BIO Boot Camp – June 3, 2018

KATHRYN DOYLE, Ph.D., J.D.

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What Can a Patent Owner Do To Maximize Patent Protection?

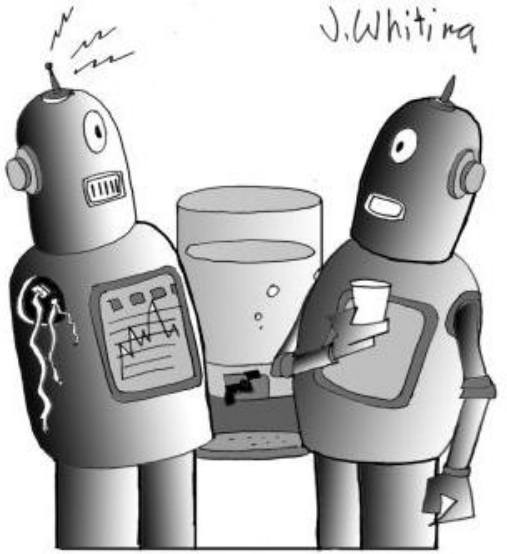
1) Avoid unrealistic expectations

2) Devise a ***STRATEGY*** early in the life of the technology

3) Be aware of what the competition is doing, and is patenting

4) Be aware of what the courts are doing

5) Be futuristic, but see (1)



"You're lucky to be built with all Open Source Hardware. They removed my right arm due to a patent dispute."

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Strategic Planning

- Does not begin with the patent application
- Begins with the invention and what your plans are for capitalization of that invention.

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Strategic Planning

- Need a strategic plan early on – why?
- You must be able to maximize patent protection for your technology
- You must be in a position to vigorously assert and defend your technology

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- IP Law primarily offers protection to the owner of IP by giving the owner a right to file a lawsuit asking the court to enforce transgressed rights.
- Rights are essentially "exclusionary," but not defensive. Owner must exercise their "affirmative" rights by taking infringers to court.
- The legal granting of rights is not "freedom to practice." A party practicing its proprietary rights may, in fact, infringe aspects owned by others.

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Freedom to Operate versus Patentability

There is no relationship between the two.

- Freedom to Operate (FTO) – you have the right to make, use or sell the product without infringing third party patents – Doorknob and button analogy
- Patentability – whether or not you can obtain a patent for your invention – is your invention *novel, non-obvious, useful and have you enabled it and satisfied the written description requirement*?

Objectives of Patent Strategy

- Obtain a Monopoly in your space

- Develop an Offensive and a Defensive IP position

<u>Offensive</u>

- File applications covering your product, processes, treatment modalities, formulations, delivery, packaging, etc.
- Do not ignore filing "follow-on applications to cover more defined aspects of the base technology

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Bottom Line

- Develop a patent strategy that maximizes patent protection for your products/methods
  - Multiple layers of protection: composition, method of use, method of making, different components or subsystem of a device, etc.
  - International filing: market potential, enforceability; local considerations, e.g., China, Hong Kong, Netheland, Hungary
  - Timing – PCT; regular vs accelarated
  - Within the budget

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Other Aspects to Strategic Planning

- Must have a plan to deal with competitors
- Must have a plan that takes regulatory review into account
- Must have a plan to ensure commericalization of the invention!!

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Implementation of the Strategic Plan

- When should you file?
- Why should you file?
- What should you file?
- What are the competitors doing and how far along are they compared to you?
- What is the status of the technology?
  - Lead technology?
  - Follow-on technology?
  - Time line for development?
  - Time line for funding/partnering/exit?

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Be Flexible

- Modify the strategy based on the new developments in-house, in the market and in patent laws

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An Assertive Approach

- Offensive
  - how to deal with third party patents that may block your ability to practice
  - How to enforce your own patents

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How to Deal with Third Party Patents That May Block Your Ability to Practice

- Design around
  - Joint effort between patent attorneys and scientists
  - Doctrine of equivalents
    - performs substantially the same function in the substantially the same way to achieve substantially same results.

