Patent Law

Prof. Roger Ford
September 11, 2017
Class 4
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 and § 112
- → Patent breadth & experimentation
- → Timing & speculation

The patent bargain and §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
- Owner gets broad rights as against the world

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(post-AIA) 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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Disclosure requirements

→ § 112(a): Written description

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→ ~~§ 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

→ What purposes does the enablement requirement serve?

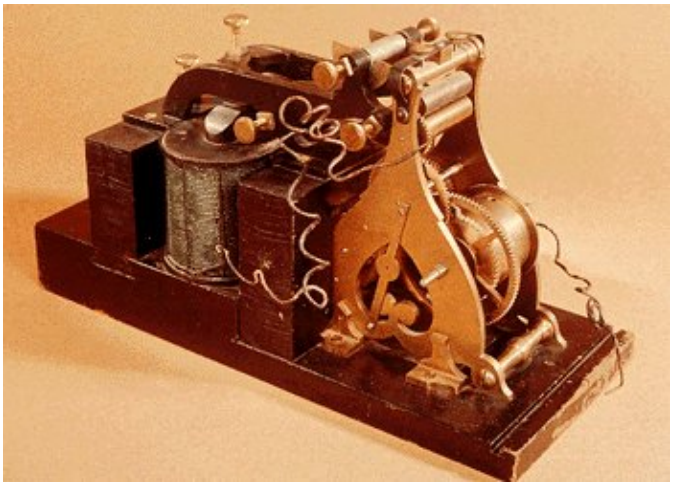
Enablement

→ Three big purposes:

- Bargain – advance the state of the art so society gets technical knowledge for future inventors to use
- Scope – ensure patentee gets rights commensurate with actual contribution
- Timing – ensure the right person gets the patent and the invention is sufficiently concrete and advanced to warrant a patent

Patent breadth

O'Reilly v. Morse



→ Telegraph model patented May 1, 1849

→ Patent No. 6,420

O'Reilly v. Morse

→ May 24, 1844:

- Samuel Morse demonstrates the telegraph, sending the message "What hath God wrought?" from the U.S. Capitol to Alfred Vail at a railroad station in Baltimore
- Vail responds a few seconds later

O'Reilly v. Morse

→ Claim 8: "I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer."

O'Reilly v. Morse

→ So what was wrong with claim 8?

O'Reilly v. Morse

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- Morse described a machine for transmitting info by electromagnetism but claimed <u>all</u> machines for doing so
- This would give him a monopoly over all improvements

O'Reilly v. Morse

→ So what was wrong with claim 8?

- Morse described a machine for transmitting info by electromagnetism but claimed all machines for doing so
- This would give him a monopoly over all improvements
- (Note: It is not clear that either of these would be disqualifying today)

O'Reilly v. Morse

→ So what was wrong with claim 8?

- (This blurs the line between written description and enablement)

"In fine he claims an exclusive right to use **a manner and process which he has not described and indeed had not invented**, and therefore could not describe when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law."

–Nard 93

"Professor Morse **has not discovered that the electric or galvanic current will always print at a distance**, no matter what may be the form of the machinery or mechanical contrivances through which it passes. You may use electro-magnetism as a motive power and yet not produce the described effect, that is, print at a distance intelligible marks or signs. **To produce that effect, it must be combined with, and passed through, and operate upon, certain complicated and delicate machinery, adjusted and arranged upon philosophical principles and prepared by the highest mechanical skill.** And it is the high praise of Professor Morse that he has been able, by a new combination of known powers, of which electro-magnetism is one, to discover a method by which intelligible marks or signs may be printed at a distance. And for the method or process thus discovered he is entitled to a patent. **But he has not discovered that the electro-magnetic current, used as motive power in any other method, and with any other combination, will do as well.**"

–Nard 94–95

O'Reilly v. Morse

→ Why does the dissent disagree?

O'Reilly v. Morse

→ Why does the dissent disagree?

- Morse has invented "a most wonderful and astonishing invention" (96)
- "If he has truly stated the principle, nature, and extent of his art or invention, how can the Court say it is too broad * * * ?" (96)
- Improvements get their own patents

Broad versus narrow enabling requirements

→ This is a dispute about claim scope

- Claim 8: broadest claim in the patent
- The broader your enablement, the broader your patent and the broader your exclusivity.
- What's the argument against allowing the broad claim?
- Is there a counterargument?

