PATENTS

Historical Overview of Patent Law

- Aristotle
- Hippodamus of Miletos calls for a system of rewards to those who discover things useful to the state
- *Patere* (to be open): referring to an open letter of privilege from the sovereign

First Patent Act (1790)

- Thomas Jefferson- Fundamental principles of American patent law (Art. I, § 8- Incentives theory)

Patent Act of 1952 (after Pearl Harbor)

- Engineers and scientists perfect new technologies during the war
- Supreme Court began asserting its appellate jurisdiction over the Federal Circuit more

The Uruguay Round of negotiations to revise the General Agreement on Tariffs and Trade (GATT) concluded in 1994 with the creation of Trade Related Aspects of Intellectual Property (TRIPS) Agreement.

- To join WTO, country must meet certain minimum standards of intellectual property protection --> **International harmonization of patent law**

Industry divergence: pharma/biotech vs. software/high tech (less number of patents with pharma)

- Natural rights vs. Utilitarian theory
    - Bob the janitor would be the inventor if it was utilitarian
    - Chemist would be the natural right inventor

Patent Claim Drafting Exercises

- Components
    - Preamble
        - Identifies what kind of invention is being claimed
        - Should be as broad as possible
    - Transition
        - "Open" Claims: "Comprising"
            - Any embodiment of the invention having elements A, B, and C, and any additional elements
        - "Closed" Claims: "Consisting of"
            - Narrower than "open" style
            - If elements addition to A, B, and C, no infringement
        - An in-between format: "Consisting Essentially of"
            - Covers a variant on the invention having element D only if element D did not make the variant essentially different from the claimed invention
        - Variants having basic and fundamental additions would fall outside the scope of the claim, but those with less significant additions would fall within it
    - Body
        - Two functions
            - List all the elements of the invention
            - Describe how they interact
        - Words approved to use: Appendix A to Richard C. Faber, Landis on Mechanics of Patent Claim Drafting (3rd Ed. 1990)
        - Three formal requirements
            - Entire claim must be stated in the form of a single sentence
            - Claim must set forth how each element interacts with at least one other element
            - Any internal references must be clear
        - Independent and Dependent Claims
            - Dependent claim specifies some feature of the general invention claimed in the independent claim to which the dependent claim refers
            - Form of insurance
        - Means-Plus-Function Elements

        - Construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof
        - Only used in combination with at least one other element
    - Jepson Claim
        - Improvements on existing technology

A Growing Foundation for Future Invention

- Overview of the Patent System
    - Two major components of the patent legal process
        - **Prosecution:** Series of negotiations between the examiner and the inventor or inventor's attorney.
            - Usually two to three years from the time it takes from filing to patent issuance
        - **Interference:** Awarding the patent to the **first to invent** (US Policy) instead of **first to file** (foreign policy).
            - 35 U.S.C. (s) 132: Applicant entitled to two rejections before final rejection
- Options after **final rejection**
    - Abandon the application
    - Appeal the examiner's rejection to the **Board of Patent Appeals and Interferences**
        - Continue the prosecution through **continuation** practice (request for continued examination)
        - **Continuation-in-part:** Preserve the filing date of the original application only if the changes to the disclosure did not add any new matter (changes only to the claims)
    - Original application is the **parent** application (after two continuations, the original application is the **grandparent**)
        - **Enforcement:**
            - Patentee brings an infringement action against an accused infringer
            - Potential infringer files a declaratory judgment action against the patentee
            - Potential infringer challenges the validity of the issued patent immediately before being sued
            - Potential infringer can always challenge that the patent is invalid
            - In addition, the potential infringer can argue that its product does not infringe the patentee's claims
            - All judgments by district courts in infringement and declaratory judgment actions are appealable to the Federal Circuit and then to the Supreme Court
    - 1982: Congress created the Federal Circuit (CAFC) combined former Court of Customs and Patent Appeals (CCPA) with special appellate court

Rules vs. Standards

- Rules: Predictable, bright line (federal circuit)
- Standards: Flexible, open-ended, balancing of different factors (SCUSA)

Patent includes only the right to exclude and nothing else (i.e. rights to stop others from using)

- **Overlap:** When A patents a broad basic technology and B patents an improvement within that technology, both A and B have the right to exclude within the area of overlap

Pathway to Patentability

Invention → 35 USC §101 → 35 USC §102 → 35 USC §103 → Patentable Invention

Patent Application → 35 USC §112, 1&2 → Patent

A. Introduction to the Patent Act

- There are two criteria for determining subject matter eligibility and both must be satisfied.
- The claimed invention:
    - must be directed to one of the four statutory categories; and

    - must not be wholly directed to subject matter encompassing a judicially recognized exception.
- Three specific exceptions to §101's broad patent-eligibility principles: laws of nature; physical phenomena; and abstract ideas. The policy behind this principle it improperly seeks to claim a monopoly over a basic scientific relationship. *See Funk Bros*. Therefore, it is against public policy to hold people liable for innocently using methods they assumed could not be patented.
    - Methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. *See Diehr* (particular application of Arrhenius equation); *but not Flook* (limiting abstract idea to one field of use or adding token post-solution components do not make concept patentable).
- **Machine or Transformation Test** (Fed. Cir. Test, Benson, Bilski) is also used when evaluating patent-eligibility of method claims that does not include particular machines.
    - Under this test, a claimed process is patent-eligible under §101 if: 1) it is tied to a particular machine or apparatus; or 2) it transforms a particular article into a different state or thing.
    - Process will satisfy the transformation prong 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.
    - Not the sole test for deciding whether an invention is a patent-eligible process. *See Bilski*.
- **Four categories of inventions**/discoveries eligible for protection
    - **Processes** (aka method) is a series of steps for carrying out a given task; can be granted for a novel and nonobvious method of making an old product; includes a new use of a known process, machine, manufacture, composition of matter, or material.
        - Patentable
            - Diehr; Telephone Cases; Medical/surgical procedures patentable; State Street
        - Not Patentable
            - In re Comiskey (Metal process not patentable); Bilski; Prometheus
    - **Machines** (aka apparatus) is a concrete thing, generally consisting of moving parts, or of certain devices and combination of devices. This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.
        - Computers operating under the control of software programs generally patentable
    - **Manufacture** is an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or machinery. See Chakrabarty.
        - In re Beauregard (Computer software embodied in a particular medium potentially patentable); In re Nuitjen (electric signal not manufacture because manufacture must be a tangible article or commodity)
    - **Composition of matter** is all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture; physical structure of the composition must be novel, not merely its properties (if it's the same structure, may be patentable as a process); can include living organisms. See Chakrabarty.
        - Patentable
            - Parke-Davis; Myriad (isolated from natural state/purification generally patentable)

Exceptions (not protected under common law)

- **Abstract Ideas:** a principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. See Le Roy. A claim that attempts to patent an abstract idea is ineligible subject matter under 35 USC §101. See Bilski (the concept of hedging reduced to a mathematical formula is an unpatentable abstract idea just like the algorithms at issue in Benson and Flook. Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an

abstract idea.
  - Patentable
    - Diehr
  - Not patentable
    - Benson; Bilski; Flook
- **Laws of nature:** manifestation of laws of nature is part of the storehouse of knowledge, free to all men and reserved exclusive to none. There must be human intervention. See Funk Bros.
  - Patentable
    - Myriad
  - Not Patentable
    - Morse; Prometheus; Lab. Corp.; Funk Bros

PATENTABILITY

- **Diamond v. Chakrabarty** (SCUSA 1980)
  - **Invention**: Genetically engineered bacterium that break down crude oil
  - **Issue**:
    - Whether a live, human-made microorganism is patentable subject matter under 35 U.S.C. § 101. Yes
    - Whether respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the meaning of the statute. Yes.