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- Challenge the validity of the patent
  - Inter Parties Review (IPR)

based on patents and printed publications; can be initiated immediately following issuance of patents examined under the first to invent rules or 9 mo after issuance of patents examined under the first to file rules (March 15, 2013)

  - Post Grant Review (PGR)

based on any grounds that can be used to challenge the validity of a patent claim (with the exception of failure to disclose the best mode; can be initiated within 9 mo after issuance of patents examined under the first to file rules

  - Declaratory Judgment

- Ask a federal court to declare non-infringement, invalidity, and/or unenforceability of a patent
- Need existence of an actual controversy

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How to deal with third party patents that may block your ability to practice

- License and cross license
  - ***IP due diligence***
  - ***Future IP***

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IP Due Diligence

- Different parties will have different objectives and focus
- The VC will be focused on the exit strategy
- Big Pharma, Big Biotech will take a longer view and focus on the product pipeline
- As the technology matures and makes its way through clinical trials, expect more IP and FDA due diligence

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The "Acid Test of IP"

- Who really owns the technology?
  - Assigned?
  - Licensed? What are the terms?
  - Collateral?
  - **Compliance with Bayh Dole? If not, can it be cured?**
- Integrity of the patents in hand or pending
  - What is really covered? – hopefully the lead product
  - Are the claims too broad, could they be invalidated under current law?
  - Nature of PTO Office Actions
  - Time to expiration
  - Improvements
  - Position of patent(s) in industry/sector patent mapping
- Freedom to practice – when to assess and at what level?
  - Does what is covered completely define the product?
  - Are there other patents that block entry?
  - Are those patents available for purchase or license?
    - At what cost?

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The “Acid Test of IP”

What agreements has the university entered into?

MTA, CDA, Collaboration Agreements, Sponsored Research Agreements with academic institutions, etc.

How do the provisions of those agreements affect your IP?

Are there agreements that have been terminated where some terms survive and affect your IP?

What does your license agreement look like? Provisions to comment on prosecution? What do they mean?

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How to Manage Your IP in Preparation for Due Diligence

Organize and Identify your Patent Portfolio

- Include a complete patent docket including all foreign IP
- Have all IP Protocols, Invention Disclosures and procedures available

If you have Opinions, Reports & Litigation

- Be aware of Attorney-Client privileged communications and/or work-product documents

Make sure you understand your Regulatory Issues

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Patents:
Standing in the shoes of the investor/partner

- **Integrity of the patents or patent applications – for each patent or application:**
  - Who owns it?
  - What is really covered by the claims – is the lead product covered?
  - If pending, will a patent issue?
  - If issued, will it withstand challenge?
  - What is the enforceable patent term?

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INVENTORSHIP

OWNERSHIP

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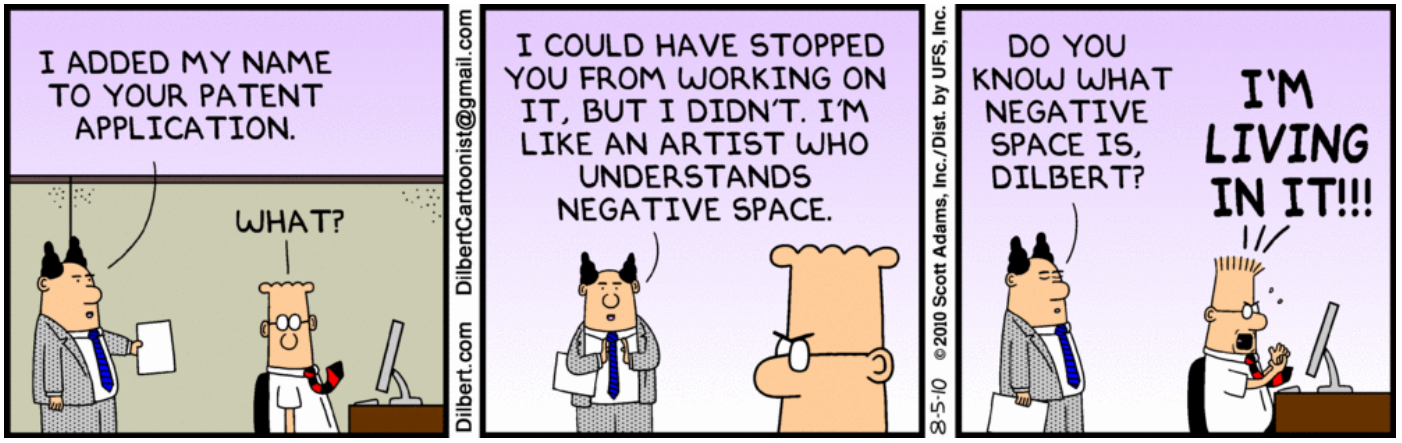
Inventorship