Broad versus narrow enabling requirements

→ Against broad claims:

- It makes it harder for others to do follow-on research
- (And/but, it also makes it easier for the inventor to do follow-on research!)
- "[W]hile he shuts the door against inventions of other persons, [Morse] would be able to avail himself of new discoveries" by others (93)

Broad versus narrow enabling requirements

→ For broad claims:

- Morse has invented something amazing! We want people to do that – so we should give big incentives
- "This doctrine has not been found to retard the progress of invention in the case of machines, and I can see no reason why a contrary one should be applied to an art." (96)

Broad versus narrow enabling requirements

→ Ex ante versus ex post incentives:

- Broad patents maximize ex ante incentives of inventors
- Narrow patents maximize ex post incentives of improvers

Broad versus narrow enabling requirements

→ 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

→ *Brenner v. Manson* (US 1966):

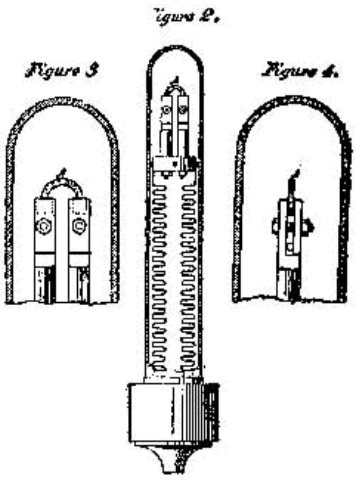
- An early, broad patent "may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public."

Broad versus narrow enabling requirements

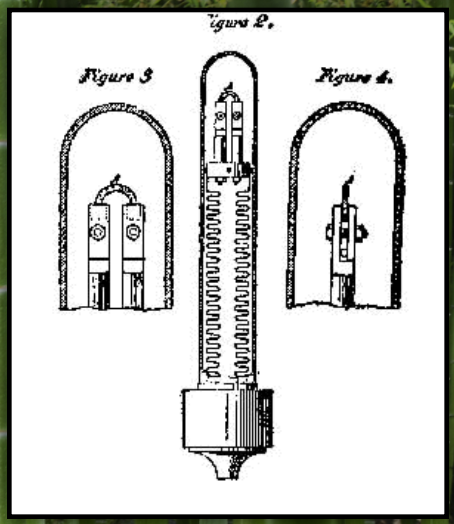
→ Merges & Nelson:

- "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."

The Incandescent Lamp Patent



The Incandescent Lamp Patent



The Incandescent Lamp Patent

→ Timeline:

- 1880 – Edison issued patent
- 1885 – Sawyer & Man issued patent
- Later – Sawyer & Man's company sues Edison's company for infringement

The Incandescent Lamp Patent

→ "The defendants justified [their actions] under certain patents to Thomas A. Edison..." (96)

- How are Edison's patents relevant?

→ "It is admitted that the lamp described in the Sawyer and Man patent is no longer in use, and was never a commercial success ... [and] is substantially the Edison lamp..." (100)

- How is the Sawyer & Man commercial product relevant?

The Incandescent Lamp Patent

→ Lawsuit is for infringement of the Sawyer & Man patent

→ Fundamental issues in the case:

- Is the Sawyer & Man patent infringed by the McKeesport Light Company product?
- Is the patent valid?

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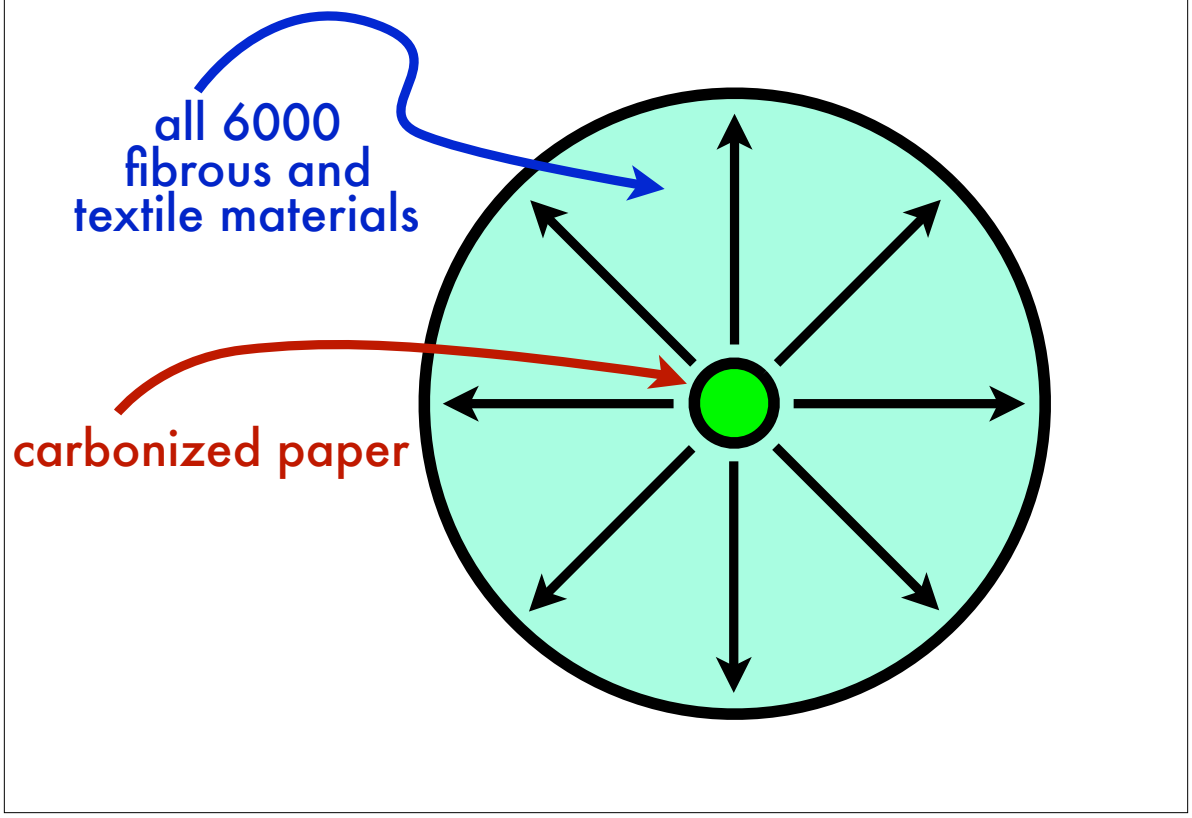
- Is the patent valid?

