly interpreted claim be met in the accused device, either literally or equivalently. This doctrine is termed the “all-limitations rule.”

Infringement cannot be determined by comparing the claimed and accused devices as a whole; the analysis must be performed on a limitation-by-limitation level. Each limitation of a patent claim is material. If even a single limitation is not met in the accused device, there cannot be infringement.

### Literal infringement

Literal infringement is found where the accused subject matter falls precisely within the express boundaries of the claim.

For example, if a claim recites:

*1. A composition of matter comprising 20-30% of component X by weight.*

And the accused composition includes 25% component X, then claim 1 is literally infringed. However, if the accused composition contains only 15% component X, then claims 1 is not literally infringed.

In practice, instances of literal infringement are quite common. This follows from the uncertainty of claim interpretation, that is, the pre-litigation ambiguity of the literal scope of the claims.

### Infringement under the Doctrine of Equivalents

US patent law also recognizes the possibility of “nonliteral” infringement under the doctrine of equivalents. The doctrine of equivalents is entirely judge-made law; it does not appear in the Patent Act.

#### Historical origins

* *Winans v. Denmead*
	+ The Court found that a patent claiming the configuration of a railroad coal car having a cylindrical, cone-like shape was infringed by an accused car shaped in cross-section like an octagon.
	+ *Winans* does not expressly refer to a doctrine of equivalents, but such a doctrine is implied in the result of the case.

#### Policy rationales

The doctrine of equivalents is a judicial response to the practical reality that if a patent can be avoided by copying the claimed invention while making a minor, insubstantial change of just enough scope to take the copied matter outside of the literal boundaries of the claim, the right to exclude that the patent bestows will not be worth very much.

#### All-limitations (all-elements) rule

The doctrine of equivalents is to be applied on a claim limitation-by-limitation basis rather than to the “invention as a whole.”

For example, if a patent claim recites “a widget comprising lever A, pulley B, and spring C,” the doctrine of equivalents must be applied separately to determine if (1) lever A of the claimed invention is equivalently met in the accused device; (2) pulley B of the claimed invention is equivalently met in the accused device; and (3) spring C of the claimed invention is equivalently met in the accused device. If any of these three limitations is not met equivalently (or literally), there can be not infringement.

#### What is a limitation?

Applying the all-limitations rule requires the identification of each limitation of a claim. The level of generality versus specificity that the district court applies when enumerating the individual limitations of a claim can have a very real impact on the determination of technologic equivalency in the second step of the infringement analysis.

Generally speaking, an accused infringer will attempt to establish the greatest possible number of limitations, making more burdensome the patentee’s job of having to establish insubstantial differences with respect to each such limitation. In contrast, a patentee generally will seek to minimize the number of limitations so as to lessen her burden.

Example: think of the term “having a plastic tube”; an accused infringer would argue two limitations (1) plastic, and (2) tube, creating two limitations for which the patentee would need to establish insubstantial differences. Conversely, a patentee would argue one limitation (1) plastic tube; thereby, only having to prove an insubstantial difference for one limitation.

#### Determining technologic equivalence

If the doctrine of equivalents applies in a given case to a particular claim limitation, the determination of whether the limitation is equivalently met in the accused device is a question of fact rather than law.

***An accused device infringes patent under the doctrine of equivalents if it performs substantially the same function in substantially the same way to obtain the same result.*** This has been referred to as the function/way/result, FWR, triple identity or tripartite test. However, the Federal Circuit has also stated that the FWR inquiry seems best suited for mechanical inventions but is often not helpful with respect to biotechnological subject matter.

#### Reverse doctrine of equivalents

The reverse doctrine of equivalents acts as a defense to a charge of literal infringement. The doctrine absolves an accused infringer from infringement liability where the accused device, although literally falling within the scope of the asserted patent claim, is so far changed in principle from the claimed invention that a finding of liability cannot be justified as a policy matter.

The doctrine applies when the accused infringer proves that, despite the asserted claims literally reading on the accused device, it has been so changed that it is no longer the same invention.

**Note**: the reverse doctrine of equivalents has rarely been applied by the courts to excuse liability and the Federal Circuit has never affirmed a finding of non-infringement under the doctrine.

## Legal Limitations on the Doctrine of Equivalents

### Overview

The *Warner-Jenkinson* court held that a patentee may not avail itself of the doctrine of equivalents if certain legal limitations preclude it from doing so. If these limitations are triggered, an infringement case may be resolved on summary judgment and the fact question of technologic equivalency may never reach the fact finder.

The legal limitations of the doctrine of equivalents appear below:

* ***Prosecution history estoppel***: the doctrine of prosecution history estoppel (PHE) provides that a patentee may not seek to ensnare under the doctrine of equivalents any subject matter that it surrendered in order to obtain the patent
* ***All-limitations rule***: if even a single claim limitation is not met, either literally or equivalently, in the accused device, there is no infringement. Every limitation of a claim is considered material and must be met in the accused device in order to have infringement.
* ***Vitiation of a claim limitation***
* ***Prior art***: a patentee cannot obtain coverage through the doctrine of equivalents over subject matter that it could not have obtained in the first instance – i.e., because of prior art
* ***Dedication to the public***: a patentee may not attempt to cover through the doctrine of equivalents any subject matter that it disclosed but did not claim in its patent application, thereby avoiding USPTO examination on that subject matter.
* ***Foreseeability***: a patentee may not encompass through the doctrine of equivalents reasonably foreseeable alterations to claimed structure when it had an opportunity to negotiate broader claim coverage but did not do so.

