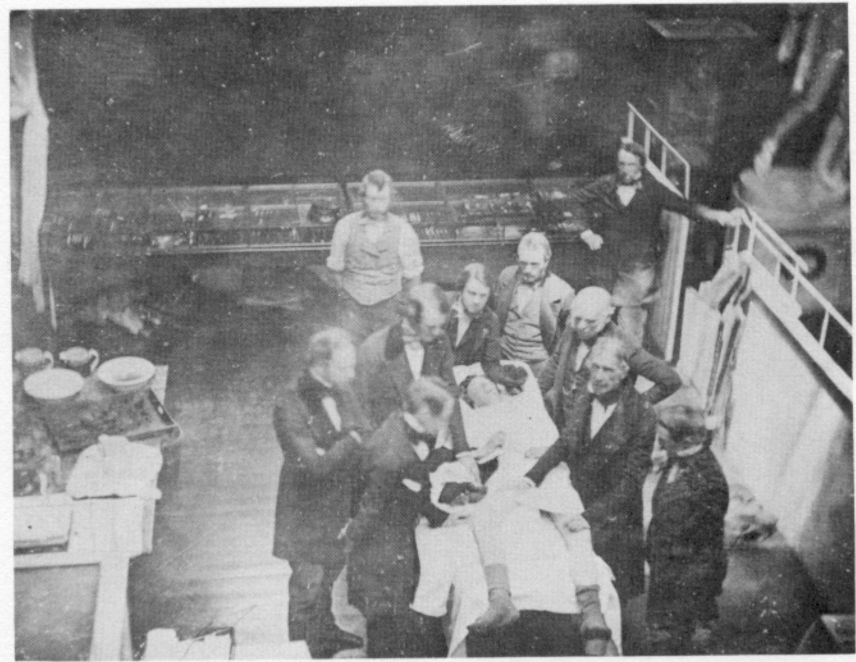
Patent Law:
What Anesthesiologists Should Know

Kirk Hogan MD, JD

ISAP 23rd Annual Meeting

October 10, 2014

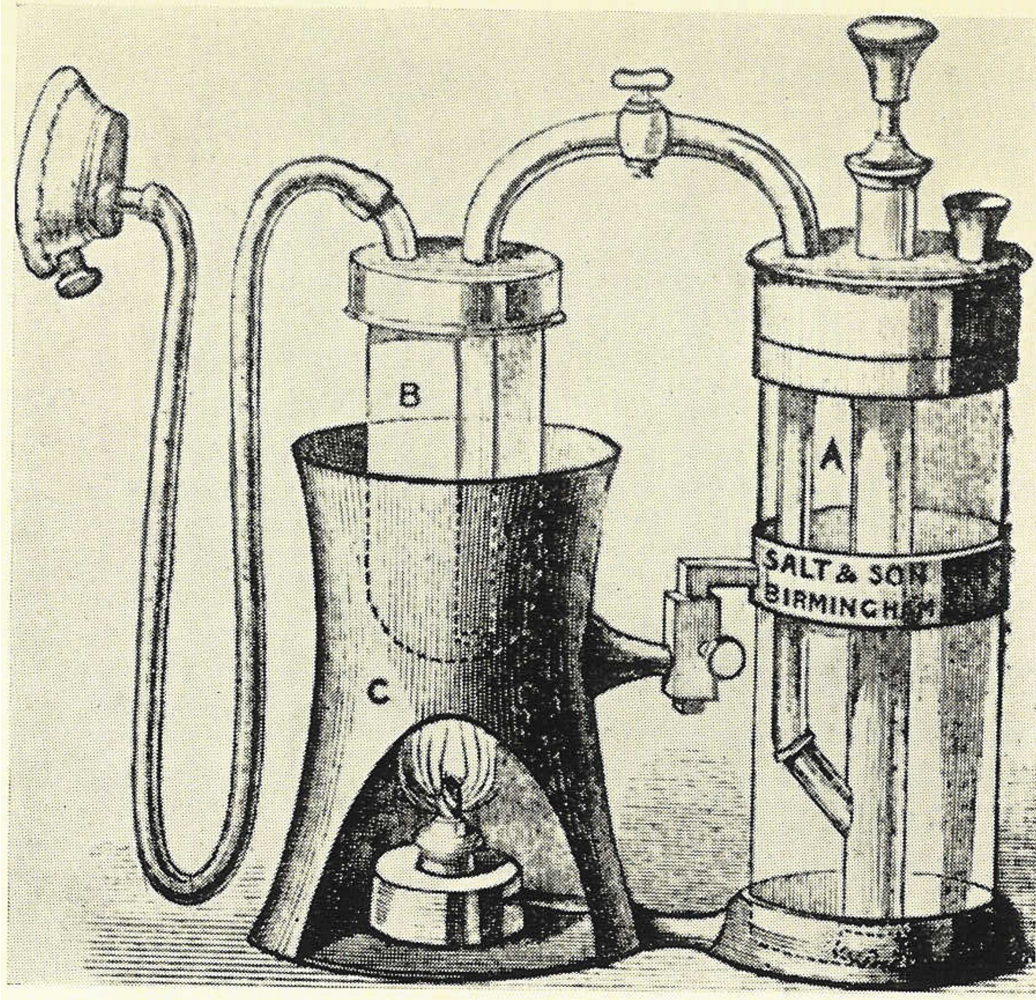
khogan@wisc.edu, kjhogan@casimirjones.com