- A Patent Application must name the correct inventors
- A legal determination; NOT a moral decision



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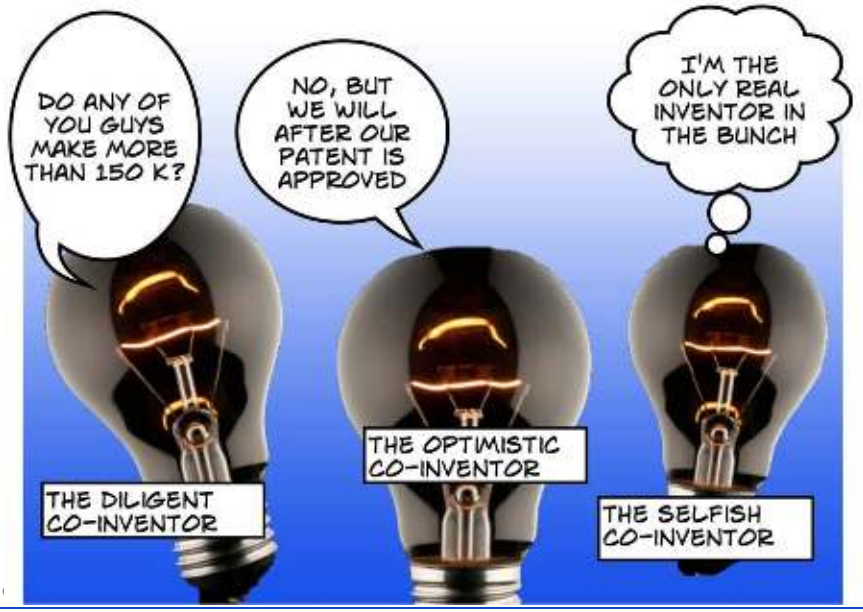
Ownership

- Ownership resides solely with the named inventor(s), unless there is an agreement that assigns the invention to another
- Each co-inventor owns an undivided interest in the entire patent, irrespective of their level of contribution
- A joint inventor who contributed to the invention of only one claim has an undivided interest in the whole patent



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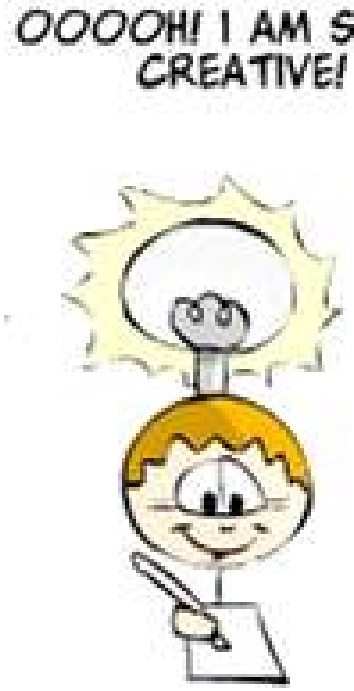
Conception

A definite and permanent idea of a complete and operative invention, including every feature of the subject matter sought to be patented



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Joint Invention

Joint Inventors:

- Need not have physically worked together or at the same time
- Need not make an equal contribution
- Need not make a contribution to the subject matter of every claim
- Must have a collaboration

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Joint Inventorship Problems

- Collaborations often do not go well
- One group begins a project and another takes it over
- What happens when chemical compounds invented by one party for which a use is discovered by another party?

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What Can Possibly Go Wrong?