### Prosecution history estoppel (PHE)

#### Definition

Prosecution history estoppel is based on the notion that if a patent applicant surrendered certain subject matter in the USPTO in order to obtain its patent (e.g., by narrowing the scope of a claim through amendment in order to distinguish subject matter disclosed in a cited prior art reference), it cannot thereafter rely on the doctrine of equivalents to obtain exclusionary rights over that same subject matter.

##### Narrowing claims

The most common form of PHE result from narrowing amendments made to the patent application claims during prosecution.

* *Dixie USA v. Infab Corp.*
	+ The claim was directed to a type of plastic “stretcher” for use in transporting hospital patients. The applicant narrowed its claims through amendment to add “rectangular openings and rounded openings” and stated that having both shapes distinguished it from prior art – patent was granted.
	+ Thereafter, an accused device did not literally infringe the patent because its handhold openings were all rectangular. The court held no infringement.
	+ Regardless of whether the accused stretcher performed the same function as the claimed invention, in substantially the same way, to achieve substantially the same result, the patentee in this case was estopped from relying on the doctrine of equivalents to establish infringement liability.

##### Applicant’s arguments alone

However, the claims need not be amended at all in order to create PHE. In some cases, the applicant’s arguments alone, generally made in the form of the applicant’s written “remarks” filed in response to the examiner’s rejections, can create estoppel.

A “clear and unmistakable surrender of subject matter” is necessary to invoke this form of PHE.

#### Scope of Estoppel

Assuming that a patentee’s actions during prosecution triggered PHE, the next step of the analysis is to determine the proper scope of that estoppel. In other words, may the patentee narrow its claim via amendment in response to a rejection and yet still retain some scope of equivalents beyond the literal scope of the amended claim?

In *Festo II*, the Supreme Court announced a “presumptive bar” rule that lies somewhere between the flexible and complete bar rules.

#### Presumption of Estoppel – no reason for amendment revealed (Warner-Jenkinson)

The Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, announced a presumption with respect to PHE in the case of a silent or unexplained record, where the prosecution history does not reveal the reason for amending the claims.

In this situation, the burden of establishing a reason for the amendment is placed on the patent owner. Where no explanation is established, it is presumed that the patent applicant had a substantial reason related to patentability for making the amendment.

If the patent owner is unable to rebut the presumption that the change was made to the claims for a reason related to patentability, PHE bars the application of the doctrine of equivalents as to the amended element.

#### Presumption of Surrender (Festo II)

The Supreme Court in *Festo II* adopted a *rebuttable* presumption that a narrowing amendment surrenders the particular equivalent in question.

The presumption can be overcome in one of the following ways:

1. The patentee demonstrates that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment,
2. The rationale underlying the narrowing amendment bears no more than a tangential relation to the equivalent in question, or
3. That there is “some other reason” suggesting that the patentee could not reasonably have been expected to have drafted a claim encompassing the alleged equivalent at the time the patentee narrowed its claim.

When the patentee has chosen to narrow a claim, courts may presume the amended text was composed with awareness of this rule and that the territory surrendered is not an equivalent of the territory claimed.

#### Questions from Festo II

##### Unforeseeability

Unforeseeability is an objective inquiry asking whether the alleged equivalent would have been unforeseeable to a PHOSITA at the time of the amendment. Later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro in relation to fasteners) generally would not have been foreseeable, while technology known in the art at the time of the patentee’s amendment would more likely have been foreseeable.

***Objective unforeseeability depends on underlying factual issues such as the state of the art and the understanding of a PHOSITA.***

##### Mere tangentialness

***Mere tangentialness asks whether the reason for a narrowing amendment was peripheral, not directly relevant/unrelated, to the alleged equivalent.***

The inquiry must focus on the patentee’s objectively apparent reason for the narrowing amendment; thus, ***a court is limited in answering this question to consideration of the intrinsic evidence***. Whether the reason for the amendment was merely tangential to the accused equivalent is for the court to determine from the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record.

***This occurs when there is an amendment but does not pertain to the element we are analyzing.*** Example: a claim recites “a wooden rod comprised of a hollow core filled with a lead material with an eraser,” but was thereafter amended to be “a wooden rod comprised of a hollow core filled with a lead material with an eraser attached to one end by way of a metal clasp.” Here, if we were analyzing DOE with respect to a lead material, the amendment to the eraser is tangential to the lead material element analysis.