Petitioner (Board)	SCUSA
1970 Plant Variety Protection Act excluded bacteria from its protection (manufacture doesn't include living things)	Plant Patent Act- Legislative intent did not exclude living things from manufacture or composition of matter because it suggest that relevant distinction was between products of nature (living or not) and human-made inventions
Micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection (Flook)	Court should construe the language Congress employed under §101 (consistent with Flook); If unanticipated inventions are not protected, it defeats the concept of patent law
Genetic research is risky and bad	Patentability should not deter scientific mind

  - **Reasoning**: Burger
    - "Manufacture" in § 101 is read broadly to include production that materials new forms by hand-labor or by machinery
    - Respondent's micro-organism is not a natural phenomenon, but to a non-naturally occurring manufacture or composition of matter
  - **Dissent**: Brennan, White, Marshall, Powell
    - Whether Congress intended that respondent be able to secure monopoly on the living organism itself, no matter how produced or how used. No; It is not the Court's role to broaden the reach of the patent laws.
  - **The Importance of Chakrabarty-** Important for biotechnology industry/genetic engineering (whether living or not) eligible for patenting. See e.g., J.E.M. Ag Supply, Inc. v. Pioneer (2001) (newly developed plant breeds may be protected under general patent statute, PPA, and PVPA).
- **Bilski v. Kappos** (SCUSA 2010)
  - **Issue**: Whether a business method is patentable
  - **Invention**: A procedure for instructing how to protect against hedging risk in energy markets
  - **Procedure**: Appeal from applicant (Fed Cir. solely relied on M-or-T Test → not patentable)

Patent Office	SCUSA
It is not tied to a machine and does not transform an article	The Court looks to ordinary meanings of the word "process"
It involves a method of conducting business	Business method is allowed under the statute
It is merely an abstract idea that solves a purely mathematical problem without any limitation to a practical application	Basic concept of hedging is a fundamental economic practice; cannot grant monopoly over abstract idea

- **Reasoning**: Kennedy, Roberts, Alito, Thomas, Scalia
  - Machine-or-transformation test not a sole test
    - Benson (Algorithm is abstract): Algorithm to convert binary-coded decimal numerals into pure binary code not patentable because algorithm is a fundamental truth, formula is a practical effect, no one can claim exclusive right
    - Flook (Algorithm is abstract): Attempted to patent a procedure for monitoring the conditions during the catalytic conversion process in the petrochemical and oil-refining industries (new math algorithm)
      - Math algorithm within the prior art
      - Prohibiting against patenting abstract ideas cannot be circumvented by limiting use of formula to one industry
    - Diehr: Application of a law of nature to a known structure or process is patentable in considering the whole invention
  - Method may include business methods, but some business method patents too vague
    - Hedging, reduced to a mathematical formula, is an unpatentable abstract idea, and patenting it would grant monopoly over an abstract idea
  - Method must still fulfill §102, § 103, and §112 requirements
- **Concurrence**: Stevens, Ginsburg, Breyer, Sotomayor
  - Issue: Whether the machine-or-transformation test is the exclusive test
    - Historical M-or-T test not exclusive
    - Not process b/c it's general method in business transactions
  - **STEVENS**: Majority rule needs to be clarified

- **State St. Bank v. Signature Fin. Group. Inc.** (Fed. Cir. 1998)
  - Claim: System for managing a partner-fund financial services configuration
  - Procedure: Dist. Court held patent invalid because it was business method and algorithm
  - Holding: Business methods potentially patentable
    - Utility was evidenced by production of useful, concrete, tangible result (even though result is in numerical value), now an inadequate test under Bilski.

LAWS OF NATURE, PHYSICAL PHENOMENA AND ABSTRACT

- **Natural Laws**
  - **O'reilly v. Morse** (SCUSA 1854)
    - Claim: Patent on the telegraph using electromagnetism
    - Procedural: Infringement action
    - Reasoning: Taney
      - Claims an exclusive right to use electro-magnetic current in a manner and process which he has not described and not invented, and this monopoly would deprive public of benefit
      - **Neilson**: Rejected claims for improved application of air to produce heat where no particular mode of constructing the receptacle specified
    - Dissent: Wayne, Nelson, Grier

        - Taking new element and making it useful or applying it to perfect a new and useful art can receive patent law protection
    - **Telephone Cases** (SCUSA 1888)
        - Bell filed a patent application entitled improvement in telegraphy
        - Issue: Whether claim to transmit voice telegraphically valid
        - Reasoning: Waite
            - Bell claims the art of creating changes of intensity in a continuous current of electricity, corresponding to the changes of density in the air caused by the vibrations which accompany sounds
            - Bell's claims are valid because creating changes of intensity in a continuous current of electricity is in regard to the particular process with which it was connected in the patent (use of electricity in connection with the patent)
    - **Lab Corp of America v. Metabolite Labs., Inc.** (SCUSA 2006)
        - Metabolite claims method for detecting vitamin B12/B9 deficiency where tests elevated levels of amino acid homocysteine
        - Metabolite sued LabCorp for infringing.
        - **LabCorp**: claim covered an unpatentable principles of nature
        - **Metabolite**: patentable subject matter issue never raised below
            - Correlation is patentable because it is a form of process
                - Entails physical transformation of matter
                - Produces useful tangible result
        - Majority: Metabolite wins on infringement issue
        - Dissent: Breyer, Stevens, Souter
            - Patent should have been invalidated on the ground that it improperly seeks to claim a monopoly over a basic scientific relationship (Correlation between homocysteine and vitamin deficiency is a natural phenomenon)
- **Abstract Ideas & Software: Benson and its Progeny**
    - **Gottschalk v. Benson** (SCUSA 1972)
        - Benson claimed method for converting binary-coded decimal (BCD) numerals into pure binary numerals for a general computer purpose
        - Issue: Whether the method described and claimed is a process within the meaning of the Patent Act
        - Benson:
            - Inventor had to identify a specific and pragmatic application or use of such phenomena to receive a patent
        - Government:
            - A process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing
        - Holding: Douglas
            - Claim was not limited to any particular type of programmable digital computer and neither involved special purpose implementing machinery nor a transformation of substances
            - Alternate means to protect programs → Copyright protection
    - **Diamond v. Diehr** (SCUSA 1981)
        - Issue: Whether a process for curing synthetic rubber which includes in several of its steps the use of a mathematical formula and a programmed digital computer is patentable subject matter under 35 U.S.C. § 101.
        - Claim: A process for molding raw, uncured synthetic rubber into cured products.
        - Diehr (inventors):
            - Process ensures the production of molded articles which are properly cured; constantly measures the actual temperature inside

the mold to calculate the cure time by using Arrhenius equation (where temperature is a variable)
        - Holding: Rehnquist
            - Not unpatentable just because computer is involved
            - Claims involve the transformation of an article
            - Step-by-step method
            - Respondents do not seek to patent a mathematical formula, they seek protection for a process of curing synthetic rubber
        - Dissent: Stevens, Brennan, Marshall, Blackmun
            - Court is not authorized to address whether computer programs should be given patent protection
            - Bright line Rule no program-related invention is a patentable process
- **Natural Products and Substances**
    - **Naturally Occurring, But Artificially Packaged**
        - **Funk Bros Seed Co. v. Kalo Inoculant Co.** (SCUSA 1948)
            - Procedure: Patent infringement suit involving only product claims.
            - Claims: Multi-purpose packages of inoculating root-nodule bacteria
            - Issue: Whether multi-purpose inoculant product comprising a mixture of mutually non-inhibitive strains of Rhizobia was patentable
            - Holding: Douglas
                - The properties of inhibition or of non-inhibition in the bacteria were the work of nature and therefore not subject to being patented
                - Merely advance of packaging of the inoculants
                    - Same effect as before: No new bacteria, no change in species of bacteria, no enlargement of the range of their utility, all it is are mixed inoculants
                    - Enlargement of the range of utility of what exists in nature
                - He who discovers an unknown phenomenon of nature has no claim to a monopoly of it. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end
            - Concurrence: Frankfurter
                - Claims do not meet both of the two requirements:
                    - Useful property results from combination: YES
                    - Particular strains are identifiable and adequately identified: NO; Qualities of product and specific combination need to be specified
    - **Naturally Occurring, But Isolated and Purified**
        - **Parke-Davis & Co. v. H.K. Mulford & Co.** (S.D.N.Y. 1912)
            - Procedure: Infringement suit against HK Mulford
            - Claims: Takamine purified adrenaline and isolate it in the form of a chemical base (medically superior to the older isolates of suprarenal glands)
            - Issue: Whether it was a patentable composition of matter within the meaning of the Patent Act
            - Holding: Hand
                - A person could obtain a patent for isolation of a purified substance even if that is a naturally occurred product of nature