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 know?

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

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

- What would Edison learn from it?

"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. * * *"

–Nard 100

"* * * 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.**"

–Nard 100

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**."

–Nard 101

"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."

–Nard 102

The Incandescent Lamp Patent

→ The classic patent race:

- 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

Experimentation

Cedarapids

→ 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.

Cedarapids

→ So what's the problem with this patent?

Cedarapids

→ So what's the problem with this patent?

- It says to increase the throw and speed without saying how much to do so
- So, arguably, someone of ordinary skill in the art can't make and use the invention

Cedarapids

→ For example, *In re Fisher*:

- Patent: a hormone preparation containing "at least 1.0 International Unit of ACTH per milligram"
- Disclosure: potencies from 1.11 to 2.30 IU/mg
- Court: the claim is invalid

Cedarapids

→ Court: Actually, no problem here

- "Rock crusher technology is not in the same category as the chemical arts where a slight variation in a method can yield an unpredictable result or may not work at all." (115)

Cedarapids

→ Court: Actually, no problem here

- "The fact that some experimentation is necessary does not preclude enablement; all that is required is that the amount of experimentation 'must not be unduly extensive.'" (116)

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- "The fact that some experimentation is necessary does not preclude enablement; all that is required is that the amount of experimentation 'must not be unduly extensive.'" (116)
- (Note: not a statutory test; essentially common law.)

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*

→ Patent: Method to detect a particular hepatitis B surface antigen through the use of particular 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 procedure
- Procedure got low yield, but that was normal

Undue experimentation: *In re Wands*

→ Contrast *Amgen v. Chugai Pharm.*: Claims cover any analog for natural EPO protein that causes bone marrow cells to produce red blood cells

→ Disclosure: one working example

→ Court: Claim was not enabled

- Number of potential analogs is enormous; there are many possible modifications to natural EPO and field was unpredictable

Undue experimentation: *In re Wands*

→ Vaccine preparation?

→ Biotech work?

→ Software?

→ Jet engines?

→ An improved stapler?

Automotive Techs. v. BMW

→ Means-plus-function claim term under § 112(f) / § 112 ¶ 6:

- "means responsive to the motion of said mass upon acceleration … for initiating an occupant protection mechanism

→ Spec described two kinds of means:

- Mechanical
- Electronic

→ Only enabled mechanical, though

Automotive Techs. v. BMW

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- Electronic

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Automotive Techs. v. BMW

→ Court: The claim is invalid

- The full scope of the claims must be enabled
- The patent did not enable someone of ordinary skill in the art to implement the claims with an electronic means

Automotive Techs. v. BMW

→ Bottom line: The full claim scope must be enabled

- You don't have to teach every possible implementation
- But you have to teach enough to apply the invention to different technologies that fall within the claims

Automotive Techs. v. BMW

→ Bottom line: The full claim scope must be enabled

- Scope of enablement must be at least roughly commensurate with the claim scope
- Scope of enablement is that disclosed in the specification plus what one of ordinary skill in the art would know without undue experimentation

Timing & speculation

Enablement

→ Three big purposes:

- Bargain – advance the state of the art so society gets technical knowledge for future inventors to use
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Timing & speculation