* *Biagro Western v. Grow More*
	+ Patentee limited its claims to specify a concentration level of about 30-40%. The limitation was added to avoid prior art with a *lower* concentration, and the patentee was now trying to use DOE to asserts rights against a product with a *higher* concentration.
	+ The Court held the amendment not merely tangential because both the amendment and equivalents issue dealt with concentration levels; therefore, the patentee was barred by PHE from asserting DOE.
* *Primos, Inc. v. Hunter’s Specialties*
	+ The patent claim, in original and amended form, included a “plate” while the accused product included a “dome.” The patentee was trying to use the DOE to expand plate to cover domes.
	+ During prosecution, the “plate” element was amended by adding the limitation “differentially spaced.” That amendment was considered tangential because the dome in the accused product was also “differentially spaced.”
	+ Thus, the amendment did not change the equivalents analysis that would have been applied even under the original language; therefore, the patentee was permitted to assert DOE.

##### “Some other reason”

This suggests that a patentee could not reasonably have been expected to have claimed the insubstantial substitute in question.

## Inducing Infringement under §271(b)

The act of inducing infringement is analogous to the act of aiding and abetting a crime. Inducing infringement requires that the alleged inducer actively and knowingly aids and abets another’s direct infringement. The inducer must have actual or constructive knowledge of the patent.

Inducement cases typically involve one actor (the inducing infringer) providing another (the direct infringer) with instructions and information about how to make or use the accused device or carry out the accused process.

Proving inducement under §271(b) requires proving two elements (1) direct infringement occurred; and (2) the accused inducer had the requisite intent to induce infringement.

### Direct infringement

***Holding an accused infringer liable for inducement under §271(b) requires proving direct infringement under §271(a); direct infringement is a necessary predicate for the existence of inducing infringement liability***. In some cases the accused infringer may be a consumer who allegedly directly infringed by following instructions provided by the alleged inducing infringer.

In inducement cases, circumstantial evidence is sufficient to establish the direct infringement predicate. This means, a patentee need not show a consumer actually infringed, just that there was no other viable option for the consumer once he/she brought the accused infringer’s product.

Note that induced infringement does not require any activity by the indirect infringer in the US as long as the direct infringement occurs in the US.

### Requisite intent

To prove the accused inducer had the requisite standard of intent, the plaintiff/patentee must show that the alleged infringer knew or should have known his actions would induce actual infringements. The requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent

## Contributory Infringement under §271(c)

Contributory infringement involves one entity (the contributory infringer) supplying a “nonstaple” component of a claimed invention to another entity (the direct infringer), who makes, uses, or sells the entire invention.

A nonstaple component is a component part of an invention that is not suitable for any substantial use other than in the patented invention.

Where an article is “good for nothing but infringement, there is no legitimate public interest in its unlicensed availability, and there is no injustice in presuming or imputing an intent to infringe.”

* *Dawson Chemical Co. v. Rohm & Haas Co.*
	+ The accused infringer supplied herbicide propanil to farmers. By using the propanil to control weeds in their rice crops in accordance with the process claimed in the patent suit, the farmers became liable as direct infringers (presumably for “using” the patented process without authorization),
	+ While not covered by a patent, the herbicide propanil was a qualifying nonstaple commodity that had no use other than in the claimed method.

***The staple/nonstaple distinction is the key to contributory infringement. §271(c) provides a patent owner with “a limited power to exclude others from competition in nonstaple goods,” but does not permit her to control the supply of staple goods, which could have many non-infringing uses***.

For example, a baker is accused of using a patent cookie making process; the party supplying the salt to the baker *cannot* be liable for contributory infringement because salt is a staple that has many uses other than in the claimed process.

### Permissible “repair” v. infringing “reconstruction” (i.e., a new making)

* *Aro Mfg. Co. v. Convertible Top Replacement Co.*
	+ The patent suit was directed to a top assembly for convertible cars. The claimed assembly required several different components, one of which was a fabric top. These tops tended to wear out much more rapidly than the other components of the assembly and consumers purchased replacement fabric tops directly from the defendant supplier.
	+ The patentee sued the supplier contributory infringement. The Supreme Court held that no such liability existed because no direct infringement had occurred. The replacement of the fabric top was within the consumer’s implied to repair their property.
	+ ***Replacement of the fabric top did not amount to an infringing reconstruction (i.e., a new making) of the entire claimed assembly. Because the consumer purchasers were not direct infringers, the defendant supplier of the replacement tops could not be liable as a contributory infringer.***

## Component Imports/Exports – territorial issues

### Exports

35 U.S.C. §271(f) concerns arts of infringement that are completed outside of the geographic borders of the US, but were begun by inducing or contributory activity within the US. The extraterritorial activities must have a nexus to acts occurring within the US.

The liability created under §271(f) is an exception to the general rule that infringement occurs when a patented product is made and sold in another country.

***Infringement liability if supplying (1) all of a substantial portion of the invention, or (2) a nonstaple component of the invention, outside of the US for the use in manufacturing the patented invention.***

§271(f) (1) creates infringement liability for supplying from the US all or a substantial portion of the components of a patented invention in such a manner as to actively induce the combination of such components outside of the US.

§271(f)(2) creates infringement liability for supplying from the US a nonstaple component of a patented invention intending that such component will be combined outside of the US.