        - No one had ever isolated a substance not in salt form
    - Use of isolates of suprarenal glands now best form of therapy
    - Authoritative scientific assistance in the administration of justice is needed
- **Mayo Collaborative Services v. Prometheus Laboratories, Inc.** (SCUSA 2012)
    - Issue: Whether the claims do significantly more than simply describe natural relations between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective
    - Holding: Unanimous opinion by Breyer
        - Relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiourine drug will prove ineffective or cause harm is law of nature
            - Method determining the correct dose already known methods (conventional, routine)
        - Needs additional features that provide practice assurance that the process is more than a drafting effort designed to monopolize the law of nature itself
- **Ass'n for Molecular Pathology v. USPTO (Myriad)**, (SDNY 2010, Fed Cir 2012)
    - Claims: Isolated DNA sequences (Breast Cancer Susceptibility Genes 1&2)
    - Issue: Whether claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception to § 101

SDNY (Sweet)- Not patentable	Fed. Cir. (Lourie)- Patentable
Parke-Davis doesn't apply because Parke was §102 question	Parke-Davis: Purification of naturally occurring compounds that do not exist in nature in pure form renders such compounds patentable
Need to possess a new or distinctive form, quality, or property compared to naturally occurring article (more than mere advance in degree of purity)	Native and isolated DNA markedly different; Non-naturally occurring (Chakrabarty); chemical transformation
Purification of native DNA does not alter its essential characteristics (same nucleotide sequence)	Isolated DNA used in application where native DNA is unsuitable, different genetic information
Identifying doesn't entitle to a patent	Isolated genes are identified (contra Funk Bros.)
Diehr says to consider the claims as a whole	

UTILITY

Story (1819- yes) → Brana (1995- yes) → Fisher (2005- no) → Brenner (1966- no)

- If inoperable, not useful (and one cannot logically describe how to use inoperable invention in accordance with § 112). But see In re Anderson (Fed. Cir.) (presence of some inoperable embodiments does not necessarily render a claim invalid as lacking utility, as long as PHOSITA can select or discern which embodiments are operable)
- **Immoral or deceptive inventions.** See Murphy (Gambling machine, the USPTO is not going to enforce a standard of morality, by refusing, on the ground of lack of patentable utility, to grant a patent on a game of chance if the requirements of the Patent Act would otherwise have been met); Juicy Whip (Slurpee like dispenser; USPTO not proper arbitrar of whether invention is moral)
- Lack of utility can support both a rejection under § 101 and § 112 because if certain compositions are useless, then specification cannot have taught how to use them

Brenner v. Manson (SCUSA 1966) (Standard in utility = specific and substantial utility) (Research in steroid chemistry was unpredictable, too preliminary a stage to permit patent protection, a patent is not a hunting license, and not a reward for the search, but compensation for its successful conclusion)

- Claims: process for making a known steroid
- Issue: Whether a practical utility of the compound produced by a chemical process is an essential element in establishing a prima facie case for patentability of the process (what constitutes utility in chemical process claims)
- Holding: Fortas- NOT PATENTABLE
    - Trend
        - Patent Office: Not useful, not patentable
        - CCPA: (Application of Nelson) Despite absence of evidence that any of the steroids thus ultimately produced were themselves useful, as long as not detrimental to the public interest
        - Statutory requirement of usefulness of a product cannot be presumed because it happens to be closely related to another compound which is known to be useful
    - Respondent did not disclose a likelihood that the steroid yielded by his process would have tumor-inhibiting characteristics
    - Whether a chemical process is "useful" within the meaning of §101 should be interpreted in light of the general intent of Congress (otherwise it would create a monopoly of knowledge)
- Dissent: Harlan
    - In the absence of legislative history, court looks to policy and practice
    - Majority's definition of useful is too narrow
        - Process is useful because it facilitates further research into possible product uses
    - Public interest
        - Majority's decision has a negative impact on chemical research; A researcher who discovers a new chemical has an incentive to keep the discovery secret while a use for the chemical is sought

Brana (Fed. Cir. 1995) (1) clarified the procedural burdens borne by the patent applicant and the USPTO during a utility determination [USPTO has initial burden challenging that applicant's presumptively correct assertion of utility, only after USPTO provides evidence showing that PHOSITA would reasonably doubt utility, does burden shift to applicant, which can be shown through submissions of test data, experimental results, affidavits of experts]; 2) biomedical invention may possess patentable utility even though not yet at the stage of development necessary for sales approval by FDA.

- Claims: 5-nitrobenzo [de]isoquinoline-1,3-dione compounds (antitumor substances)
- Issue: What must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is sought.
- Holding: Patentable
    - Only after PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence- PTO haven't met this burden
    - People of ordinary skill in the art would not doubt utility
    - Applicant offered sufficient evidence to convince utility

Fisher (Fed. Cir. 2005) (an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public and in order to demonstrate a substantial utility)

- Claims: Five purified nucleic acid sequences that encode proteins and protein fragments
    - Serving as a molecular marker; Measuring level of mRNA; Providing a source for primers; Identifying the presence or absence of a polymorphism; Isolating promoters; Controlling protein expression; Locating genetic molecules
- Holding: Michel

- *Specific and substantial utility* must have significant and presently available benefit to public
- Claimed ESTs are research intermediates to help identify what genes are unknown
- Underlying genes have no known function
- Fisher talks about hypothetical possibilities, not how they have been used in the real world
  - No evidence showing how it is used; Asserted uses are not specific; No evidence of purchase by agriculture companies

- Dissent:
  - ESTs have some utility: a research tool in isolating and studying other molecules
  - ESTs are beneficial to society

§ 112: WRITTEN DESCRIPTION

35 USC §112 requires that the specification shall contain adequate disclosure of the invention. The elements of the disclosure requirement are: **1) enablement; 2) written description** (the inventor must describe what she claims, and claim what she describes); **3) definiteness of claims** (the claims must allow others to easily discern the boundaries of the patent holder's right); and **4) best mode** (an inventor must disclose to the public the best mode she knows for practicing the claimed invention).

1) Enablement:

- The enablement requirement requires the inventor to describe her invention clearly enough so that one skilled in the art can understand it well enough to make and use it.
- TEST: whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. See In re Wands (it did not require undue experimentation); see c.f., The Incandescent Lamp Patent (to claim a genus, patent applicant must provide a structural similarity or relationship between species that a person having ordinary skill in the arts would recognize).

2) Written description:

- TEST: a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. However, showing possession alone does not cure the lack of a written description.

3) Definiteness of claims:

- TEST: whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. See Orthokinetics (as long as those of ordinary skill in the art realized the dimensions could easily be obtained, §112 requires nothing more).

4) Best mode:

- Two-prong inquiry:
  - whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention (subjective);
  - if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a PHOSITA could practice it (objective) Chemcast Corp. v. Arco Industries.

ENABLEMENT: PHOSITA can make or use the invention without undue experimentation

- **Undue Experimentation**
  - **The Incandescent Lamp Patent (SCUSA 1895):** (Test for claiming genus- to claim the whole genus, you must provide a structural similarity or relationship between species that a PHOSITA would recognize)
    - Claims: Electric lamps employing an incandescent conductor made of fibrous and textile materials (including Edison's specialized Bamboo)
    - Issue: Whether Sawyer and Man could claim for all fibrous and textile materials including discoveries made by others

        - Holding: Brown- Not patentable
            - Fibrous and textile materials was too broad and attempted to monopolize use of all fibrous and textile materials
    - **In re Wands (Fed. Cir. 1988)** (Enablement- a person having ordinary skill in the arts can make or use the invention without undue experimentation)
        - Issue: Whether it would require undue experimentation to produce high-affinity IgM monoclonal antibodies. No.
        - Claim: Immunoassay *methods* for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype
        - Holding: Smith
            - What constitutes undue experimentation requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art
                - The inventor must be able to reproduce the starting materials; Doesn't need to be 100% success in reproducing but should be reasonable within the state of the art
            - **Factors to determine whether disclosure requires undue experimentation (from In re Forman):** Quantity of experimentation necessary; The amount of direction or guidance presented; The presence or absence of working examples; The nature of the invention; The state of the prior art; The relative skill of those in the art; The predictability or unpredictability of the art; Breadth of the claims
- **Speculation and Prophesy** (an example may be working or prophetic. A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved)
    - **Janssen Pharms. v. Teva Pharms. USA Inc. (Fed. Cir. 2009)** (Constructive model for the state of art not sufficient)
        - Claims: Method for treating Alzheimer's disease w/ galanthamine (1 pg. spec)
        - Issue: Does the patent meet the enablement? No.
        - Holding: Dyk
            - No in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided
            - Inventor admitted to not being sure that galantamine would ever work, and its potential benefits speculative
            - Spec 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

