Patent Law

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January 21, 2015
Class 3
Disclosure: Enablement

Recap

Recap

- → Mechanics and formalities of patent claims
- → Claim strategy
- → Claim-drafting exercise

Today's agenda

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- → The patent bargain
- → Patent breadth & experimentation
- → Timing & speculation

The patent bargain & §112

Patents versus trade secrets

→ Trade secret

- Owner keeps invention secret
- Owner gets limited exclusive rights against misappropriators

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→ Patent

- Owner discloses invention to the world
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35 U.S.C. § 112 — Specification

(a) In General.— The specification shall contain a **written description** of the invention, and of the **manner and process of making and using it**, in such full, clear, concise, and exact terms as to **enable any person skilled in the art** to which it pertains, or with which it is most nearly connected, **to make and use the same**, and shall set forth the **best mode** contemplated by the inventor or joint inventor of carrying out the invention.

(b) Conclusion.— The specification shall conclude with **one or more claims particularly pointing out and distinctly claiming** the subject matter which the inventor or a joint inventor regards as the invention.

* * *

Disclosure requirements

- → § 112(a): Written description
- → § 112(a): Enablement
- → § 112(a): Best mode
- → § 112(b), (f): Definiteness

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→ § 112(a): Written description

→ § 112(a): Enablement

→ ~~§ 112(a): Best mode~~

→ § 112(b), (f): Definiteness

Enablement

→ The patent must teach one of ordinary skill in the art how to make and use the full scope of the claimed invention, without undue experimentation, according to the state of the art as of the effective filing date.

Enablement

→ Purposes?

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- Advance the state of the art by disclosing technical know-how

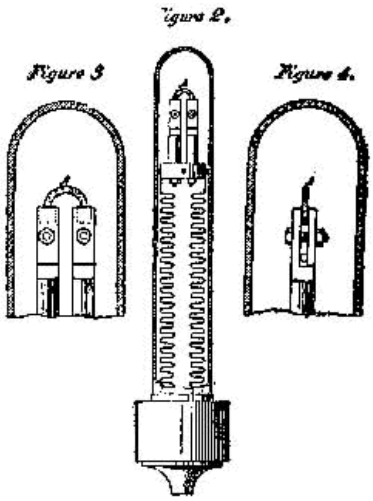
Enablement

→ Purposes?

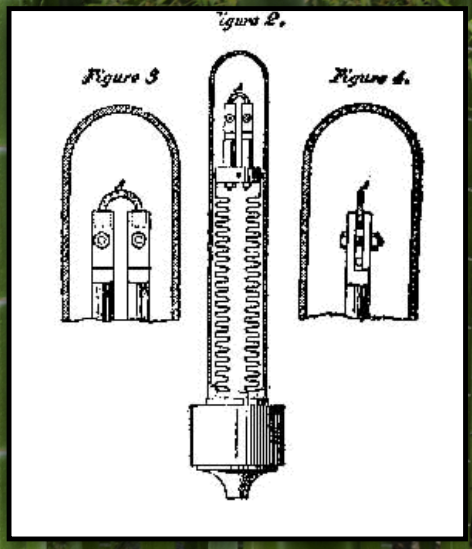
- Advance the state of the art by disclosing technical know-how
- Demonstrate that the invention is sufficiently concrete and advanced to warrant a patent

Patent breadth & experimentation

The Incandescent Lamp Patent



The Incandescent Lamp Patent



The Incandescent Lamp Patent

→ What is at issue in the lawsuit?

The Incandescent Lamp Patent

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- Lawsuit is for infringement of the Sawyer & Man patent
- Fundamental issues: Is the Sawyer & Man patent infringed by the McKeesport Light Company product? Is the patent valid?