* Remember: A nonstaple component is a component part of an invention that is not suitable for any substantial use other than in the patented invention.
* *Microsoft Corp. v. AT&T Corp.*
	+ Microsoft’s OS included code that infringed AT&T’s patent; however, infringement only occurred when the relevant code was *installed* on a computer.
	+ Microsoft circumvented this potential infringement issue by sending a master disk containing the code abroad where copies of the disk were made. These copies were then used to install the code.
	+ The court held that there was no infringement under §271(f) for the installation of the code on computers made abroad from copies also made abroad.

### Imports

Prior to the enactment of 35 U.S.C. §271(g), a U.S. process patent owner had no recourse against a competitor who carried out the process abroad (where it would not violate the US process patent) and imported the product into the US. By enacting §271(g), Congress closed the loophole.

35 U.S.C. §271(g) (1) provides there is no infringement if the imported product of the patented process is ***materially changed by subsequent processes*** before the product was imported.

# Defenses to Patent Infringement

## Laches

The equitable doctrine of laches may be asserted by accused infringers as the basis of “absence of liability for infringement” under §282, ¶2(1). A judicially created doctrine, it permits the accused infringer to limit or negate its liability when a patentee has unfairly brought suit after an unreasonable amount of delay.

This defense targets the plaintiff’s unreasonable delay in filing suit. If successfully established, laches does not bar the plaintiff’s action in its entirety but rather prevents the recovery of any damages that accrued prior to the filing of the action.

The elements of a laches defense are:

1. Unreasonable and inexcusable delay by the plaintiff in bringing suit; and
2. The defendant was materially prejudiced due to the plaintiff’s delay.

If the plaintiff brings ***within six years*** of learning about the alleged infringement, then the defendant must prove both of these factual elements. However, a presumption of laches arises in the defendant’s favor in those cases the plaintiff has delayed in filing suit *for more than six years* after the plaintiff knew or should have known of the alleged infringement.

Once the presumption is triggered, the burden of production then shifts to the plaintiff (patentee), who must attempt to rebut the presumption. If the plaintiff (patentee) establishes facts that create a genuine issue of fact with respect to either one of the two underlying facts, then the laches presumption “bursts” and the defendant must then establish the existence of both unreasonable delay and material prejudice.

When attempting to rebut a presumption of laches, the plaintiff patentee may seek to establish (1), whether the delay in bringing suit was unreasonable, by offering evidence tending to show that its delay was in fact, reasonable and justified under the circumstances.

* *A.C. Aukerman Co. v. Chaides Constr. Co.*
	+ Aukerman owned a patent on a device and method for forming concrete highway barriers. Aukerman threatened to sue Chaides and offered a license. Chaides responded the alleged infringement was only worth $200-300 per year and it was not willing to take the license. Over the next 8 years, Chaides increased its production but never heard from Aukerman.
	+ Because Aukerman waited 8 years to bring its suit, the presumption of unreasonable and unexcused delay arose. Aukerman responded with evidence that they were already in litigation and the Federal Court agreed it was at least a genuine factual issue and therefore reversed the summary judgment grant.

With respect to laches element (2), whether the accused infringer was materially prejudiced by the delay, the prejudice may take the form of loss documents and lost recollections of witness for example. This may also be economic, as where the accused infringer has changed its economic pattern during the period of the plaintiff’s delay. For example, prior to the plaintiff filing suit, the accused infringer may have made investments in manufacturing facilities or entered a contractual agreement to produce the alleged infringing object.

In attempting to rebut a presumption of laches, the patentee may attempt to create a genuine issue of fact with respect to element (2) by establishing that the evidence supporting the accused infringer’s defenses (such as non-infringement and/or invalidity) remain available, or that the accused infringer has not suffered any substantial economic change during the period of the patentee’s delay.

## Inequitable Conduct

The defense of inequitable conduct asserts that a court should refuse to enforce a patent if it was procured through improper conduct before the USPTO. The *ex parte* nature of patent prosecution before the USPTO drives the inequitable conduct defense. The USPTO rules require that all persons substantively involved in the patent application process owe a duty of candor to the agency, which includes a duty to disclose to the agency all known information that is material to patentability.

If the defense of inequitable conduct is proved, the entire patent (i.e., all claims, regardless of their validity) is rendered enforceable.

The proponent of the inequitable conduct defense must prove, by clear and convincing evidence: (1) materiality, and (2) intent to deceive the USPTO.

### Materiality

To constitute inequitable conduct, a patent applicant’s conduct before the USPTO must involve the nondisclosure or wrongful submission of information that is material to patentability. Such nondisclosure or wrongful submission is typically:

1. Failure to disclose to the USPTO information known to the applicant that is material to patentability,
2. Submission to the USPTO of false information that is material to patentability, or
3. Affirmative misrepresentations made to the USPTO that are material to patentability.

In determining whether information qualifies as material, the Federal Circuit inquires whether a hypothetical “reasonable examiner” would have considered the information “important” in determining whether to allow the application to issue as a patent.

If that question is answered affirmatively, then the information satisfies the materiality element of the inequitable conduct defense. It is not necessary that the information be invalidating, that is, that the information would have rendered the patent application’s claims unallowable if the examiner had been aware of it.