THE WRITTEN DESCRIPTION REQUIREMENT

- **Limitations on Amendments**
    - § 120. Benefit of Earlier Filing Date in the United States
    - § 132. Notice of Rejection; Reexamination
    - **The Gentry Gallery, Inc. v. The Berkline Corp. (Fed. Cir. 1998)** (sofa case- later claims need to be supported by initial disclosure as claims can only be broad as their disclosure; a claim need not be limited to a preferred embodiment, but the scope of the right to exclude may be limited by a narrow disclosure especially if it is an essential element of invention)
- **Limitations on Claim Breadth**
    - **UC v. Eli Lilly (Fed. Cir. 1997): Constructive Model** (sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of genus)

- Claims: UC researchers discovered complimentary DNA sequence for rat insulin
  - Included a prophetic general example describing how to obtain the human cDNA sequence in patent
- Issue: Whether UC had to wait until they had done additional research before filing on a claim for the microorganism containing the cDNA coding for human insulin. Yes.
- Holding:
  - Too much of a leap from rat insulin to function in humans
  - In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. PHOSITA can distinguish such a formula from others and can identify many of the species that the claims encompass. Therefore, such formula is normally adequate description of the claimed genus.
  - In claims to genetic material, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes or any structural features, and a PHOSITA cannot as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. Therefore, definition only by function does not suffice to define genus.

- **Ariad v. Lilly (Fed. Cir. 2010): Constructive model similar to Janssen** (**Possession Test:** specification must demonstrate possession, i.e., PHOSITA recognized & identified the invention at time of the application)
  - Procedure: Ariad sues for infringement
  - Claims: Method for regulating eukaryotic cell (genus claims)
  - Issue: Whether the disclosure of the application reasonably conveys to PHOSITA that the inventor had possession of the claimed subject matter as of filing date. No.
  - Holding: Lilly wins
    - An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it
    - §112 requirements
      - Precise definition- structure, formula, chemical name, physical properties sufficient to distinguish the genus from other materials
      - Functional claim when the art has established a correlation between structure and function
    - Must satisfy the inventor's obligation to disclose technologic knowledge upon which the patent is based and demonstrate that patentee was in possession of the invention
    - **Possession test:** PHOSITA recognize/identify the invention
    - **Enablement test:** PHOSITA can make/use invention without undue experimentation
    - Ariad didn't disclose enough species for a claim of genus, only disclosed key structure 2 years after application

  Dissent: There is no additional "possession" requirement under the statute

DEFINITE CLAIMS: Can one skilled in the arts make and use invention?

- **Orthokinetics, Inc. v. Safety Travel Chairs, Inc.** (Fed. Cir. 1986) (claim definiteness is to be determined from the perspective of one skill in the art)
  - Claims: Collapsible pediatric wheelchair that facilitates the placing of wheelchair bound persons in cars

- Holding (Markey): The "so dimensioned" claim language is definite enough- It would be obvious to PHOSITA that dimensions depend on car model

THE BEST MODE REQUIREMENT: Not only should the patent be enabling, but should set forth what the inventor considers to be the "preferred embodiment" or the best way of practicing the invention at the time the patent application is filed

- **Randomex, Inc. v. Scopus Corp. (Fed. Cir. 1988)**
  - Claims: Portable apparatus used to clean computer disk packs
  - Issue: Was Randomex's indiscriminate disclosure of best mode sufficient? Yes.
  - Holding: Bissell- Patent is valid
    - PHOSITA with some experimentation could have figured out not to use 91% alcohol because it's dangerous
    - Nondisclosure of the cleaning formula per se did not rise to the level of violating the statutory requirement to disclose the best mode
    - Plaintiff's disclosure of the preferred cleaning fluid along with another possible fluid satisfied the best mode requirement
      - Although a trade name along may be inappropriate in a best mode disclosure when suitable substitutes are unavailable, commercial substitutes were available in the prior art and trade name is mere surplusage
  - Dissent: Meyer
    - Knew other solutions could be dangerous but still did not disclose the best method (bad faith, concealment)
- **Chemcast Corp. v. Arco Industries (Fed. Cir. 1990)**
  - Procedure: Chemcast sued for patent infringement
  - Claims: Plaintiff held a patent for a dual durometer grommet
  - **BEST MODE TEST:** Whether at the time of his patent application the inventor subjectively knew of a better mode (yes); Whether the inventor's disclosure was objectively adequate to enable one skilled in the art to practice the best mode (no)
  - Holding: Mayer- Patent invalid
    - One skilled in the art could not divine the inventor's preferred material given the specification
      - Failure to specify: 1) particular type; 2) the hardness; and 3) supplier and trade name, of the material used to make the locking portion of the grommet
    - Where the inventor has failed to disclose the only mode he ever contemplated of carrying out his invention, the best mode requirement is violated

NOVELTY REQUIREMENT (3rd party activity based on the date of invention)

- **Subsection (a)**
  - **No patent if BEFORE date of invention, the invention was:**
    - **Known**
    - **Used**
    - **By others**
    - **In this country**
  - **No patent if BEFORE date of invention, the invention was:**
    - **Patented**
    - **Described in printed publication**
    - **Anywhere (globally)**
- *Inventor's own work can never destroy novelty*
  - *§102(a)(1) limited to activities of others*
  - *§102(a)(2) implicitly limited*
- Subsection (e); Subsection (g)

Statutory Bar (either 3rd party or inventor activity, based on 1 year priority to an application's filing date)

- Subsection (b), (c), Subsection (d)

Derivation: Subsection (f)

The Structure of Novelty Analysis and the Parlance of Patent Law

- **Analysis for determining Novelty**
  - **Whether some item can qualify as a reference under one or more relevant subsections of §102**
    - Published US patent applications qualify as references (§102(e)(1))
  - **The relative timing**
    - **Critical date**
      - Refers to the date of the applicant's invention
      - Also used in analyzing statutory bars → refers to the date one year prior to the application filing date
        - **Prior art**: Any reference having an effective date before the critical date
  - **Anticipation** (i.e., lack of novelty): Whether the information disclosed in a pre-critical date reference is sufficient to render the applicant's invention non-novel

The Standard for Anticipation

- **The Identity Requirement**
  - **Every element test:** A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Thus, inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. See Shering Corp.; see also, MEHL/Biophile Int'l Corp. (where the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results). Cases dealing with accidental, unwitting, and unappreciated anticipation also do not show that inherency requires recognition. See In re Seaborg.
  - **In Re Robertson** (Fed. Cir. 1999) (diaper case §102(e))
    - Claim: Fastening and disposal systems for diapers
      - Claim 76 is for an improved mechanical fastening system → Two mechanical fastening means to attach the diaper
      - Wilson does not provide a separate fastening means to be used in disposing the diaper
    - Holding: Friedman- Inventor wins
      - If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is inherent in its disclosure
        - To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present (not possibilities or probabilities) in the thing described in the reference and that it would be so recognized by persons of ordinary skill
  - **Anticipation-Infringement Symmetry**
    - Anticipation analysis similar to infringement analysis
  - **§ 103 and Bifurcated Invalidity Inquiry**
    - Two part analysis in Robertson whether claim is invalid
      - Anticipation
      - Obviousness
    - Rationale
      - Forces courts to identify differences between prior art and the invention
      - Demanding that the differences be evaluated under §103

