

# PATENT LAW

Randy Canis

CLASS 3

**Utility pt. 2;  
Novelty Under the AIA pt. 1;  
ST: Reading a Patent**

## Utility pt. 2

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## The Utility Requirement in Chemistry and Biotechnology

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## Brenner v. Manson

- A substance that is known to be useful only as an intermediate in the production of other compounds that have no established utility is not itself useful.
- “[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute.”

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## Brenner v. Manson

- “Unless and until a process is refined and developed to this point—where **specific benefit exists in currently available form**—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”
- “[A] patent is not a hunting license.”

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## In Re Fisher

- Invention
  - Five purified nucleic acid sequences (ESTs) that encode proteins and protein fragments in maize plants
- Case history
  - BPAI affirmed Examiner’s final rejection for lack of utility

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## In Re Fisher

- Claim 1 of the '643 application recites:
- A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

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## In Re Fisher

- Why did the Examiner reject the application?
  - Not supported by a specific and substantial utility
- What happened before the Board?
  - “The Board found that using the claimed ESTs in screens does not provide a specific benefit because the application fails to provide any teaching regarding how to use the data relating to gene expression.”

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## In Re Fisher

- What are Fisher’s asserted uses?
  - “Fisher’s alleged uses are so general as to be meaningless.”
- “We agree with both the government and the amici that none of Fisher’s seven asserted uses meets the utility requirement of § 101.”

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## In Re Fisher

- “[T]o satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.”

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## In Re Fisher

- Fisher's uses are not specific
- Fisher failed to "identify the function for the underlying protein-encoding genes."
- "Absent such identification, we hold that 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."

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## Proof Required

- Proof that a compound will cause certain effects in laboratory animals may be sufficient utility; there is no requirement of therapeutic utility in humans.
- Patents and the Federal Circuit, 7<sup>th</sup> Edition.

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## Novelty Under the AIA pt. 1

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## 102 After AIA

- (a) NOVELTY; PRIOR ART.--A person shall be entitled to a patent unless--
- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
  - (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

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## 102 After AIA

- (b) EXCEPTIONS.--
- (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.-  
-A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if--
- (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

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## 102 After AIA

- (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.--A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if--
- (A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
- (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person

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## 102 After AIA

- (c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.--Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if--
- (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
- (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

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## 102 After AIA

- (d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.--For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application--
- (1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
- (2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

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## 102 Analysis

- "The AIA provides a person is not entitled to a patent if:
- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before its effective filing date (§ 102(a)(1)); and
- (2) the claimed invention was described in a published application or issued patent that names another inventor and was filed prior to the filing date of the claimed invention (§ 102(a)(2))."

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## Applicability

- “Only the statutory bars, not the novelty provisions, can be triggered by events occurring after the date of the applicant’s invention. Note, however, that events occurring prior to the time of invention may also be relevant to the statutory bars.”
- “No references qualify under § 102(b) [(pre-AIA)] that do not also qualify under § 102(a) [(pre-AIA)].”

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## Meaning of Disclosures

- Disclosures mean all of the prior art categories set out in §102(a)(1) (AIA)
- “A disclosure under the AIA, then, means subject matter that is, prior to an applicant’s filing date: ‘patented, described in a printed publication, or in public use, on sale, or otherwise available to the public,’ under AIA § 102(a)(1); as well as subject matter ‘described in’ a patent or published application, under AIA § 102(a)(2).”

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## One Year Grace Period?

- “AIA §102(b)(1) provides a one-year grace period after a first disclosure of an invention within which to file a patent application.”

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## Two Systems

- AIA applies to any application filed on or after March 16, 2013 priority date
- Pre-AIA applies to any other application

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## Egbert v. Lippmann

- Not necessary to have more than one patented article publicly used.
- 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.
- "Some inventions are by their very nature only capable of being used where they cannot be seen or observed by the public eye. ... If its inventor sells a machine of which his invention forms a part, and allows it to be used without restriction of any kind, the use is a public one."
- Egbert v. Lippman, 104 U.S. 333

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## Egbert v. Lippmann

- "[W]hether 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."

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## Egbert v. Lippmann

- Inventor
  - No obligation of secrecy
  - No condition or restriction
  - Not presented for purposes of experimentation
  - No testing of qualities
  - Invention was complete
  - Not further changed or improved

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## Confidentiality Agreements

- Having confidentiality agreements in place may prevent something from otherwise being in public use
- The confidentiality agreement may not necessarily have to be an express agreement.
- See Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261 (Fed. Cir. 1986).

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## Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts

- Issue:
  - Does a secret, commercial use by an applicant for a patent more than one year before the filing of a patent invalidate the applicant's patent?

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**Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts**

- "... if he does beyond [the 1 year period of probation], he forfeits his right regardless of how little the public may have learned about the invention; just as he can forfeit it by too long concealment, even without exploiting the invention at all."