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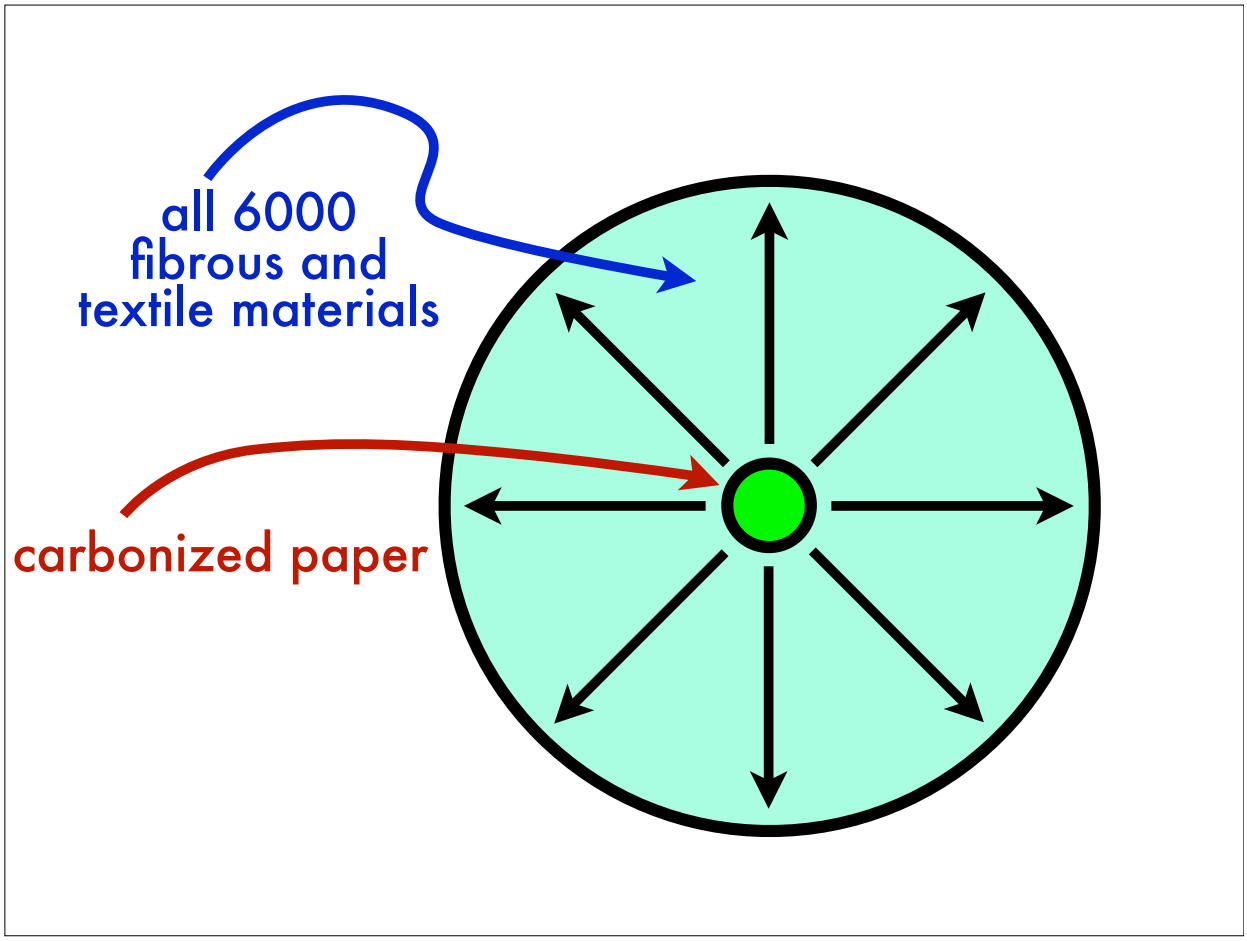
→ How are Edison's patents relevant?

→ How is the Sawyer & Man commercial product relevant?

1. An incandescing conductor for an electric lamp, of carbonized fibrous or textile material and of an arch or horseshoe shape, substantially as hereinbefore set forth.

2. The combination, substantially as hereinbefore set forth, of an electric circuit and an incandescing conductor of carbonized fibrous material, included in and forming part of said circuit, and a transparent hermetically sealed chamber in which the conductor is enclosed.