- **Accidental and Unknown Anticipations**
  - **In re Seaborg** (C.C.P.A. 1964)
    - Claims: Element 95, Americium (Am), isotope, methods of producing and purifying element and composition thereof
    - Holding: Smith- Patent valid, not anticipated
      - There is no positive evidence that americium was produced inherently in the natural uranium fuel by the operation of the reactor
      - Even if a minute amount of americium may have been produced in the Fermi reactor, it was not identified (nor it could have been identified) would preclude the application
  - **Tilghman v. Proctor** (SCUSA 1880) (same as Seaborg, not anticipated)
    - New process for breaking down animal fat into glycerine and free fat acids
    - Scientific journal disclosed accidental formation of fat acid in Perkin's engine
    - Tilghman's invention not anticipated by the Perkins engine because *if the acids were accidentally produced, while operators were in pursuit of different results, it would be absurd to say that their result anticipated Tilghman's discovery*
  - **Schering Corp. v. Geneva Pharmaceuticals, Inc.** (Fed. Cir. 2003) (a limitation or the entire invention is inherent and in the public domain if it is the natural result flowing from the explicit disclosure of the prior art)
    - Procedure:
      - Shering sues for infringement of metabolite of loratadine (DCL)
    - Holding: Rader- Patent invalid for anticipation
      - Inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure
      - DCL not formed accidentally- Inherent anticipation: DCL necessarily and inevitably forms from loratadine (prior art) under normal conditions
      - Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure
        - Anticipatory reference only needs to enable. To qualify as enabled reference, it need only describe how to make DCL in any form encompassed by a compound claim covering DCL → w/o undue experimentation
      - With proper claiming, patent protection is available for metabolites of known drugs (e.g., Kratz, Bergstrom, or as a pharmaceutical composition with a pharmaceutically acceptable carrier)
    - Dissent: Newman
      - A newly discovered attribute or property of something that was already known is patentable as a method of use
- **The Enablement Standard for Anticipation**
  - **In Re Hafner** (C.C.P.A. 1969) (§102 makes no requirement to enable PHOSITA to use the invention)
    - Claim: Hafner invented new chemical compositions, then filed two German patent applications and a US patent application, but US application was rejected under §112. Hafner filed a new application with additional disclosures but his old application became prior art. He couldn't est. invention date for purposes of §102 for work outside the US. Under §120, he can establish date of invention by reference to a foreign filed patent app if satisfied §112 (which he didn't)
    - Holding: Rich

        - §112 provides that the spec must enable PHOSITA to use the invention whereas §102 makes no such requirement as to an anticipatory disclosure
        - Hafner is not entitled to rely on the German app. filing date or his 1960 US application to establish a date of invention for purposes of §102
    - **The Broccoli Sprout Patent**
        - Johns Hopkins University discovered method of preparing certain types of broccoli that prevents cancer. Farmers were already growing broccoli, and JH Univ. sues for infringement. Farmers argue that patent is invalid. Farmers win.
        - Court holds patent invalid because practice of growing and preparing broccoli already in use/known practice and JH Univ. doesn't need patent to make profit.
    - **Lockwood v. American Airlines** (1997)
        - SABRE developed an algorithm for an airline reservation system. SABRE system did constitute prior art because it was known or used by others
    - **Genus v. Species:** Prior art that discloses species anticipates future claim to genus. See Titanium Metals Corp. v. Banner.

References under § 102(a)

- The ***Domestic*** Inquiry: Known or Used by Others
    - ***Known by others***
        - **National Tractor Pullers Ass'n v. Watkins** (N.D. Ill. 1980) (in order to qualify as prior art under 35 USC §102, the art must be art which was known before the invention by the patentee. Prior knowledge as set forth in 35 USC §102(a) must be prior public knowledge, that is knowledge which is reasonably accessible to the public, and is not satisfied by knowledge of a single person, or a few persons working together)
            - Action for declaration of invalidity and non-infringement brought by National Tractor against the patentee because it was known/used
            - Claims: Power stopper weight transfer apparatus (tractor pulling sleds)
            - Holding: Roszkowski- Not known by others
                - **Corroboration Rule:** Need more than corroboration of testimony to show there was public access. See The Barbed Wire Patent. The policy is that witnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information.
                - **Woodland Trust v. Flowertree Nursery** (Fed. Cir. 1998)
                    - Nursery- a system for preventing freeze damaging plants
                    - §102(a) not satisfied by knowledge of a single person, or a few persons working together
        - ***Lost Art***
            - **Gayler v. Wilder** (US 1850) (prior art device built by Connor, which had been lost and whose details of construction had been forgotten by all concerned, did not anticipate the patented invention at issue)
            - Now the standard is CLEAR AND CONVINCING EVIDENCE of public access
    - ***Used by Others***

- **Rosaire v. Baroid Sales Division, National Lead Co.** (5th Cir. 1955) (the fact of public knowledge does not need to be shown before invalidating a patent)
    - Procedure: Infringement
    - Claims: Methods for prospecting for oil or other hydrocarbons
    - Issue: Whether Teplitz's work was an unsuccessful experiment as claimed by Rosaire or successful and reduced to practice as contended by appellee.
    - Holding: Tuttle- Public use
        - There was more than an unsuccessful or incomplete experiment, even though the work was not carried forward, and the program was suspended to examine data
        - Worked under ordinary conditions without attempt at concealment or effort to exclude the public
            - **Business as usual:** The non-secret use of a claimed process in the usual course of producing articles for commercial purposes is a public use. See WL Gore & Assocs. v. Garlock.
- **Abandoned experiments**
    - **Picard v. United Aircraft Corp**. (2d Cir. 1942)
        - Prior experiments can constitute prior art, but only under certain conditions (e.g., experiment was perfected and became publicly known)

- ***Global*** inquiries: Patents and Printed Publications
    - ***Printed Publications*** (not necessary for public use)
        - **Jockmus v. Leviton** (2d. Cir. 1928) (invention was anticipated by a product pictured in a catalogue distributed to French customers of a German firm)
            - Procedure: Plaintiff (patentee for an adjustable candle shaped light bulb holder) sued defendant for infringement
            - Holding: Hand- Anticipated
                - The catalogues are sent to targeted audience **practicing in the art** (i.e., those whose interests make them likely to observe and remember whatever it may contain that is new and useful)
                - Doesn't have to prove that the catalogue was received
        - If you don't want to disclose/limit disclosure
            - Confidentiality agreement; Non-disclosure agreement; Limit audience; Confidential notice
        - **In re Klopfenstein** (Fed. Cir. 2004) (not novel under §102(b) because it had already been described in a printed publication more than one year before the date of the patent application)
            - Procedure: Klopfenstein appeal from Board decision denying application
            - Claims: Methods of preparing foods comprising extruded soy cotyledone fiber
            - Holding: Prost
                - Publication doesn't have to be printed per se
                    - **In re Cronyn** (undergraduate thesis presented to four faculty members and later catalogued in library index not publicly accessible for purposes of §102(b)).
                    - **Hall** (thesis filed and indexed in a university library freely available to public counted as printed publication)

- **MIT v. AB Fortia** (a paper delivered orally to the First International Cell Culture Congress where copies of presentation distributed considered printed publication)
- **In re Wyer** (Australian patent application kept on microfilm at the Australian Patent Office was printed publication)

- **Factors considered to determine whether invention is publication**
  - **Expertise of intended audience**
    - Displayed to a large subsection of whom possessed ordinary skill in the art
  - **Expectation that the audience would not copy**
    - No notice prohibited note-taking/copying
  - **Ease of copying**
    - No copies disseminated
  - **Length of time available to the public**
    - Reference displayed for three days

- ***Patented***
  - **Reeves Bros. v. US Laminating Corp.** (2d Cir. 1969) (what is publicly known or used but not printed in a foreign country is not a bar to an American patent)
    - Claims: improvement in the method and apparatus for such lamination of polyurethane foam to fabric by the use of flame heat
      - Defendants claim Gebrauchsmuster ("GM") German patent (not printed) as anticipation

- **SRI v. ISSI Symantec** (2007)
  - A panel related to a conference receives "Emerald" from SRI. ISSI contend Emerald anticipated SRI's methods for network intrusion detection. SRI wins, Emerald not considered prior art even though it was placed on SRI's FTP server.