A patent may be held unenforceable for inequitable conduct based on the applicant’s act of withholding prior with intent to deceive the USPTO, even though the patent’s validity is sustained over that same prior art. In such cases the withheld prior art is not sufficiently relevant to invalidate the claims, but is nevertheless sufficiently material to patentability to form a basis for a judgment of inequitable conduct.

*Information is not considered material, however, if it is merely cumulative of (i.e., adds nothing new or different to) other information already before the USPTO*.

* *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*
	+ Critikon sued Becton for infringement on catheters, which included a Lemieux patent. During the course of the litigation, the Lemieux patent was reissued and Critikon amended its claims to assert the reissued Lemieux patent.
	+ The Federal Circuit found for inequitable conduct for (a) nondisclosure of a material prior art reference it knew about and (b) Critikon’s failure to inform the USPTO examiner that the Lemieux patent was the subject of a federal litigation challenging its validity.
* *Purdue Pharma L.P. v. EndoPharms. Inc.*
	+ Purdue used the language “surprising discovery” in its written description of a medicine stating results for certain dosages but at no time prior to issuance did Purdue have clinical data to support this.
	+ Although the application never stated it was clinically tested, the court held Purdue failed to disclose material information to the USPTO stating the discovery was the inventor’s “insight” without scientific proof.
	+ The lack of statements indicating the true origin of the “surprising discovery” was enough to suggest clinical trials had been performed. The failure to make this distinction to the USPTO was a failure to disclose material information.

### Intent to deceive

A breach of a patent applicant’s duty of disclosure to the USPTO, without more, does not establish the defense of inequitable conduct. The party asserting the defense also must establish that material information was withheld (or falsely submitted) with an intent to deceive the USPTO.

Materiality and intent to deceive are separate elements; materiality does not presume intent.

***When an inequitable conduct charge is based on an applicant’s failure to disclose prior art to the USPTO, “clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”***

Such intent may be proved through direct evidence or through inference. However, inferred evidence of intent nevertheless must satisfy the “clear and convincing” quantum and proof. ***Moreover, “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”*** (*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*)

### Intent to deceive after *Therasense*

Under *Therasense*, specific intent to deceive the USPTO must be proven by clear and convincing evidence. If this is inferred, it must be the single most reasonable inference possible. Knowledge of the information’s materiality and decision to withhold is also required.

#### Specific intent to deceive

* + - * + Know of relevance and its materiality
				+ Deliberately withholding the reference
				+ Clear and convincing evidence
	+ Can infer intent but only if single most convincing inference to be drawn
		- * + Exception for affirmative egregious behavior then you can bypass the showing of specific intent
				+ Independent elements
				+ Court is likely to state that the showing of materiality is a but-for standard meaning USPTO would have disallowed the claim but-for the patentee’s omission or act; however, there is an exception for affirmative egregious behavior.

# Remedies

## Injunctions – 35 U.S.C. §283

An injunction is an order by the court, commanding an infringer to cease any further infringement (direct, inducing, or contributory) in the US during the term of the patent.

The Supreme Court clarified in *eBay, Inc. v. MercExchange, LLC*, that injunctive relief is not automatic even though a patent is adjudged infringed and its validity sustained. The use of the word “may” is §283 makes clear that injunctions are optional, not mandatory, equitable remedies.

FRCP 65 requires that injunctive orders provide clear notice and specific detail concerning the conduct being enjoined.

### Permanent injunctions

A permanent injunction is one that is raised after a final judgment of infringement and no invalidity or unenforceability.

* *eBay, Inc. v. MercExchange, LLC*
	+ The Court stated that a district court’s decision to impose or deny a permanent injunction in a patent case should be made after consideration of traditional equitable principles.
	+ Patentee, MercExchange, a patent holding company (patent troll), licensed its patents but did not manufacture any products. It alleged that the “Buy It Now” feature of eBay’s popular online auctions infringed MercExchange’s ‘265 business patent. eBay refused to take licenses and MercExhcnage sued for infringement.
	+ A jury sustained the ‘265 patent’s validity, found that eBay infringed, and awarded damages to MercExchange. The district court denied MercExchange’s motion of permanent injunctive relief against eBay. The Federal Circuit reversed and it was appealed to the Supreme Court.
	+ The Court vacated the Federal Circuit’s ruling and stated that rather than following any general rule or presumption regarding injunctive relief in patent cases, district courts should apply “well established principles of equity.”

***The holding from eBay requires a patent owner seeking a permanent injunction must satisfy the following factors:***

1. ***That it has suffered an irreparable injury;***
2. ***That remedies available at law, such as monetary damages, are inadequate to compensate for that injury;***
3. ***That, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and***
4. ***That the public interest would not be disserved by a permanent injunction***.

With respect to the irreparable harm factor, the Supreme Court cautioned courts not to assume that all non-practicing patentees will be unable to satisfy the four-factor test. The Court observed that “some patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves.”

### Preliminary injunctions

A preliminary injunction is “preliminary” because it is entered before trial, that is, before a complete adjudication on the merits of the infringement issue. Preliminary injunctions also are referred to as interlocutory. The goal of a preliminary injunction is to protect the rights of the parties during pendency of the infringement lawsuit, which can take years, by preserving the *status quo* until final disposition of the case.