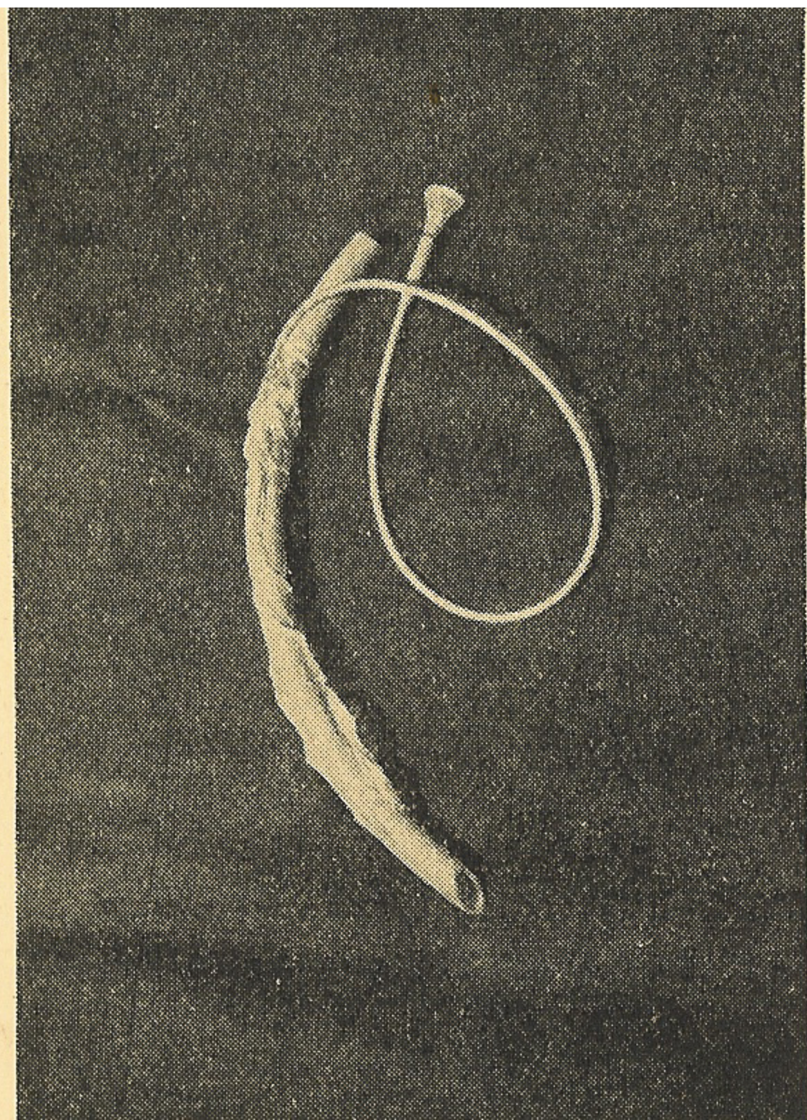


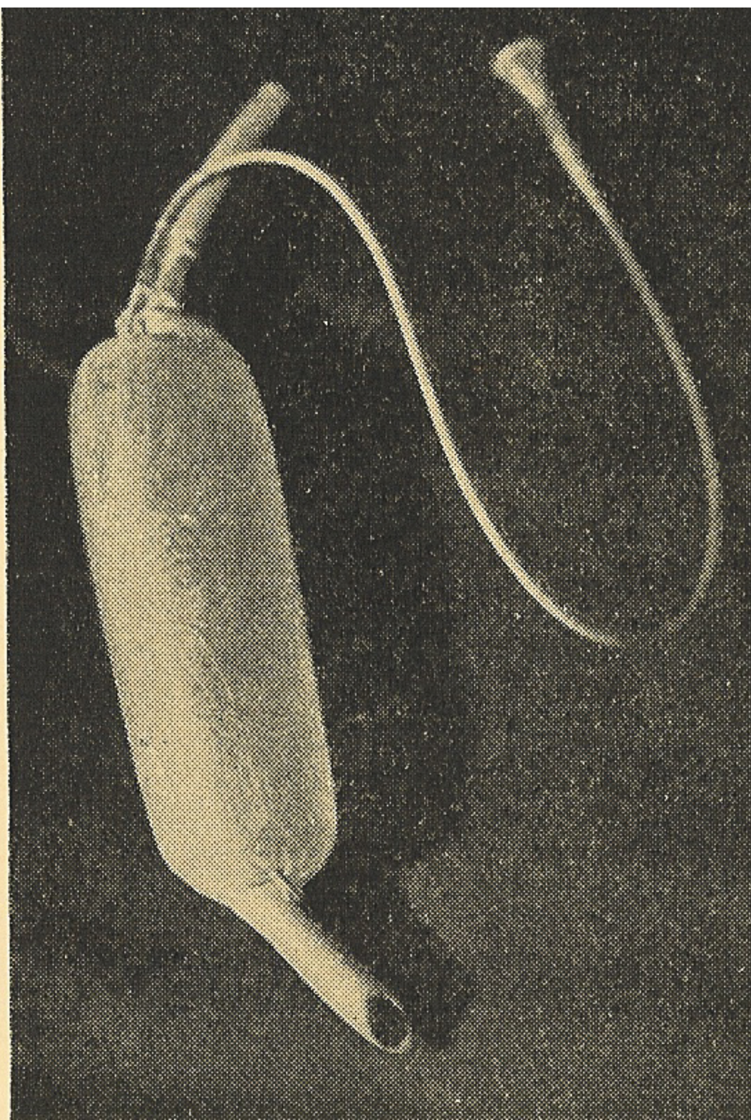
"How Nobody Invented Anesthesia"

(J. M. Fenster, American Heritage, Summer,1996)

- "THE MEN WHO FINALLY **promoted** anesthetic gases were not "inventors" or "discoverers."
- "They just had a fresh perspective."
- !!!


B
A
SALT & SON
BIRMINGHAM
C





Overview

- MFAQs
- Precautions and practical Tips
- America Invents Act 2013

Where Does Patent Law Come From?

- Constitution – the right to **exclude**
- **CONGRESS**
- United States Patent Office (USPTO) and Court of Appeals for the Federal Circuit (CAFC) - **Prosecution**
- Federal District Courts, CAFC, United States Supreme Court - **Litigation**
- vs. State contract law – the right to **use**
- Lawyers and juries, not scientists, inventors, not even patent lawyers
- Lobbying and capture