3. The incandescing conductor for an electric lamp, formed of carbonized paper, substantially as described.



The Incandescent Lamp Patent

→ What did Sawyer and Man contribute to the state of the art?

→ What does the specification teach someone of ordinary skill in the art?

- What would Edison have learned from it?

→ Why was it not enough?

"Is the complainant entitled to a **monopoly of all fibrous and textile materials** for incandescent conductors? If the patentees had discovered in fibrous and textile substances **a quality common to them all, or to them generally**, as distinguishing them from other materials such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, **such claim might not be too broad**. * * * But if woods generally were not adapted to the purpose, and yet the patentee had discovered **a wood possessing certain qualities which gave it a peculiar fitness** for such purpose, it would not constitute an infringement for another to discover and use **a different kind of wood** which was found to contain similar or superior qualities. * * *"

-page 268

"* * * The present case is an apt illustration of this principle. Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. **Instead of confining themselves to carbonized paper**, as they might properly have done, and in fact did in their third claim, **they made a broad claim for every fibrous or textile material**, when in fact an examination of over 6,000 vegetable growths showed that **none of them possessed the peculiar qualities** that fitted them for that purpose. **Was everybody, then, precluded by this broad claim from making further investigation? We think not.**"

-page 268

The Incandescent Lamp Patent

→ What did one of ordinary skill in the art have to do to get the invention to work?

"The injustice of so holding is manifest in view of the **experiments made and continued for several months by Mr. Edison and his assistants** among the different species of vegetable growth for the purpose of ascertaining the one best adapted to an incandescent conductor. * * * After **trying as many as thirty or forty different woods of exogenous growth, he gave them up as hopeless**. But finally, while experimenting with a bamboo strip which formed the edge of a palm leaf fan, cut into filaments, he obtained **surprising results**. * * * It seems that the characteristic of the bamboo which makes it particularly suitable is that the fibers run more nearly parallel than in other species of wood. Owing to this, it can be cut up into filaments having parallel fibers, running throughout their length, and producing a homogeneous carbon. There is **no generic quality**, however, in vegetable fibers, because they are fibrous, **which adapts them to the purpose**. Indeed, the fibers are **rather a disadvantage**."

–pages 268–69

"If, as before observed, there were some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose, the man who discovered such quality might justly be entitled to a patent; but that is not the case here."

–page 270

The Incandescent Lamp Patent

→ Are we okay with broad patents, if they're fully enabled? Why or why not?

The Incandescent Lamp Patent

→ The classic patent race (page 271):

- 1802: incandescence
- 1841: incandescence in vacuum chamber
- 1860: carbonized incandescence in globe
- 1865: improved vacuum pump
- 1870: economical generators
- 1875: high vacuum in glass globes

The Incandescent Lamp Patent

→ Complements and substitutes for the patent system

- Trade secrecy
- Legal monopoly — Edison locking up sources of bamboo

Undue experimentation: *In re Wands*

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

Undue experimentation: *In re Wands*

→ *Wands:* Immunoassay method to detect a particular hepatitis B surface antigen through the use of particular monoclonal antibodies that have a high affinity for binding with the hepatitis B surface antigen

→ PTO: The claims required undue experimentation because the inventor had only deposited one antibody-producing cell line

→ Court: No, this is enough

- Cell line was produced with a commercially available kit and a well-known screening procedure
- Procedure got low yield, but that was standard in the field

Undue experimentation: *In re Wands*

- → *Amgen v. Chugai Pharmaceutical*: Claims cover any analog for natural EPO protein that causes bone marrow cells to increase red-blood-cell production
- → Disclosure contained only one working example
- → Court: Claim was not enabled
  - Number of potential analogs is "potentially enormous," since there may be many possible modifications to natural EPO to make it and the field was complex and unpredictable

Undue experimentation: *In re Wands*

- → Vaccine preparation?
- → Biotech work?
- → Software?
- → Jet engines?
- → An improved stapler?