Section 102(e): Disclosures in Earlier-Filed U.S. Applications

- **Alexander Milburn Co. v. Davis-Bournonville Co.** (SCUSA 1926)
  - Procedure: Infringement case
  - Claim: Improvement in welding and cutting apparatus
  - Issue: Whether Clifford's disclosure made it impossible for Whitford to claim the invention at a later date. Yes.
  - Holding: Holmes- Anticipated, Clifford wins
    - Publication in a periodical is a bar
      - It would have been no bar to Whitford's patent if Clifford had written out his prior description and kept it in his portfolio uncommunicated to anyone
        - Whitford was not the true first inventor, evidence shows Clifford invented first
      - Clifford included his invention in his written description
    - A description that would bar a patent if printed in a periodical or in an issued patent is equally effective in an application so far as reduction to practice goes

Section 102(f): Derivation from Another. No one is entitled to a patent if the invention was derived from someone else's work. The other person's work may be public or private, written or oral, domestic or foreign. In all circumstances, the patent law does not reward the thief.

- **Campbell v. Spectrum Automation Co.** (6th Cir. 1975) (spring coil in belt buckle)

- Procedure: Campbell sued for Infringement **(Clear and convincing standard- higher standard than preponderance of evidence in interference case)**
- Issue: Who is the true inventor of the flexible feed track? Zimmerman.
- Claim: "Open flex" feed track for delivering articles (Zimmerman used to work with Campbell but left and started own company)
- Holding: Phillips
  - Because Zimmerman was the true inventor, the patent is invalid under §102(f)
  - Proof sustaining existence and use must be *clear, satisfactory, and beyond a reasonable doubt*
    - Trial court's findings of fact and determinations of credibility, coupled with corroboration, sustain the heavy burden necessary to establish that Zimmerman is true inventor

Timing Issues: §102(g) priority of invention

- The first to reduce the invention to practice usually has priority
- Filing a valid application constitutes a constructive reduction to practice
- The first to conceive may prevail over the first to reduce to practice if the first to conceive was diligent from a time prior to the other inventor's conception through to her own reduction to practice (either actual or constructive)
- Any reduction to practice that has been abandoned, suppressed, or concealed is disregarded
- **Dow Chemical Co. v. Astro-Valcour, Inc.** (Fed. Cir. 2001) (foam case §102(g)(2))
  - Procedure: Dow sued AVI for infringement and AVI counterclaimed for declaratory judgment
  - Claim: Plastic foam blowing agents
  - Issue: Whether, when challenging the validity of a patent under 35 U.S.C. (s) 102(g), a prior inventor must have know that he was an inventor. No.
  - Holding: Dyk- AVI wins
    - Astro-Valcour, Inc. was the first inventor
      - Foam made by AVI prior to Dow met all limitations of Dow patent
      - Employees qualify as prior inventors under §102(g). See Heard; Silvestri.
    - A prior inventor doesn't need to know that he was an inventor or appreciate the patentability of the invention, just needs to appreciated what they made and its significance
    - Apotex: If a patentee's invention has been made by another, and prior inventor has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent
    - AVI did not abandon, suppress, or conceal its invention
      - **Two types of abandonment**
        - Inventor **actively** abandons, suppresses, or conceals his invention from the public
        - Abandonment, suppression, or concealment may be **inferred** based upon the prior inventor's unreasonable delay in making the invention publicly known
          - There is no time limit regarding time period between making of invention and disclosure
          - A prior inventor is only to make reasonable efforts to bring the invention to market

Establishing a Date of Invention: Rule 131

- § 1.131 Affidavit or Declaration of Prior Invention: When the reference is not a statutory bar under 35 USC §102(b), (c), or (d), applicant can overcome the rejection by swearing back of the reference through the submission of an affidavit under 37 CFR 1.131. See In re Foster.

- Allows a patent applicant to show invention before the date of a prior art reference to swear behind or antedate the reference
- **Two limitations to Rule 131**
  - **Cannot be used where allegedly anticipatory reference is a US Patent or US Patent Application claiming the same invention → Interference must be declared**
  - **Cannot be used where the examiner has rejected the patent application based on a statutory bar (§§ 102(b), (c), (d))**
    - Statutory bar subjections of §102 don't depend on date of applicant's invention

- **In re Moore** (Fed. Cir. 1987)
  - Facts: Moore filed §131 affidavit to overcome an article in British chemical journal
  - Issues: Whether Brenner undermined Wilkinson. No.
  - Holding: Baldwin- Moore wins
    - § 131(a) requires oath to facts showing a completion of invention before effective date of reference
    - § 131(b) requires showing of facts to establish prior reduction coupled with due diligence (either actual or constructive)
      - In order to overcome a reference that disclosed a chemical compound but not utility, affidavits had to prove only that the inventor made compound prior to reference not that he found use. See Wilsinson.
    - Under Wilkinson, the conception and reduction to practice, which must be established under § 131, need not be the same as what is required in the interference sense of those terms.
    - Public policy considerations for *ex parte* applicants trying to obtain a patent
      - Disclosure in an application does not give applicant the statutory right to a patent, even if there were no anticipating reference
      - Brenner (chemical process is not useful in the sense of 101 unless product has specific practical utility) not applicable because it was inter parte

STATUTORY BAR

While novelty rewards the first inventor and ensures that society receives something new when it grants a patent, statutory bars encourages early patent application filing. The statutory bars under §102(b), (c), and (d) can bar an applicant from obtaining a patent even if the applicant is the first inventor of the claimed invention. This is triggered by events after the date of invention because this aspect of the statutory bars places pressure on inventors to seek a patent quickly. Benefits to early filing include: increased reliability of public information; faster dissemination of new information and claims; and early termination of patent rights. Under §102(b), if an inventor waits more than one year to file, printed publications and other items qualify as prior art under. As such, inventor can create a statutory bar with her own work if it is patented or published before the critical date. §102(b) is triggered by activities of the applicant as well as third parties, whereas §102(c) and (d) are only triggered by activities of applicant.

Section 102(b): The General Statutory Bars

- **No patent if, more than one year (grace period) prior to application, invention:**
  - **Patented**
  - **Described in printed publication**
  - **Anywhere; or**
  - **Invention:**
    - **In public use;**
    - **On sale;**
    - **In this country**
- Review of Patents and Printed Publications
  - § 102(b)(1)(A): Patents
  - § 102(b)(1)(B): Printed publications
- **"In Public Use or on Sale"**
  - **Public Use**

- **Pennock v. Dialogue** (SCUSA 1829) (fire hose- if known or used in commerce before his supposed discovery he is not the first inventor, although he may be a true inventor)
  - Procedure: Pennock sued for infringement
  - Claim: Improvement for making tubes by joining parts
  - Issue: Whether the plaintiff meant to abandon his invention by the permission to Jenkins (third party) to use it. Yes.
  - Holding: Story
    - There must be a voluntary abandonment, negligence, or unreasonable delay in obtaining patent to destroy the right of the patentee
    - Act of congress: Not known or used in the public before application is ok
    - The use here was public
- **Egbert v. Lippmann** (SCUSA 1881) (corset case- public use only requires one person)
  - Claims: Improvement in corset-springs
  - Procedure: Egbert sued for infringement
  - Issue: Use of corset a public use within meaning of the statute? Yes.
  - Holding: Woods- Lippmann wins, public use
    - To constitute the public use of an invention it is not necessary that more than one of the patented articles should be publicly used
    - Whether the use of an invention is public or private does not depend on number of persons to whom the use is known
    - Some inventions are by their nature only capable of being used where they cannot be seen in public
    - Barnes imposed no obligation of secrecy
    - The invention was complete and not changed
    - Egbert slept on his rights for 11 years
  - Dissent: Miller
    - A private use with consent which taught the invention to only the party to whom such consent was given, was no abandonment to the public
    - The invention was always withheld from public
- **Moleculon Research Corp. v. CBS, Inc.** (Fed. Cir. 1986) (Not public use where invention not given free or unrestricted use; assignment or sale of the rights in the invention does not mean sale of invention within meaning of §102(b))
  - Procedure: Assignee (Moleculon) sued for infringement
  - Claims: Rubik's cube
- **Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.** (2d Cir. 1946) (can't keep trade secret and apply for a patent when at a risk of losing trade secret)
  - Claims: Method for conditioning metal surfaces
  - Procedure: Metallizing sued for infringement
    - Kenyon appeal
      - Patent invalid because it was in public use for more than a year
  - Issue: Whether Meduna's public use of the patented process was more than one year before August 6, 1942. Yes.
  - Holding: Hand- Kenyon wins, dismissed