- **Constant and accelerating change in patent law**

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Jon W. Dudas

Director of the United States Patent and Trademark Office

Why apply for a patent?

- Application documents intent and capacity to seek collaboration, public (SBIR) and private financing, etc.
- Preparation spurs focus and creativity, highlights scotomata
- Integrated with business plan, FDA applications, other internal and external documents
- A vocabulary, grammar and format for business
- A sword and a shield

C. M. WHEATON, DEC'D.
G. H. WHEATON, ADMINISTRATRIX.
MEANS FOR CONDUCTING SUBMARINE WARFARE.
APPLICATION FILED MAY 20, 1907.

1,131,761. Patented Mar. 16, 1915.

3 SHEETS—SHEET 1.

Fig. 1.

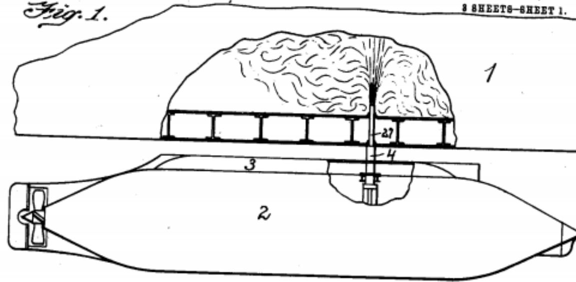
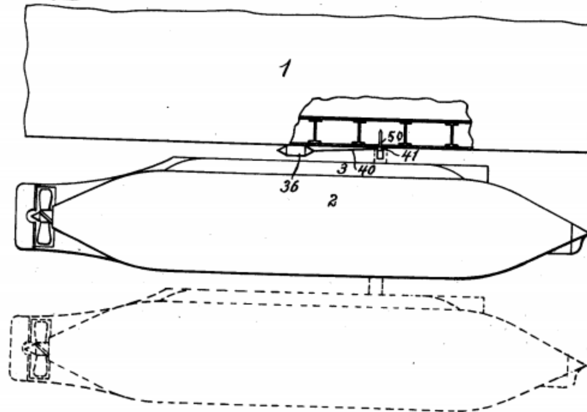


Fig. 2.