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**Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts**

- "It is indeed true that an inventor may continue for more than a year to practice his invention for his private purposes of his own enjoyment and later patent it. But that is, properly considered, not an exception to the doctrine, for he is not then making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his monopoly."

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**Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts**

- "... it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly."

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## Secret, Commercial Use

- Secret commercial exploitation of an invention by the inventor is a public use under 102(b)(pre-AIA).
- What about under the AIA?

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## Statutory Bars (pre-AIA)

§102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless—

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

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## Statutory Bars

- Under 102 (pre-AIA), timely filing and disclosure of inventive activity are encouraged.
- An inventor must file within a year of any public use or offer to sell the invention.
- Anyone, including individuals unknown to the inventor, can defeat the patent by placing the invention in public use or sale.
- The 1-year grace period permits the inventor to weigh the advantages of patent protection, to perfect the invention, and to draft a patent application.

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## Trade Secret... then Patent?

- Under 102 (pre-AIA), an inventor cannot maintain and use an invention under trade secret law and then later (i.e., greater than a year later) seek to patent it.

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## Non-Informing Uses = Public Use?

- One Position
  - Inventor's non-informing public use qualifies as a public use
  - Third party non-informing uses are not public uses
  - Thus, no change
- Another position
  - Non-Informing uses are not public use

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## Who is Learned Hand?

- 1872-1961
- Judge of U.S. District Court for the Southern District of New York, 1909-24
- Judge of U.S. Court of Appeals for the 2nd Circuit, 1924-51
- Very well renown for his decisions, especially his patent law decisions
- See <http://www.conservativeforum.org/authquot.asp?ID=915>
- <http://www.hup.harvard.edu/catalog/GUNLEX.html>

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## On Sale

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## Pfaff v. Wells Electronics, Inc.

- Issue:
  - Does the commercial marketing of a newly invented product mark the beginning of the 1-year grace period even though the invention has not yet been reduced to practice?

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## Pfaff v. Wells Electronics, Inc.

- “Pfaff did not make and test a prototype of the new device before offering to sell it in commercial quantities.”

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**Pfaff v. Wells Electronics, Inc.**

- Invention
  - inventor's conception rather than a physical embodiment of the idea
- How does reduction to practice come into play?
  - an invention may be patented before it is reduced to practice
- “[I]t is evident that Pfaff could have obtained a patent on his novel socket when he accepted the purchase order from Texas Instruments for 30,100 units.”

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**Pfaff v. Wells Electronics, Inc.**

- “On Sale” Test
  - 1) The product must be the subject of a commercial offer for sale
  - 2) The invention must be ready for patenting
    - Proof of reduction to practice before the critical date; or
    - Proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention

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**Sale of Rights**

- What about sale of the rights to the patent before the critical date?

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## Single Sale

- Can a single sale bar patentability?

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## Abbott Laboratories v. Geneva

- Procedural Background:
  - 1999: Appeal before U.S. Court of Appeals for Fed. Circuit
- Factual Background:
  - Abbott sued Geneva, Novopharm, and Invamed for infringement of the '207 patent after each of them filed an Abbreviated New Drug Application (ANDA) at the United States Food and Drug Administration seeking approval to market a generic version of Hytrin containing the Form IV anhydrate.1 ... The defendants each raised the affirmative defense of patent invalidity under the on-sale bar of 35 U.S.C. 102(b), asserting that Form IV was anticipated because it was sold in the United States more than one year before the '207 patent's filing date, October 18, 1994.

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## Abbott Laboratories v. Geneva

- “It is an act of patent infringement under certain circumstances to file an ANDA seeking approval to commercial manufacture, use or sell a drug claimed in a patent before the expiration date of such patent. See 35 U.S.C. §271(e)(2)(A).”

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**Abbott Laboratories v.  
Geneva**

- Test – “Before the critical date, the invention must both be the subject of a commercial sale or offer for sale and be ‘ready for patenting.’”

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**Abbott Laboratories v.  
Geneva**

- “[T]here 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 of these characteristics at the time of the offer.”

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**Abbott Laboratories v.  
Geneva**

- “If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.”

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**Abbott Laboratories v.  
Geneva**

- During an offer for sale, it is irrelevant as to whether another knew that the novel aspect was part of the sale to trigger the on sale bar.

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**“On Sale” Bar - Suppliers**

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**Hamilton Beach Brands, Inc. v.  
Sunbeam Prods., Inc.**

- “An invention is “ready for patenting” when prior to the critical date:
- (1) the invention is reduced to practice; or
- (2) the invention is depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention. []
- The on-sale bar is a question of law based on underlying factual findings.”

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Hamilton Beach Brands, Inc. v.  
Sunbeam Prods., Inc.