- *Peerless Roll Leaf* (machine was secret, but its output was freely sold on the market, sustained patent) was wrongly decided, and must be overruled
  - *Gillman v. Stern* was rightly decided though, even though it followed *Peerless Roll Leaf*
- Same principle as Pennock- The period of monopoly is not extended even if done in secret

- **On Sale**
  - **Pfaff v. Wells Electronics, Inc.** (SCUSA 1998)
    - Issue: Whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice. Yes.
    - Claims: Computer chip socket
    - Procedure: Pfaff brought infringement action
    - Holding: Stevens- BARRED to patent
      - Invention may be patented before it is reduced to practice. *See e.g., Telephone cases*
      - **Two part test for triggering on-sale bar**
        - **Invention is offered for sale** (to Texas instrument)
        - **Invention is ready for patenting** (had drawings)
          - **Proof of reduction to practice before critical date**
          - **Proof that prior to the critical date the inventor had prepared drawings or other description of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention**
  - **Abbott Lab. v. Geneva Pharma., Inc.** (Fed. Cir. 1999)
    - Procedure: Abbott alleged infringement
    - Claims: Chemical compound for treatment of hypertension and benign prostatic hyperplasia
      - Abbott marketed the compound
      - Byron made three sales of same compound (outside US)
    - Issue: Does third party activity bar patent under §102(b)? Yes.
    - Holding: Lourie- BARRED to patent
      - There is no requirement that a sales offer specifically identify all the characteristics of an invention offered for sale or that the parties recognize the significance of all these characteristics at the time of the offer
      - If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale (two foreign manufacturers already reduced it to practice)
      - Statutory on-sale bar not subject to exceptions for sales made by third parties either innocently or fraudulently
        - Irrelevant that third party made sale
- **The Experimental Use Exception.** Experimental use exception does not apply to market testing and it also does not apply after an invention is reduced to practice.
  - **City of Elizabeth v. American Nicholson Pavement Co.** (SCUSA 1877)
    - Procedure: Infringement case (wooden pavement)
    - Holding: Bradley- NOT BARRED, FALLS UNDER EXCEPTION
      - Not public use because it was an experimentation

- Nicholson (inventor) remained in control of his invention
  - Took notes; Regularly checked on it; Evidence corroborated by several other witnesses

- **Lough v. Brunswick Corp.** (Fed. Cir. 1996)
  - Claim: Seal assembly resistant to corrosion tested on friends' boats
  - Holding: Lourie- BARRED
    - **Whether a use is experimental (Totality of the circumstances)**
      - Various objective indicia of experimentation surrounding the use; Number of prototypes; Duration of testing; Records or progress reports; Existence of a secrecy agreement between the patentee and the party performing the testing; Whether the patentee received compensation for the use of the invention; Extent of control the inventor maintained (given the greatest weight)
    - The inventor never asked for a feedback, didn't keep records

- **Third Party Statutory Bar Activity**
  - **Baxter Int'l v. Cobe Lab., Inc.** (Fed. Cir. 1996)
    - Procedure: Baxter sued Cobe Lab for infringement
    - Claims: Sealless centrifuge for separating blood into its components
    - Holding: Lourie- Cobe wins
      - **Policies underlying the public use bar:**
        - **Discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available**
        - **Favoring the prompt and widespread disclosure of inventions**
        - **Allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent**
        - **Prohibiting the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time**
      - Lack of direction or control over Suaudeau's use
      - No duty to maintain confidentiality
      - Lab located in public building, accessible by other employees
      - The centrifuge that Suaudeau was using met all the limitations of the patent
      - Suaudeau and Ito weren't trying to refine the invention
  - **W.L. Gore & Associates, Inc. v. Garlock, Inc.** (Fed. Cir. 1983)
    - Procedure: Gore sued Garlock for infringement of '566 patent
    - Claim: Machine rapidly stretching Teflon. (sold to third party w/ trade secret provision in sales agreement)
    - Holding: Markey- Not barred under §102(b)
    - Issue: Whether Budd's sale would defeat Gore's right to a patent on the process inventions set forth in the claims. No.
    - Holding: Markey- NOT BARRED
      - There was no evidence that the public could learn the claimed process by examining the tape
  - **Trade Secret**- Widely known but contractually confidential information

        - Generally, patentee can't profit from disclosing information yet keep it secret (disseminate information, build an early demand, improve it) without statutory bar consequences
        - New problem: electronic confidentiality agreements
            - Exceptional cases when Court will not invalidate patent for prior use
                - Court may negate patent law effect of a confidentiality agreement if it purported to protect a ubiquitous source relied on by an industry
                - Hard to enforce confidentiality agreements

A. Introduction: Nonobviousness and Invention

- Measure of technical accomplishment
    - Whether a development is a significant enough technical advance to merit the award of a patent
    - Is it more than merely a trivial change to the prior art
- Economic justifications
    - If an idea is so obvious that people in the field would develop it without much effort, then the incentives provided by the patent system may be unnecessary to generate the idea
    - Granting patents to obvious developments may comprise the incentives that the patent system provides to develop nonobvious inventions
    - Granting obvious patents may create a proliferation of economically insignificant patents that are expensive to search and to license
- **Hotchkiss v. Greenwood** (US 1851)
    - Procedure: Hotchkiss sued for infringement
    - Claims: Improvement in manufacturing door and other knobs of all kinds of clay used in pottery, and of porcelain
    - Holding: Nelson- Not patentable
        - The only novelty which could be claimed is the adaptation of clay or porcelain knobs (not wood or metal)
            - This does not result from a new mechanical device, just better material → can't patent this
                - E.g., old machine and new machine function same way but new machine is made of different material
                - E.g., button made out of different material
    - Dissent: Woodbury
        - The test is whether patent protects invention new enough or distinguished enough from a former invention, not whether it is valuable or material enough per se to be protected by patent
        - The invention was better and cheaper, so the trial court could have suggested this criteria as a guide to the jury
        - Entitled to patent protection because they improve or increase the power, convenience, and wealth of the community
        - For invention to be new and useful, long and profound experiment and research not necessary
- Notes on nonobvious → Pretty inconsistent standard
    - Hotchkiss standard (more lax than modern law)
        - Patentability could be presumed where, because of the inventor's efforts, a machine has acquired new functions and useful properties
    - **Pearce v. Mulford** (1880) (patentable invention is involving something more than what is obvious to persons skilled in the art to which it relates)

- **Atlantic Works v. Brady** (1883) (invention which adds to our knowledge and makes a step in advance in the useful arts)
  - Unpatentable- trifling device, which would spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures
- **Cuno Engineering Corp. v. Automatic Devices Corp** (1941) (stringent- flash of creative genius test)
  - Automatic electric cigarette lighter for cars
  - Lighter showed ingenuity but unpatentable because it failed to reveal the ***flash of creative genius***

B. Section 103 and the Basic Graham Inquiry

Framework for the objective analysis for determining obviousness under §103 is stated in Graham v. John Deere Co. Obviousness is a question of law based on the following four factors: 1) determining the scope and content of the prior art (prior art can be either in the field of applicant's endeavor or be reasonably pertinent to the problem with which the applicant was concerned); 2) ascertaining the differences between the claimed invention and the prior art (requires interpreting the claim language, and considering both the invention and the prior art as a whole); 3) resolving the level of ordinary skill in the pertinent art; and 4) whether subject matter of the claimed invention is obvious.

Secondary considerations include evidence of: commercial success; long-felt but unsolved needs; failure of others; unexpected results. The weight to be given any secondary considerations is made on a case-by-case basis.

Factors that may be considered in determining the level of ordinary skill in the art may include: 1) type of problems encountered in the art; 2) prior art solutions to those problems; rapidity with which innovations are made; 4) sophistication of the technology; and 5) education level of active workers in the field. See In re GPAC.