Witnesses:
H. L. Robbins
A. C. Folsom

Inventor:
C. M. Wheaton
by Wright Brown Quinby & May
Attys.

What kinds of patents are there?

- Products, compositions of matter
- Methods of use, methods of making
- Kits
- Systems

What is patentable?

- Utility
- Novelty (vs. a single "reference")
- Written description – no secrets
- Enablement – no perpetual motion
- "Non-obviousness" (vs. multiple "references")

What is NOT patentable?

- National security
- Lack of "Moral utility"
- Countries differ widely
- No medical procedure, tax strategy claims in USA
- **AIA** - "No patent may issue on a claim directed to or encompassing a human organism."
- "USPTO has taken the position that this section of the Act merely codifies existing practice."
- Law of nature (isolating, purifying)

Who Decides Patent Validity?

- Prosecution with USPTO Examiner
- Appeal to USPTO Patent Appeal Board
- Appeal to CAFC
- Appeal to US Supreme Court
- *Ex parte* re-examination
- Post grant review
- *Inter partes* review
- Civil litigation – judges, juries, more judges

How much is a patent worth?

- All valuable patents are challenged for validity and infringed
- Usually validity and value is uncertain until the patent is sustained against an infringement suit, or two
- Patent burn-out

How does a patent make money?

- Inventorship vs. ownership
- Multiple inventors
- Multiple owners
- Assignment
- Patent vs. license

How long does it take to get a patent?

- From date of filing about 1.5 years to first "exam", and 3-4 years to issue
- Can be much, much longer
- "Continuation" patent portfolios, trunk and branch
- Original patent expires 20 years from formal filing date, but its progeny may live on ("ever-greening")

How much does a patent cost?

- To file: small provisional application $3 - $5,000,
- $10 – $15,000 for full utility application
- To prosecute: $30 – $100,000, much more if also overseas (translation costs), maintenance fees and annuities
- To defend: $200,000 - $2,000,000 and up (way up)
  - Interference (before March, 2013) – who invented first?
    vs. Derivation (after March, 2013)
  - Infringement
  - Post-issue practice

How does a patent make money?

- Inventorship vs. ownership
- Multiple inventors
- Multiple owners
- Assignment
- Patent vs. license
- Small vs. large entities
- **Tip - identify a solvent licensee early on**

When to File a Patent Application?

- Tricky under AIA – no perfect answer
- Before disclosure
- Early to preserve priority date, limit “art” that can be cited against novelty and non-obviousness
- Later when a working prototype with preferred ranges, unexpected properties, surprising results are in hand, and data to rebut enablement rejections
- Early **and** late
- Effects of AIA on timing and strategy

Where to file a patent application?

- Patent Cooperation Treaty (PCT)
- National entry up to 30 months after first provisional US application
- $$$$
- Markets
- Foreign patent offices
- Foreign attorneys, judges and juries

What Does a Patent Lawyer Do?

- Patentability and validity opinions
- Prosecution
- Litigation - enforcement of intellectual property rights
- Agreements – licensing, material transfer, consulting, sponsored research, non-disclosure, technology transfer, etc.
- Due diligence in financing and acquisition
- Portfolio management
- Law, business and science integration

External Disclosure Precautions - Tips

- Be extraordinarily careful with regard to timing abstract presentations
- Be very careful about prophetic ideas in chapters and reviews
- You may defeat your own novelty
- Q: Should you withhold? With AIA vs. academic freedom?
- A: File, then disclose
- Cascading provisional applications

Internal Record Precautions

- See **Handout**
- Take **great care** with notebooks, lab records, hard data, photos, printouts, etc. Copy and store in separate buildings.
- Keep track of thoughts, meetings, **dead ends*** (non-obviousness), do not disparage your own work
- Signed by lab director, and dated
- If what you are doing leads to products, your notebooks will be very closely scrutinized years into the future
- Illegibility will work against you, not for you.