- “Second, **there is no ‘supplier exception’ to the on-sale bar.** [] Thus, it is of no consequence that the ‘commercial offer for sale’ at issue in this case was made by Hamilton Beach’s own supplier and was made to Hamilton Beach itself.”
- “[A] commercial offer for sale made by a foreign entity that is directed to a United States customer at its place of business in the United States may serve as an invalidating activity.”

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The Medicines Company v.  
Hospira, Inc.

- Case History
- D.C - Claims not invalid under §102(b);  
“Hospira’s generic product did not infringe the asserted claims.”
- Panel Fed. Cir. – reversed (vacated)
- En Banc Fed. Cir. O’Malley – Affirmed D.C.
- Issue
  - “[T]he circumstances under which a product produced pursuant to the claims of a product-by-process patent is “on sale” under [] §102(b)”

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The Medicines Company v.  
Hospira, Inc.

- Invention
  - bivalirudin drug products
  - “used to prevent blood from clotting and are regarded as highly effective anticoagulants for use during coronary surgery.”

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**The Medicines Company v.  
Hospira, Inc.**

- Background
  - Hospira sought FDA approval to sell generic bivalirudin drug products before the expiration of the '727 patent and the '343 patent by filing an ANDA

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**The Medicines Company v.  
Hospira, Inc.**

Claim 1.  
Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier, for use as an anticoagulant in a subject in need thereof, said batches prepared by a compounding process comprising:

- (i) dissolving bivalirudin in a solvent to form a first solution;
- (ii) efficiently mixing a pH-adjusting solution with the first solution to form a second solution, wherein the pH adjusting solution comprises a pH adjusting solution solvent; and
- (iii) removing the solvent and pH-adjusting solution solvent from the second solution; wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp9-bivalirudin that does

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**The Medicines Company v.  
Hospira, Inc.**

- Applications filing date – 7/27/08
- Critical date – 7/27/07

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**The Medicines Company v.  
Hospira, Inc.**

- Late '06 - MedCo paid Ben Venue to manufacture
- 10/31/06 – 1<sup>st</sup> batch completed
- “It was not until August 2007, after the July 27, 2007 critical date, that MedCo released the three batches from quarantine and made them available for sale.”

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**The Medicines Company v.  
Hospira, Inc.**

- “Pfaff itself said little about the first prong of the two-prong test—what constitutes a patent-defeating ‘commercial offer for sale’—however. The Court did emphasize that ‘[a]n inventor can both understand and control the timing of the first commercial marketing of his invention,’ and that a transaction that is “experimental in character” is distinct from one that is for purposes of such commercial marketing.”

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**The Medicines Company v.  
Hospira, Inc.**

- “We have held that ‘the question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be **analyzed under the law of contracts** as generally understood.’ ... We also have held that, to be true to Pfaff when assessing prong one of §102(b), we must focus on those **activities that would be understood to be commercial sales and offers for sale ‘in the commercial community.’**”

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The Medicines Company v.  
Hospira, Inc.

- “Applying §102(b) in light of *Pfaff*, we conclude that the transactions between MedCo and Ben Venue in 2006 and 2007 **did not constitute commercial sales** of the patented product. We, thus, affirm the district court’s conclusion that those transactions were not invalidating under §102(b).”

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The Medicines Company v.  
Hospira, Inc.

1. “[T]he mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a ‘commercial sale’ of the invention”
2. “[S]tockpiling’ by the purchaser of manufacturing services is not improper commercialization under §102(b)”
3. “[T]he transaction must be one in which the product is ‘on sale’ in the sense that it is ‘commercially marketed.’”

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The Medicines Company v.  
Hospira, Inc.

- “[W]e have never espoused the notion that, where the patent is to a product, the performance of the unclaimed process of creating the product, without an accompanying “commercial sale” of the product itself, triggers the on-sale bar.”

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**The Medicines Company v.  
Hospira, Inc.**

- "We still **do not recognize a blanket 'supplier exception'** to what would otherwise constitute a commercial sale as we have characterized it today. While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is **not alone determinative**. Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under §102(b). The **focus must be on the commercial character of the transaction, not solely on the identity of the participants.**"

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**Otherwise Available to the  
Public**

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**Knowledge of Publications**

- "... [A patent reference] on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which is registered and protected under [foreign] law. Such a burden, however is by law imposed upon the hypothetical person of ordinary skill in the art who is charged with knowledge of all the contents of the relevant prior art."
- Does actual knowledge matter?

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## In re Hall

- “[P]ublic accessibility” has been called the touchstone in determining whether a reference constitutes a “printed publication” bar under 35 U.S.C. §102(b) ... The proponent of the publication bar must show that prior to the critical date the reference was **sufficiently accessible** ... so that such a one by examining the reference could make the claimed invention without further research or experimentation.”

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## In re Lister

- “[O]ur cases have held that once accessibility is shown, it is unnecessary to show that anyone actually inspected the reference.”