Claim scope: *Sitrick v. Dreamworks*

- → Patent: Method for integrating or substituting a user-generate image for pre-generated character images in video games
- → Specification: Describes system that intercepts electronic signals coming from a gaming card corresponding to characters, and modifies them to replace the original character
- → Claims: Cover film special effects, which don't have signals corresponding to different characters
- → Valid?

Claim scope: *Sitrick v. Dreamworks*

- → Court: The claims are not valid.
- → Films don't have signals corresponding to individual characters; they use different tech.
- → The patent did not enable someone of ordinary skill in the art to implement the claims in film.

Claim scope: *Sitrick v. Dreamworks*

→ Bottom line: The full claim scope must be enabled.

- You don't have to teach every conceivable implementation.
- But you have to teach enough for those of ordinary skill in the art to apply the invention to different technologies that fall within the claims.

Timing & speculation

Timing & speculation

→ The key date for measuring enablement is the effective filing date of the patent application

→ The state of the art in a field evolves

- An early patent will require more explanation than a late patent in the same field

→ A specification can be supplemented with evidence of the knowledge of those of ordinary skill in the art, but only as of the time of the effective filing date

Janssen v. Teva

→ Janssen: name-brand (they say "pioneer" or "innovator") drug company

→ Teva: generic drug company

→ This is a Hatch-Waxman Act case

Hatch-Waxman Act

→ Name-brand drug maker gets FDA approval for a drug

→ Name-brand drug maker lists applicable patents in the Orange Book

→ Generic can file an Abbreviated New Drug Application (ANDA) once the patents expire, or earlier if they assert the patents are invalid or not infringed

→ Companies then litigate the patent

Janssen v. Teva

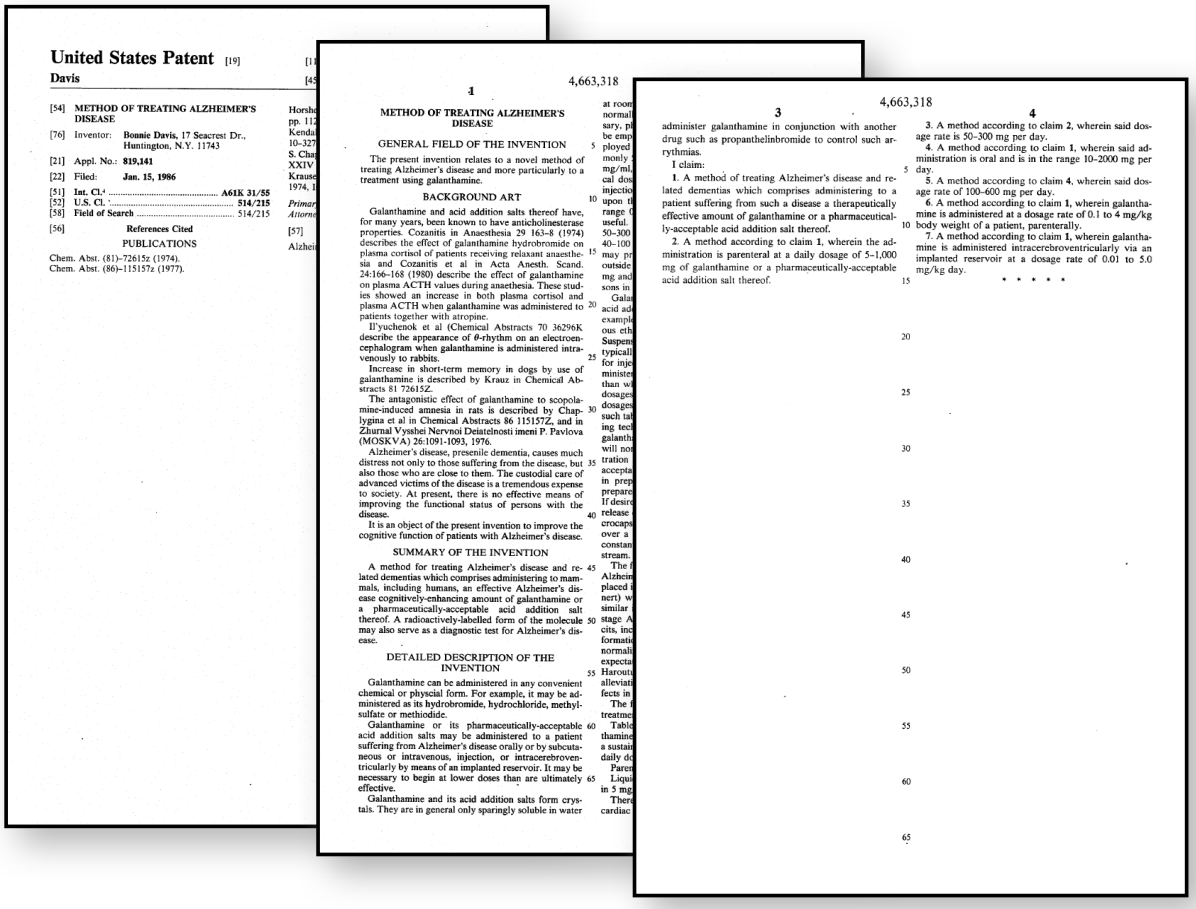
→ So we have a granted patent:

I claim:

1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

2. A method according to claim 1, wherein the administration is parenteral at a daily dosage of 5–1,000 mg of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

→ ...and FDA approval



United States Patent [19]
Davis

[54] METHOD OF TREATING ALZHEIMER'S DISEASE

[76] Inventor: Bonnie Davis, 17 Seacrest Dr., Huntington, N.Y. 11743

[21] Appl. No.: 819,141

[22] Filed: Jan. 15, 1986

[51] Int. Cl.[4] A61K 31/55

[52] U.S. Cl. 514/215

[58] Field of Search 514/215

[56] References Cited
PUBLICATIONS

Chem. Abst. (81)–72615z (1974).
Chem. Abst. (86)–115157z (1977).

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METHOD OF TREATING ALZHEIMER'S DISEASE

GENERAL FIELD OF THE INVENTION

The present invention relates to a novel method of treating Alzheimer's disease and more particularly to a treatment using galanthamine.

BACKGROUND ART

Galanthamine and acid addition salts thereof have, for many years, been known to have anticholinesterase properties. Cozanitis in Anaesthesia 29 163–8 (1974) describes the effect of galanthamine hydrobromide on plasma cortisol of patients receiving relaxant anaesthesia and Cozanitis et al in Acta Anesth. Scand. 24:166–168 (1980) describe the effect of galanthamine on plasma ACTH values during anaesthesia. These studies showed an increase in both plasma cortisol and plasma ACTH when galanthamine was administered to patients together with atropine.

Il'yuchenok et al (Chemical Abstracts 70 36296K describe the appearance of θ-rhythm on an electroencephalogram when galanthamine is administered intravenously to rabbits.

Increase in short-term memory in dogs by use of galanthamine is described by Krauz in Chemical Abstracts 81 72615Z.

The antagonistic effect of galanthamine to scopolamine-induced amnesia in rats is described by Chaplygina et al in Chemical Abstracts 86 115157Z, and in Zhurnal Vysshei Nervnoi Deiatelnosti imeni P. Pavlova (MOSKVA) 26:1091–1093, 1976.

Alzheimer's disease, presenile dementia, causes much distress not only to those suffering from the disease, but also those who are close to them. The custodial care of advanced victims of the disease is a tremendous expense to society. At present, there is no effective means of improving the functional status of persons with the disease.

It is an object of the present invention to improve the cognitive function of patients with Alzheimer's disease.

SUMMARY OF THE INVENTION

A method for treating Alzheimer's disease and related dementias which comprises administering to mammals, including humans, an effective Alzheimer's disease cognitively-enhancing amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof. A radioactively-labelled form of the molecule may also serve as a diagnostic test for Alzheimer's disease.

DETAILED DESCRIPTION OF THE INVENTION

Galanthamine can be administered in any convenient chemical or physcial form. For example, it may be administered as its hydrobromide, hydrochloride, methylsulfate or methiodide.