Other Tips

- The PTO web site (www.uspto.gov) is a great place to research a topic. Patent applications because of legal requirementsprovide useful bibliographies
- Read issued claims in your area of expertise
- Learn how to broaden and tier claims
- Know your IP lawyer's and tech transfer officer's birthdays
- **Never** hide a reference or trade secret - "inequitable conduct" is MUCH more than what you can get away with at the USPTO

Fallibility

- There is no “I” in patent – you must be **PATIENT** – prosecution involves baby talk with lawyers, and worse, with the USPTO and all others, supervisors, judges, juries
- You haven’t been singled out, don’t get discouraged
- ***Colleagues and authorities are fallible***, defy “conventional wisdom”
- Technology transfer agencies are fallible esp. re: commercial value
- Patent attorneys are fallible
- Patent offices are fallible
- Juries and judges are **very** fallible

AIA - Transition

- **March 16, 2013** – filing date determines
- Before – pre-AIA law until March 15, 2033
- After – post-AIA law
- Must affirm for FTO, diligence, competition, business strategy, etc.
- **Tip** – be VERY clear with counsel and all stakeholders

AIA – "First to File"

- Expanded period (*i.e.*, to file date), and definition of novelty-destroying "prior art"
- Another's prior "date of invention" does not disqualify a second inventor for patents filed on or after March 16, 2013
- One year "grace period" for inventor's **own** public disclosures – **not** prior art in US, but **is** prior art elsewhere
- International patent rights are lost on date of disclosure
- First to disclose but second to file within one year of disclosure may receive a patent in US (*i.e.*, if the disclosure and patent claims are the same)

AIA – “First to File” - Tips

- Great care with academic disclosures – designate pages for deletion
- Strong internal company policies for public disclosures
- Earliest possible provisional application with cascading provisional applications with subsequent “enablement”, then file as a bundled single “converted” utility application for examination
- Provide support for future claims
- Maintain at least one application pending in each lineage at all times
- Tier claim breadth to assure that some survive challenge
- Claim or disclose in view of competitive trajectories (blocking patents)
- Anticipate trolls – NPEs - “non-performing entities”

AIA – “Derivation”

- Must show: 1) conception and 2) communication
- Must file the petition one year from publication of the earlier application
- **Tips - MUST MONITOR** activities of others!
- Internal diligence
- **Pristine notebook practice**
- Regulate and document communication esp. between entities
- Negotiate “no derivation” warranties in license agreements
- Negotiate who pays and controls derivation proceedings
- Consider licensing possibly harmful prior art before filing own patent application

Post-Issue Practice

- “quasi litigation”, “opposition” procedures – door opens to intellectual and commercial rivals
- Infringers favored – most claims are amended or cancelled
- + for small entities – remove questionable references, FTO, less costly, faster and better decision makers at PTAB, expert testimony
- - for small entities – easier to invalidate a patent, multiple (4) onslaughts to reduce valuation of small entity’s IP
- Very likely to be asserted against ALL commercially valuable patents
- **SUMMARY –** present day best practices are rewarded

Post-Issue Practice - Tips

- Don’t risk crown jewel patents – thickets and moats
- Negotiate who pays and who controls post-issue practice in licenses
- Use patent owner ***ex parte*** **reexamination** to USPTO CRU to remove troublesome art (anonymous)
- Generally cheaper than civil litigation, but not cheap

Post-Grant Review

- Within 9 months from issued claims, no pending civil litigation
- Not anonymous
- Novelty, obviousness, and enablement (challenge priority date of cited references)
- Raise all issues
- Limited appeal
- **Tip –** closely monitor competitor’s patents and applications

Inter Partes Review

- After 9 months from issued claims, less than one year after service in civil litigation
- Not anonymous
- Novelty and obviousness **only** – patents and publications
- Raise all issues
- Limited appeal
- **Tip –** closely monitor competitor's patents and applications

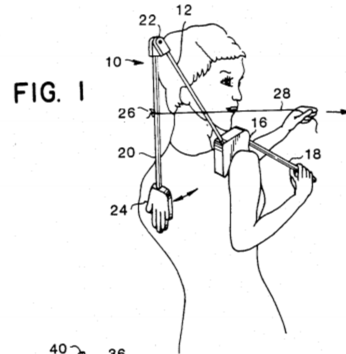


FIG. 1

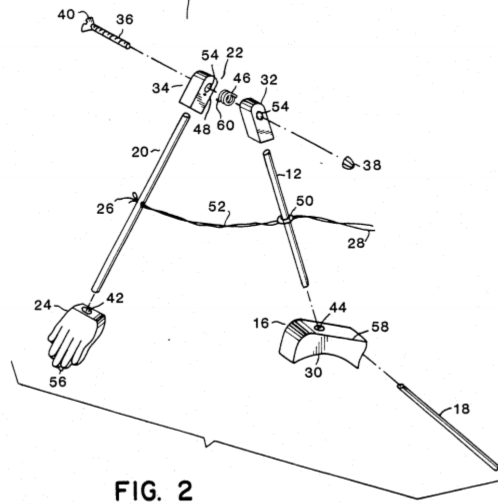


FIG. 2