A preliminary injunction is an extraordinary remedy, not routinely awarded, and will only be granted on a strong showing of the necessary factors by the patentee (the movant).

***A district court must consider the following in evaluating whether to grant a preliminary injunction in a patent case:***

1. ***A reasonable probability of success on the merits (i.e., movant will prepare at trial);***
2. ***Irreparable harm to the movant if the preliminary injunction is not granted;***
3. ***The balance of the hardships tipping in the movant’s favor; and***
4. ***The impact, if any, of the injunction on the public interest.***

No factor is dispositive, but the first two factors are deemed critical such that if a district court finds that the movant/patentee has failed to satisfy either, it may deny the injunction without making findings on the third and fourth.

Note: Procedurally, the party sought to be enjoined must be given advance notice. FRCP 65(c) requires that before an injunction is entered, the movant/patentee must give security; movant must post a bond in an amount that the district court deems proper for payment of costs and/or damages that could be suffered by the accused infringer if that party is later found to have been wrongfully enjoined.

#### Likelihood of success on the merits

This factor is generally considered the most important of the four preliminary injunction factors because if it is “clearly established,” the second factor of irreparable harm will be presumed.

Although these are labeled “factors,” all must be shown – i.e., essentially elements/

***The patentee must show a reasonable probability of success that (1) it will establish infringement by a preponderance of the evidence, and (2) that the accused infringer will not be able to establish invalidity or unenforceability of the patent by clear and convincing evidence.*** Note, on a motion for a preliminary injunction, the patentee carries the burden of showing likelihood of success on the merits with respect to the patent’s validity, enforceability, and infringement.

*Remember, that the patent is presumed to be valid. So, does the challenger raise a substantial question of validity?*

As to infringement, the patentee/movant will often attempt to establish similarity between the accused product and other products that have previously been adjudicated as infringing the same patent.

* + This will be done by looking at the claim construction. Why does with the claim construction? We need to know what it anticipates (102/103 purposes and infringement purposes).
* *Apple v. Samsung*
	+ Process for finding whether a preliminary injunction is appropriate:
1. Start with claim construction;
2. Is the patent valid?; and
3. Is there infringement?
	* The court looks at the fact that this is one small component of a very advanced technology and there had been some evidence of licensing so it seems like this weighs in favor of no injunction.

As so validity, the patentee’s chances of success are strengthened if the validity of its patent was previously sustained against a challenge by a different defendant. The patentee may also rely on evidence of public acquiescence in the patent’s validity or conclusive direct technical evidence of validity.

#### Irreparable harm

Here the patentee must show that it will suffer irreparable harm if the preliminary injunction is not granted.

In practice, the irreparable harm factor will typically be presumed by the court if the patentee has made a “clear” or “strong” showing on the first factor, probability of success on the merits.

How else should we show irreparable harm:

* Brand name damage
* Decreased market share to accused infringer?
* Increased notoriety of accused infringer in field?

An accused infringer may seek to rebut the irreparable harm factor by introducing evidence that there has been a long period of delay by the patentee in moving for a preliminary injunction after learning of infringement may also refute irreparable harm. Likewise, evidence that the patentee has engaged in a pattern of licensing the patent to others, indicating that the receipt of royalties is a sufficient remedy for the patentee’s surrender of exclusivity may be grounds for rebuttal of the irreparable harm presumption.

#### Balance of the hardships tipping in movant’s favor

A court must weight and balance the equities of the parties’ respective positions before granting an injunction. The court must exam the hardships that may ensue if it grants the injunction versus those that will occur if it does not. If an injunction is to be entered, the district court should conclude that the balance of hardships tips in the patentee’s favor.

* *Polaroid v. Kodak*
	+ The accused infringer, Kodak, asked for a stay in the entry of an injunction against it pending appeal. Kodak contended that entry of the injunction would shut down Kodak’s instant photography business, putting over 4,000 employees out of work and would result in investments in equipment and facilities of over $200 million.
	+ Kodak’s claims of hardship did not persuade the court: “to the extent Kodak has purchased its success at Polaroid’s expense, it has taken a ‘calculated risk’ that it might infringe existing patents. Thus, the court found the potential harm to Kodak was outweighed by the harm that would result to patentee Polaroid.

#### Public interest

The district court should consider what, if any, impact the grant of an injunction would have on the public’s interest. The public has an interest in ensuring valid patents are enforced; this maintains the incentives for innovation. On the other hand, the infringer may be supplying the public with an additional source of a critical product in short supply. For example, a breakthrough drug that the patentee is unable to manufacture in large quantities. Cutting off the infringer would likely result in a price increase and supply constrictions that could mean the difference between life and death to sick patients.

* *Hybritech, Inc. v. Abbott Labs*
	+ The Federal Circuit affirmed a district court’s grant of a preliminary injunction that prevented the alleged infringer Abbot from continuing to sell certain accused products but permitted it to continue selling others: a cancer test kit and a hepatitis test kit.
	+ The district court had determined that the public interest was best served by the continued availability of the kits.