- **Graham v. John Deere Co.** (US 1966)
  - Facts:
    - **Graham v. John Deere Co**.
      - Infringement suit
      - Clamp for vibrating shank plows
      - Patent invalid
        - A person having ordinary skill in the prior art would invert the shank and the hinge plate
        - Free-flex was not an element mentioned in the claims
    - **Calmer, Inc. v. Cook Chemical Co.; Colgate-Palmolive Co. v. Cook Chemical Co.**
      - Cook had Calmer initially produce a finger operated sprayer but when Calmer was acquired by another company, Cook hired Scoggin to develop a better sprayer and Calmer later developed a bottle similar to Scoggin's
      - District and Court of Appeals sustained the patent
      - Patent invalid
        - Invention is construed not only in the light of the claims, but also with reference to the prosecution history
          - No mention of sealing features initially in the claims but later relied on use of a rib after rejection
            - Can't obtain patent only by accepting the limitations imposed by the examiner
        - The rib seal is descriptive of an element but not part of the invention

- The seal was already disclosed to the public by Livingstone patent
    - Livingstone was in a different industry of insecticide but the court said that if the inventor is trying to solve the same problem then it is analogous
- Secondary considerations do not tip the scales of patentability

- Holding: Clark
    - **Graham Factors**
        - **Scope and content of the prior art (See Clay Test);**
            - Two factors in determining if a reference was an analogous art
                - Whether the art is from the same field of endeavor, regardless of the problem addressed;
                - If the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved
                    - Reasonably pertinent if, it is one, which because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.
        - **Differences between the prior art and the claims at issue**
            - What problems is the invention solving
            - Requires interpreting the claim language
        - **Level of ordinary skill in the pertinent art**
            - Type of problems encountered in the art
            - Prior art solutions to those problems
            - Rapidity with which innovations are made
            - Sophistication of the technology
            - Educational level of active workers in the field
    - **Secondary considerations**
        - **Commercial success**
            - Because of innovative nature of invention not advertisement
        - **Long felt but unsolved need**
        - **Failure of others**
        - **Copying by industry**
        - **Unexpected results**
            - US v. Adams (US 1966) (wet batteries)
            - Arkie Lures, Inc. v. Gene Larew Tackle, Inc. (Fed. Cir. 1997) (fishing lures)

- **US v. Adams** (US 1966)
    - Companion case to Graham v. John Deere
    - Procedure: Adams sued for infringement
    - Claims: Wet batteries
    - Holding: Clark

- Wet battery including a combination of known elements not obvious because the operating characteristics were unexpected and improved over then-existing wet batteries (fruitful, unpredictable result)
- Battery was water-activated (even though not cited in the claims)
- Considered secondary considerations

** 1982 Fed. Cir. Formed, no §103 case in SCUSA during 1982-2007. During this time, the Fed. Cir. developed teaching-suggestion-motivation (TSM) test

C. Subtests of Nonobviousness

- **KSR Int'l Co. v. Teleflex Inc.** (US 2007)
  - Facts: Teleflex sued KSR for infringement on adjustable pedal assembly with electronic pedal sensor
  - Procedure:
    - District Court ruled in favor of KSR
    - Fed Cir reversed in favor of Teleflex
      - **Teaching-suggestion-motivation (TSM) test**
        - There must be a suggestion or teaching in the prior art to combine elements shown in the prior art in order to find a patent obvious
        - Whether there is something in the prior art to suggest the desirability, and thus the obvious nature, of the combination of previously known elements
    - SCUSA reverses in favor of KSR → OBVIOUS
  - Issue: Whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading a prior art patent with a sensor. Yes.
  - Holding: Kennedy- OBVIOUS
    - Federal Circuit erred in rigidly applying the narrow teaching/suggestion/motivation standard for obviousness
    - PHOSITA has a common sense who could find motivation implicitly in the prior art
    - In determine obviousness, what matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under §103 (if there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims)
    - When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.
- **In re Kubin** (Fed. Cir. 2009)
  - Procedure:
    - Biotech case- Isolating and sequencing of DNA
  - Issue: When is an invention that was obvious to try nevertheless nonobvious? No. (quoting In re O'Farrell, Fed. Cir. 1988)
  - Holding: Rader- OBVIOUS
    - **Two situations where obvious-to-try analysis should not apply**
      - **Throwing darts versus a finite number of identified, predictable known options**
        - KSR- Where a PHOSITA pursues known options from a finite number of identified, predictable solutions, obviousness under §103 arises

        - **Exploring new technology vs. improving known and predictable technology**
            - An impermissible obvious to try situations occurs where what was obvious to try was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it
            - KSR- §103 bars patentability unless the improvement is more than the predictable use of prior art elements according to their established functions
- Objective Indicia in Obviousness Analysis
    - **Arkie Lures, Inc. v. Gene Larew Tackle, Inc.** (Fed. Cir. 1997) (salty fishing lures)
        - Procedure: Arkie filed a declaratory judgment
        - Claims: Salt-added plastic fishing lure (improves fisherman's chance to set the hook)
            - Prior publication - Salty bait; Plastic lures; Adding organic fish attractants to plastic lures while warning against the use of plastic-insoluble additives (salt)
            - Affidavit testimony of PHOSITA- Highly skeptical about the feasibility and safety of adding salt in plastic lures
        - Holding: NOT OBVIOUS, Larew wins
            - No, prior art teaches away
            - Absent some teaching or suggestion, it is not obvious to combine known elements → Unexpected results
            - Statement that a combination should not be made is evidence of nonobviousness
    - **Hybritech, Inc. v. Monoclonal Antibodies, Inc.** (Fed. Cir. 1986)
        - Procedure: Hybritech sued Monoclonal on March 2, 1984 alleging infringement
        - Facts:
            - Hybritech developed diagnostic kits employing monoclonal antibodies that detected numerous antigens
            - Application filed Aug. 4, 1980
            - Patent issued March 8, 1983
                - Claims defining a variety of sandwich assays using monoclonal antibodies
        - Holding: Patent was valid
            - Conception 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

D. The Scope and Content of the Prior Art

- **In re Winslow** (CCPA 1966) (PHOSITA presumed to have full knowledge by the inventor of the prior art in the field of his endeavor)
    - Claim: Machine that places items inside plastic bags by blowing air and holding bags with pins to hold punctured bag flap
    - Holding: Obvious because PHOSITA would have obviously tried the pins to hold up the bags
    - Dissent: Different industries (envelopes), not related patents not obvious to try
- Prior Art for Purposes of §103
    - The Novelty Provisions of §102
        - **Hazeltine Research, Inc. v. Brenner**
            - Regis filed application while Wallace was pending, but it's still obvious because but for PTO's delay the patent would have issued

        - § 102(e) still applies (but the patent HAS to issue)
    - **Oddzon Products, Inc. v. Just Toys, Inc.** (Fed. Cir. 1997)
        - Claim: Foam football
        - Procedure:
            - Oddzon sued for infringement
        - Holding: Lourie
            - Patent was valid, not infringed
            - Two prior arts were confidential
                - What is not accessible to public is generally not prior art
                    - Public policy- if an earlier inventor hides invention from public benefit, then the subsequent inventor should prevail
- The Statutory Bars of §102
    - **In re Foster**
        - Facts: Invention related to elastomeric synthetic polymers filed in 1956, but the inventor swore back to 1952
        - Procedure: Patent office rejects Foster's application because of an article published in 1954
        - Holding: Unpatentable- You can't have a secret invention and then all of a sudden swear back when an article comes out
- The Nonanalogous Arts Limitation
    - **In re Clay** (Fed. Cir. 1992)
        - Claim: An improvement to the way oil was stored in storage tanks
        - Procedure:
            - Examiner/Board denied patent… Clay appeals
                - Hetherington: airbag filled up bottom of oil tank for storage
                - Sydansk: injected a gel underground into oil wells to improve oil flow
        - Holding: Clay wins
            - Sydansk had nothing to do with oil tanks
            - **Two factors in determining if a reference was an analogous art**
                - **Whether the art is from the same field of endeavor, regardless of the problem addressed;**
                - **If the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved**
                    - Reasonably pertinent if, it is one, which because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.
            - Can't use hindsight to determine whether something is nonobvious, but whether someone in the inventor's field would think to look at