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(19) World Intellectual Property Organization
International Bureau

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WIPO | PCT

(10) International Publication Number
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C07D 213/36 (2006.01)	*A61P 11/06* (2006.01)
C07D 295/135 (2006.01)	*A61P 19/00* (2006.01)
C07D 277/28 (2006.01)	*A61P 25/00* (2006.01)
C07D 333/20 (2006.01)	*A61P 35/00* (2006.01)
C07D 307/52 (2006.01)	*C07C 15/12* (2006.01)
C07D 233/60 (2006.01)	*C07C 13/10* (2006.01)
C07D 231/10 (2006.01)	*A61K 31/402* (2006.01)
C07D 239/26 (2006.01)	*A61K 31/4418* (2006.01)
C07D 471/04 (2006.01)	*A61K 31/4155* (2006.01)
C07D 471/10 (2006.01)	*A61K 31/427* (2006.01)
C07D 413/12 (2006.01)	*A61K 31/381* (2006.01)
A61K 31/137 (2006.01)	*A61K 31/341* (2006.01)
A61K 31/5375 (2006.01)	*A61K 31/506* (2006.01)
A61P 3/10 (2006.01)	

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(30) Priority Data:
61/657,423 8 June 2012 (08.06.2012) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

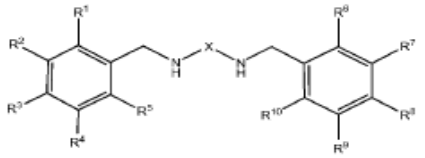
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with sequence listing part of description (Rule 5.2(a))*

(54) Title: FBXO3 INHIBITORS



(I)

(57) Abstract: The present application discloses benzathine and related compounds and their use as FBXO-3 inhibitors.

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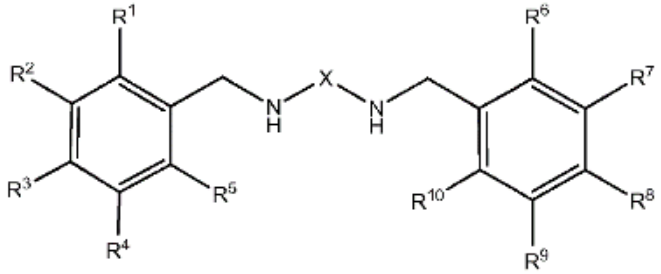
Claims of PCT/US2013/030995

1. A compound, or a pharmaceutically acceptable salt or ester thereof, having a structure of formula II:



wherein X is a divalent linking moiety; and

are each individually H, optionally-substituted alkyl, optionally-substituted alkoxy, optionally-substituted aryl, optionally-substituted cycloalkyl, optionally-substituted heterocyclic, halogen, amino, or hydroxy, provided that at least one of R^3 or R^8 is an optionally-substituted alkyl, a substituted alkoxy, optionally-substituted aryl, optionally-substituted cycloalkyl, optionally-substituted heterocyclic, or halogen.

2. The compound of claim 1 , wherein at least one of R'-R^{10} is an optionally-substituted N-heterocyclic.

3. The compound of claim 2, wherein at least one of R'-R^5 is an optionally-substituted N-heterocyclic, and at least one of R^6-R^{10} is an optionally-substituted N-heterocyclic.

4. The compound of claim 1 , wherein at least one of R^3 or R^8 is an N-heterocyclic.

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- Disclose to your Patent Manager
- They evaluate the technology to determine whether there is a commercial need and the invention is potentially patentable
- They engage a patent attorney to work with you to develop and file a patent application, usually a provisional application
- Before the one year deadline to convert, the Patent Manager and outside counsel assesses the technology and any new data
- Again work with a patent attorney to prepare a PCT application
- Thirty months from the filing date of the provisional application, the application is filed in the US and other countries

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The Process

- Examined by patent examiner in each country
- Multiple office actions may be issued rejecting the claims
- Patent attorney works with you to develop arguments and possible amendments to the claims to overcome the rejections

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Claims

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The Process

- Notice of Allowance/Notice of Intent to Grant
- Issuance/Grant of patent with an enforceable patent term of 20 years from the filing of the PCT or non-provisional filing date

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Filing Timeline

- File a U.S. Provisional Application
- One year from that filing date, file in the PCT, or US or both
- Thirty months from filing the provisional application (thirty one in some countries), file in national phase countries across the world
- Potentially can have issued patents in multiple countries all claiming priority to the originally filed provisional application

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Approx. Costs

- U.S. Provisional Application $6,000 - $12,000
- PCT $10,000; US $8,000
- National phase countries across the world $50,000 - $200,000
- Attorney prosecution and government filing fees for one family could exceed $1,000,000