#### Appellate standard of review

The grant of refusal of a preliminary injunction is immediately appealable as an interlocutory order. Because the order to grant or refuse the injunction is an equitable decision, the appellate court may overturn it only if the district court abused its discretion. The Federal Court won’t hesitate to vacate the grant of a preliminary injunction where district court fails to articulate its findings and ruling.

## Damages for Past Infringements

In addition to an injunction, the other key form of relief for patent infringement is monetary, in the amount of damages that the patentee suffered because of the infringement – Patent Act §284.

Damage awards may be of two basic types: compensatory and enhanced. Compensatory damages compensate the patentee by trying to approximate the actual monetary loss suffered. Enhanced damages are in the nature of punitive damages and are intended to punish the accused infringer for willful conduct. Enhanced damages cannot be awarded for compensatory purposes; rather, they may be awarded “only as a penalty for an infringer’s increased culpability, namely willful infringement or bad faith.

The Federal Circuit has taken the position that any doubts as to the amount of a damages award are to be resolved against the infringer as the wrongdoer.

### Compensatory Damages

*Federal Circuit authority expresses the basic goal of compensatory damages: putting the patentee in as good a position as it would have been had there been no infringement*. U.S. patent law attempts to restore the patentee to its financial position but for the infringement.

Unlike copyright infringement, the patent laws do not provide for an award of “statutory damages” within a specified range of dollars. The amount of the patentee’s compensatory damages for infringement of a U.S. utility patent: lost profits and reasonable royalty.

#### Lost profits

Damages computed on a theory of lost profits are intended to approximate the profits that the patentee lost because of sales diverted by the presence of the infringing product in the marketplace. The key element that a patentee must prove to attain a lost profits recovery is causation – that the infringement was the cause of the patentee’s lost sales rather than some other cause such as the marketplace availability of non-infringing alternatives to the patented item.

The patentee bears the burden of establishing causation; the patentee must show that but for the infringement, the patentee would have made the sales for which it seeks lost profits.

##### The *Panduit* Analysis

*Panduit Corp. v. Stahlin Bors. Fibre Works, Inc.* set forth the following factors as the elements that a patentee must prove in order to obtain damages on lost profits:

1. Demand for the patented product
2. Absence of acceptable non-infringing substitutes
3. Manufacturing and marketing capability
4. Amount of profit patentee would have made

###### Demand for the patent product

The demand for the patented product is usually presumed from the fact of infringement. The Federal Circuit considers “a substantial number of sales” of infringing products containing the patented features to be, itself, “compelling evidence” of the demand of the patented product.

###### Absence of acceptable non-infringing substitutes

An award of lost profits must not be speculative; rather, the patentee’s burden is to show a reasonable probability that, absent the infringement, it would have made the infringer’s sales.

Earlier Federal Circuit decisions appeared to require that an acceptable non-infringing substitute possess all the advantages or beneficial characteristics of the patented device.

However, more recently, the Federal Circuit has focused on whether the proffered alternative “competes in the same market for the same customers” as the patented device. This analysis looks at prices as well as product features, and requires careful definition of the “relevant market.”

The patentee must show that the patentee and the infringer sell substantially similar products in the same market. To be acceptable to the infringer’s customers in an elastic market, the alleged alternative “must not have a disparately higher price than or possess characteristics significantly different from the patented product.”

When dealing with multiple manufacturers in a market, the Federal Circuit applies a “market share” approach which permits a patentee to substitute evidence of its share of a multi-supplier market in place of evidence that would satisfy the absence of acceptable non-infringing alternatives *– need clarification*.

###### Manufacturing and marketing capability

The patentee must show that it had or could have obtained the manufacturing capacity to make all the sales in question, that is, its own and the infringer’s.

The patentee can satisfy this factor by reliance not only on its own manufacturing capability but also by evidence of the potential for licensing and contracting for the manufacture.

###### Amount of profit

The amount of lost profits must be computed using an incremental income approach that excludes that patentee’s fixed costs (i.e., those costs that do not vary with increases in production) , such as management salaries, property taxes, and insurance.

$$Amount of lost profits=lost revenues-incremental costs$$

Lost revenues = the number of additional sales that the patentee would have made but for the infringement, multiplied by the plaintiff’s historical prices (pre-infringement prices).

Incremental costs = variable, not fixed costs

##### The *Rite-Hite* Expansion

Prior to *Rite-Hite*, Federal Circuit cases held that lost profits damages were to be based on diverted sales of the product covered by the infringed patent. The underlying analytical assumption was that each sale by the infringer meant a corresponding lost sale by the plaintiff’s patented product. The Federal Circuit in *Rite-Hite* expanded damages law by holding that a patent owner also can potentially recover lost profits on lost sales of *unpatented* products (or products covered by patents other than the one in suit) that compete with the infringing device, so long as the patentee can establish causation.