Galanthamine or its pharmaceutically-acceptable acid addition salts may be administered to a patient suffering from Alzheimer's disease orally or by subcutaneous or intravenous, injection, or intracerebroventricularly by means of an implanted reservoir. It may be necessary to begin at lower doses than are ultimately effective.

Galanthamine and its acid addition salts form crystals. They are in general only sparingly soluble in water

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administer galanthamine in conjunction with another drug such as propanthelinbromide to control such arrythmias.

I claim:

1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

2. A method according to claim 1, wherein the administration is parenteral at a daily dosage of 5–1,000 mg of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

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3. A method according to claim 2, wherein said dosage rate is 50–300 mg per day.

4. A method according to claim 1, wherein said administration is oral and is in the range 10–2000 mg per day.

5. A method according to claim 4, wherein said dosage rate of 100–600 mg per day.

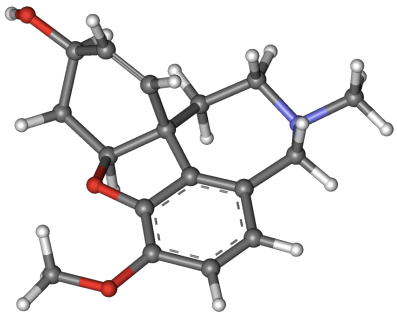
6. A method according to claim 1, wherein galanthamine is administered at a dosage rate of 0.1 to 4 mg/kg body weight of a patient, parenterally.

7. A method according to claim 1, wherein galanthamine is administered intracereboventricularly via an implanted reservoir at a dosage rate of 0.01 to 5.0 mg/kg day.

* * * * *

Janssen v. Teva

→ Galanthamine: Alkaloid isolated from the bulbs and flowers of *Galanthus caucasicus*, the Caucasian snowdrop, and other plants



Janssen v. Teva

→ What was disclosed in the spec?

Janssen v. Teva

→ What was disclosed in the spec?

→ Six studies:

- One showing galanthamine crossing the blood-brain barrier and affecting the nervous system
- Four showing galanthamine affecting memory in animals
- One describing an animal model for replicating effects of Alzheimer's disease

→ None linking galanthamine and Alzheimer's, or even the animal model

Janssen v. Teva

→ What would one of ordinary skill in the art take away from the spec?

Janssen v. Teva

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→ Testimony:

- The spec "connected the dots" for galanthamine as a potential treatment
- "[W]hen I submitted this patent, I certainly wasn't sure, and a lot of other people weren't sure that cholinesterase inhibitors would ever work."

Janssen v. Teva

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→ Court: The spec "does no more than state a hypothesis and propose testing"

→ So no enablement

Analytic reasoning v. prophetic examples

→ Prophetic examples (paper examples) are okay as long as it's clear they haven't been performed yet

→ How is this different from the *Janssen* patent?

"Use of prophetic examples, however, does not automatically make a patent non-enabling. The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling. Du Pont did not meet that burden here. To the contrary, the district court found that the 'prophetic' examples of the specification were based on actual experiments that were slightly modified in the patent to reflect what the inventor believed to be optimum, and hence, they would be helpful in enabling someone to make the invention."

Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569 (Fed. Cir. 1984).

Broad versus narrow enabling requirements

→ So what's the tradeoff in granting patents earlier in the development cycle?

Broad versus narrow enabling requirements

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- Prospect theory (Kitch, 1977): the first patent owner is in the best position "to coordinate the search for technological and market enhancement of the patent's value so that duplicative investments are not made and so that information is exchanged among researchers."

Broad versus narrow enabling requirements

→ So what's the tradeoff in granting patents earlier in the development cycle?

- *Brenner v. Manson* (US 1966): "Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public."

Broad versus narrow enabling requirements

→ So what's the tradeoff in granting patents earlier in the development cycle?

- Merges & Nelson: "Without extensively reducing the pioneer's incentives, the law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm."

Next time

Next time

→ Disclosure: written description