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## Printed Publications

- What qualifies as a printed publication on the Internet?

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### Voter Verified v. Premier Election Solutions

- Case History
- D.C. for M.D. of Florida
  - Claims 1-93 not infringed
  - Claims 49 and 94 invalidated
  - Claims 1-48, 50-84, and 86-92 are not invalid
- Panel Fed. Cir. of Lourie, Reyna, and Wallach
  - Affirmed

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### Voter Verified v. Premier Election Solutions

- Invention
  - “automated systems and methods for voting in an election, featuring a self-verification procedure by which ‘machine and human error may be detected and corrected before the ballot is submitted by the voter for tabulation.’”

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### Voter Verified v. Premier Election Solutions

- Claim 49  
A method of voting providing for self verification of a ballot comprising the steps of:
  - (a) voting by a voter using a computer voting station programmed to present an election ballot, accept input of votes from the voter according to the election ballot, temporarily store the votes of the voter;
  - (b) printing of the votes of the voter from the votes temporarily stored in the computer for the voting station;
  - (c) comparison by the voter of the printed votes with the votes temporarily stored in the computer for the voting station;
  - (d) decision by the voter as to whether a printed ballot is acceptable or unacceptable;
  - (e) inputting of information as to the acceptability of a printed ballot by the voter; and
  - (f) submission of an acceptable printed ballot for tabulation.

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Voter Verified v. Premier Election Solutions

- Issue – is the Benson article prior art?

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Voter Verified v. Premier Election Solutions

- Voter Verified's position
- “[A] web-based reference like the Benson article must be ‘searchable by pertinent terms over the internet’ to qualify as a prior art ‘printed publication’ as defined by 35 U.S.C. § 102(b)”
- “Defendants ‘provided no evidence of any indexing on any database’ that would have allowed the interested public to locate the Risks Digest website, much less the Benson article contained therein”

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Voter Verified v. Premier Election Solutions

- Defendant's position
- “[T]he Benson article qualifies as prior art because it was posted on a public website well known to those interested in the art of voting technologies—the Risks Digest—and could be retrieved from that website by searching based on subject matter.”

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Voter Verified v. Premier Election Solutions

- “When considering whether a given reference qualifies as a prior art ‘printed publication,’ the key inquiry is whether the reference was made ‘sufficiently accessible to the public interested in the art’ before the critical date.”

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Voter Verified v. Premier Election Solutions

- “Whether a reference is publicly accessible is determined on a case-by-case basis based on the ‘facts and circumstances surrounding the reference’s disclosure to members of the public.’”

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Voter Verified v. Premier Election Solutions

- “[!]ndexing is a relevant factor in determining accessibility of potential prior art, particularly library-based references.”
- “But indexing is not ‘a necessary condition for a reference to be publicly accessible’; it is but one among many factors that may bear on public accessibility.”

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### Voter Verified v. Premier Election Solutions

- “[T]he ultimate question is whether the reference was ‘available to the extent that persons interested and ordinarily skilled in the subject matter or art[,] exercising reasonable diligence, can locate it.’”
- “[W]hile often relevant to public accessibility, evidence of indexing is not an absolute prerequisite to establishing online references like the Benson article as printed publications within the prior art.”

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### Voter Verified v. Premier Election Solutions

- The Risks Digest website was undisputedly open to any internet user by the critical date. Whether or not the website itself had been indexed by 1999 (through search engines or otherwise), the uncontested evidence indicates that a person of ordinary skill interested in electronic voting would have been independently aware of the Risks Digest as a prominent forum for discussing such technologies. And upon accessing the Risks Digest website, such an interested researcher would have found the Benson article using that website’s own search functions and applying reasonable diligence.

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### Disclosures in United States Patent Applications - §102(a)(2)

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## 102(e)(pre-AIA)

- A person shall be entitled to a patent unless –
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent, or

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## 102(e) Amendments

- Amendments since 1952
  - “[D]isclosures in a PCT application would be effective prior art as of the date when the PCT application enters the U.S. ‘national stage’ of prosecution, which may be later than the international filing date of the PCT application.”
  - “[D]isclosures in a patent application constitute prior art provided that the application either issues as a granted patent or is published pursuant to § 122(b)”

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## “Patent”

- Not all foreign patent rights are equivalent to US patent rights

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## Reading a Patent

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## Reading a Patent

- Front Page
  - Title
  - Abstract
  - Single Drawing
  - Inventor
  - Assignees
  - Search data and references
  - Examiner(s) & Firm
- Drawings
- Specification
- Claims

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## Reading a Patent

What portion(s) of the patent/patent application should you look at to determine:

1. whether the patent is relevant to you?
2. whether you have an infringement concern?
3. what the reference teaches?

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***Program  
Completed***

All course materials - Copyright 2002-16 Randy L. Canis, Esq.

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