* *Rite-Hite*
	+ Rite-Hite’s patent suit was directed to a manual safety device for securing a truck to a loading dock – the MDL, which sold for $500. It also sold an automated version – the ADL, which sold for $1000-1500. The ADL was covered by a US patent but not the one in the suit; therefore, it was considered “unpatented.” Both the MDL and ADL devices competed directly with Kelley’s device. Kelly’s infringement on the MDL had been confirmed in court – damages were to be decided.
	+ The Federal Court affirmed an award of lost profits for lost sales of the unpatented ADL, even though the device wasn’t covered by the patent in this suit.

The court expansively held that in patent cases “if a particular injury was or should have been reasonably foreseeable by an infringing competitor in the relevant market, that injury is generally compensable absent a persuasive reason to the contrary.”

In the Federal Circuit’s view, Kelley’s accused device directly competed with the plaintiff’s unpatented APL-100 device. In light of this competition in the marketplace, Kelley should have reasonably foreseen that its infringement would cause Rite-Hite a loss of not only the patented MDL device, but also lost sales of the directly competing but unpatented APL-100.

#### Entire Market Value Rule/Convoyed Sales

Patentees often will seek to recover damages for the lost profits they would have made, but for the infringement, on accessory items that typically would be purchased with the patented item.

In the *Rite-Hite* case, the Federal Circuit considered whether the patentee could recover lost profits on diverted sales of its “Dock Levelers,” unpatented items frequently sold as accessories with the patentee’s MDL and ADL devices.

***The Federal Circuit applies the “entire market value rule.”*** This states that damages for component parts used with a patented apparatus were recoverable if the patented apparatus “was of such paramount importance that is substantially created the value of the component parts.”

The court characterized the entire market value rule as having “typically been applied to include in the compensation base unpatented components of a device when the unpatented and patented components are physically part of the same machine,” acknowledging that the rule “has been extended to allow inclusion of physically separate unpatented components normally sold with the patented components.”

In such cases, the “unpatented and patented components together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.”

Rule: the unpatented components must function together with the patented component in some manner so as to produce a desired end product or result. All the components together must be analogous to components of a single assembly or be parts of a complete machine, or they must constitute a functional unit. Liability will not be extended to include items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage.

Under this formulation as applied to the facts of the case, patentee Rite-Hite could recover damages for diverted sales of its Dock Levelers. Although the Dock Levelers may have been used together with Rite-Hite’s MDL and ADL restraints, “they did not function together to achieve one result and each could effectively have been used independently of each other.”

Unlike the dock levelers in *Rite-Hite*, the syrup and dispenser in *Juicy Whip* were not sold together “only as a matter of convenience or business advantage;” rather, “the dispenser needs syrup and the syrup is mixed in a dispenser.”

A functional relationship between a patented device and an unpatented material used with it is not precluded by the fact that the device can be used with other materials or that the unpatented material can be used with other devices.

#### Reasonable Royalty

Where lost profits cannot be proved, the patentee is entitled to an award of damages based on a theory of reasonable royalty. ***A reasonable royalty has been defined as an amount which a person, desiring to manufacture and sell a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make and sell the patented article, in the market, at a reasonable profit***.

* + §284 of the Patent Act provides that the reasonable royalty is the minimum or floor below which damages assessment cannot go.

In determining this reasonable royalty, look to see if there is an “established royalty” based on industry standard or through extensive prior licensing by the patentee. Otherwise, look to the two approaches below.

##### Hypothetical negotiation

Under this approach, the district court must attempt to discern what royalty rate the patentee would have accepted at the time the infringement began – approximating what royalty the parties would have agreed to.

Assumptions:

1. That the licensor is willing to license; and
2. The licensee is willing to admit infringement of a valid patent

##### Analytical approach

In the analytical approach, the court takes an infringer’s anticipated net profit margin as the starting point and from this subtracts some “industry standard” or “acceptable” level of profit, so as to leave that amount for the infringer; the remaining portion of the anticipated profit is awarded to the patentee as a reasonable royalty.

### Enhanced Damages and Willful Infringement

35 U.S.C. § 284 states that a district court has the discretion to increase damages up to three times the amount of the compensatory award.

Enhanced damages are frequently awarded when a defendant’s infringement is found to be “willful.” The Federal Circuit in *In re Seagate Tech., LLC*, required that in order to prove willfulness a patentee must establish that the infringer acted in an objectively reckless manner.

The *Seagate* court announced a substantially heightened burden for a patentee seeking to establish that an accused infringer acted willfully. The court adopted an objective standard for willfulness that requires “reckless” conduct by an accused infringer, stating:

*We hold that proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness.*

The Federal Circuit set forth the following two-part standard to establish willful infringement:

1. The patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.
2. The patentee must also demonstrate that this objectively-defined risk was either known or so obvious that it should have been known to the accused infringer.

Finally, concerning waiver of the attorney-client privilege when asserting an advice of counsel defense, the Federal Circuit held as a general proposition that asserting the advice of counsel defense and disclosing opinions of opinion (patent) counsel do not constitute waiver of attorney-client privilege for communications with trial counsel.

* + This means that if the accused infringer asserts an opinion of a patent counsel that they obtained prior to acting stating they were not infringing, they do not waive the attorney-client privilege to communications between the accused infringer and the trial counsel.