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Application: Title "*Compositions and Methods for treating a disease*"
Priority: U.S. Prov Appl 61/911,911
PCT: PCT/US2008/012345

U.S. Patent No. 9,999,999
ISSUED June 2017
Filed: July 2010 (5 OA, 2 RCE)

→ *DIV* U.S. Appl. No. 15/555,555
Filed: May 2017
PENDING

Office Action:
3mo – Jun 1, 2018
6mo – Sep 1, 2018

AU Patent No. 2009111234
ISSUED

→ *DIV* AU Pat. No. 2015200201
ISSUED

CA Patent No. 2,007,007
ISSUED

EP Appl. No. 09 703 373.2
Resp to 2nd OA: Nov 2016
PENDING

Arguments & Requests: Sep 2018
Oral Proceedings: Oct 2018

JP Pat. No. 5,666,777
ISSUED

→ *DIV* JP Pat. Appl. No. 2015-151459
Response to 1st OA: Sep 2016
ISSUED

CN Appl. No. 200987654312.1
Resp to 6th OA: Apr 2017

→ CN Appl. No. 20170999888.3
PENDING

IN Patent No. 2345678
ISSUED

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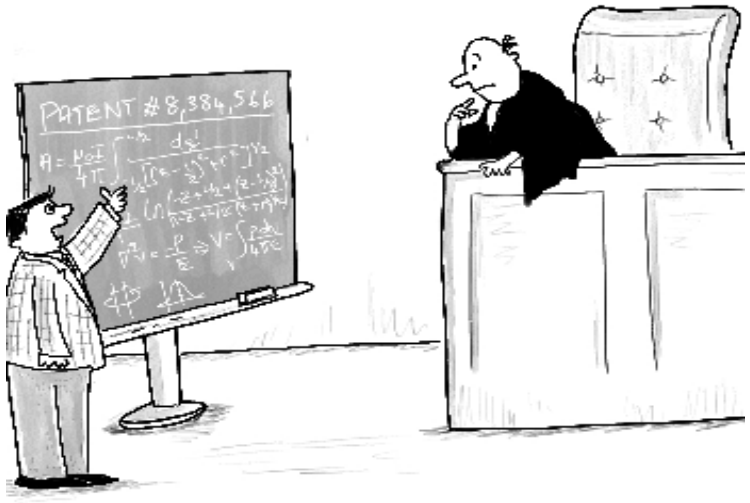
Patent Application

- **The Disclosure** – all of the text, figures, tables, etc. that disclose the invention and the manner of making and using it



- **The Claims** – a precise recitation of the invention, in numbered paragraphs at the end of the application

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Claims

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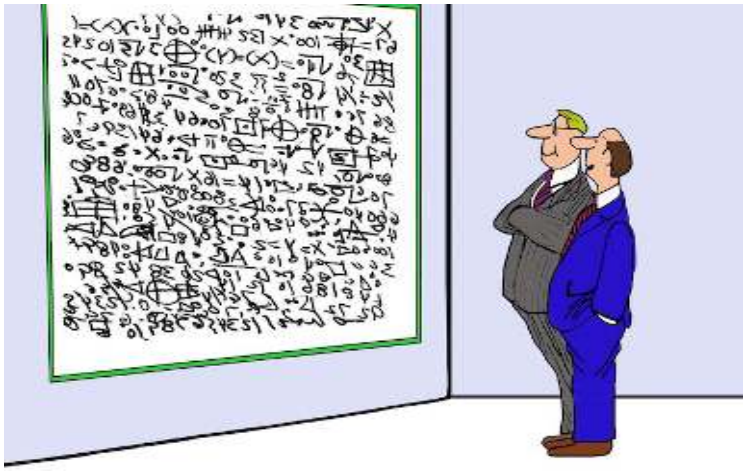
Patentability

The claims are assessed by an Examiner to see if they satisfy the following criteria:

- Utility and Non-natural [35 U.S.C. § 101]
- Novel [35 U.S.C. § 102]
- Non-obvious [35 U.S.C. § 103]
- Claims are enabled by the specification as-filed [35 U.S.C. § 112]
- Claims satisfy the written description requirement [35 U.S.C. § 112]



"When you put it like that, it makes complete sense."

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The Disclosure Dilemma
"PUBLIC DISCLOSURE"

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Thank You For Listening!

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