→ Key date for measuring enablement: 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 later patent

→ 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

Janssen v. Teva

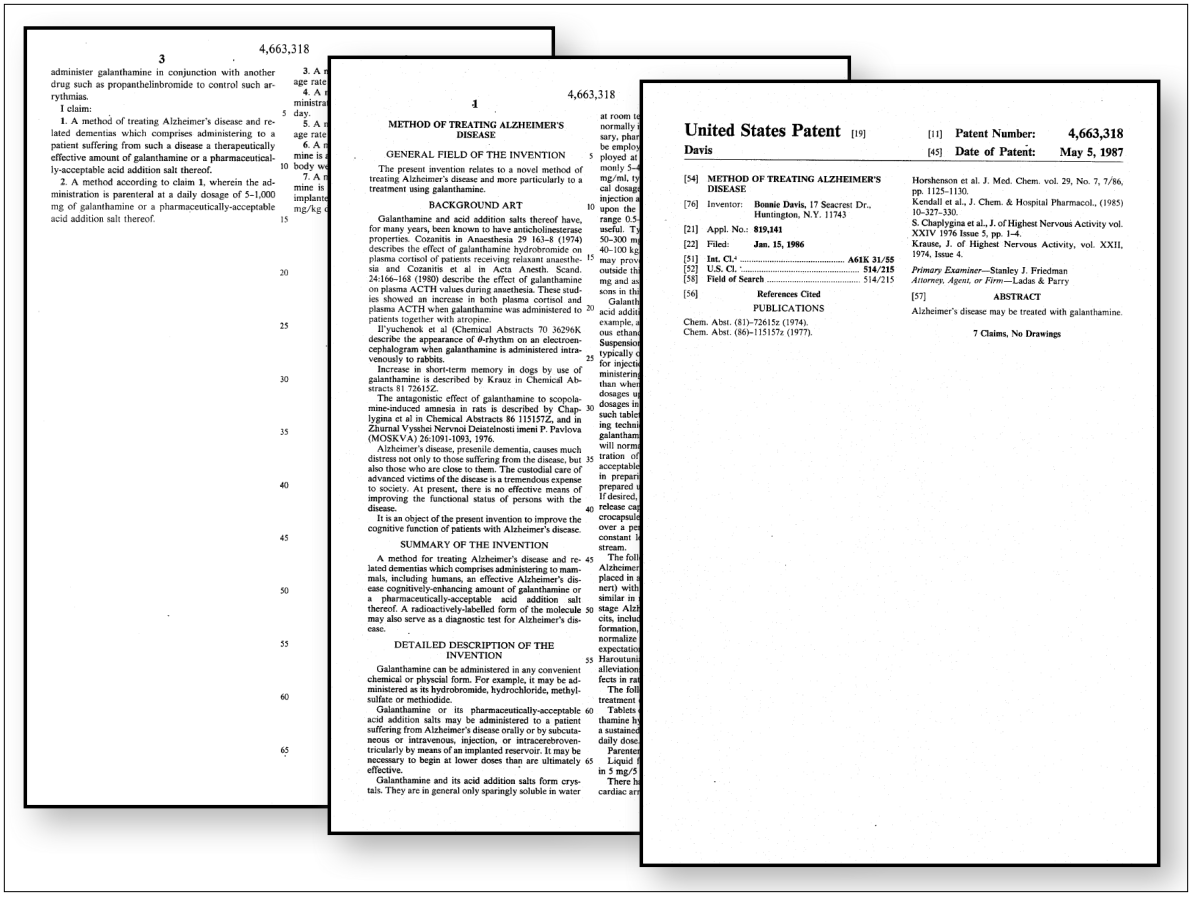
→ So we have a granted patent:

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

[11] Patent Number: 4,663,318
[45] Date of Patent: May 5, 1987

[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

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Krause, J. of Highest Nervous Activity, vol. XXII, 1974, Issue 4.

Primary Examiner—Stanley J. Friedman
Attorney, Agent, or Firm—Ladas & Parry

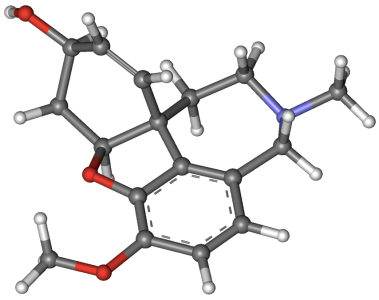
[57] ABSTRACT

Alzheimer's disease may be treated with galanthamine.

7 Claims, No Drawings

Janssen v. Teva

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



Janssen v. Teva

→ Six studies disclosed in the specification:

- 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

→ 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

"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).

Next time

→ Disclosure: written description