The Patenting Process: From Invention Disclosure to Patent
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How do we protect our IP?

*Patents - 35 USC § 101*

Patentable subject matter is “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”
Why are patents important?

• Protection for new products, uses and methods is essential.
• Without protection, new products may be reverse engineered or knocked off freely (i.e., doing R&D for competition).
• Product development makes it essential that the fruits of these efforts go as far and as long as possible.
• Licensing
• Attracting Investors
What is an “Invention”?

• An invention exists when
  – there is conception, and
  – the invention is reduced to practice.
• Conception: only ordinary skill would be necessary to practice the invention, without extensive research or experimentation.
• Reduction to practice means the invention has either been made and tested OR it is adequately described in a patent application.
The Three Parts of a Patent

Specification
• This is the descriptive part of the application
• Background, Detailed Description of the Invention, Experimental

Drawings (as necessary)

Claims
• These are what will be the enforceable part of the patent
• Claims are “negotiated” with the Examiner during the examination period

➢ There must be support for each element of each claim in the specification.
U.S. Provisional Application

- This application can be filed in an expedited fashion in order to preserve a priority date.
- It is never examined.
- “Conversion” applications must be filed before one year anniversary.

The Patent Process
One Year After Provisional Filing

- U.S. Nonprovisional Application (“Utility”)
  - Application is examined at USPTO, Office Actions are received during the examination period.
  - In response, arguments and/or claim amendments are made.
- International Application (PCT Application) – will be filed internationally

18 Months After Provisional Filing

- US and PCT applications are published.
Requirements for Patentability

- Utility (35 USC § 101)
- Novelty (35 USC § 102)
- Nonobviousness (35 USC § 103)
- Written Description/Enablement/Best Mode (35 USC § 112)

➢ All of these elements are necessary for each desired claim.
• The invention must have some useful purpose that is specific, credible, and substantial.
  – Compounds with affinity for a receptor.
  – A new medical device useful in surgery.
  – A new method of designing a semiconductor.
Novelty

• To obtain a patent, the invention cannot, before the date of invention, be:
  – patented, or
  – known or used by others, or
  – described in a publication anywhere
  – 1 year grace-period in U.S.

• Absolute novelty required for non-U.S. patents.
Public Disclosure

• Publications include journal articles, abstracts, poster presentations, and government grants.
• Many journals are now putting articles on-line before mailing of the journal.
• Many abstracts are published or available on-line prior to the date of the meeting.
Disclose to CVIP FIRST

• For public, written disclosures, submit copies of manuscripts, abstracts to CVIP prior to submission to the journal
• For public, oral disclosures, submit copies of slides and posters to CVIP well before the date of the meeting
§ 102 (Novelty):
Hypothetical compound claim

Hypothetical claim 1:
- A compound for the treatment of opioid-induced constipation having the formula:

If filed today, this claim would lack novelty in view of the prior art.
To obtain a patent, the invention must not be obvious to a person of ordinary skill in the art.

Invention must not be suggested or taught in the prior art.

An obviousness rejection is often based on the combination of two (or more) references.
Hypothetical claim 2 (let’s assume this claim is novel):

- A compound for the treatment of opioid-induced constipation having the formula:

\[ \text{or} \]

If filed today, would this claim be obvious in view of the prior art?

- Are these obvious structural changes in view of U.S. Patent 7,563,899?
Hypothetical claim 3:
• A controlled release formulation, comprising a pharmaceutically effective amount of Relistor®, and from about 0.1% to about 4.5% w/w of one or more rate controlling high viscosity cellulosic ether polymers.

Prior art:
• U.S. Patent No. 7,563,899, which discloses Relistor®.
• U.S. Patent No. 6,673,369 – Discloses controlled release formulations comprising a variety of different drug compounds and one or more of rate controlling cellulosic ether polymers.

If filed today, would this claim be obvious in view of the prior art?
An allegation of obviousness may be rebutted with evidence of “secondary indicia of nonobviousness.”

- Unexpected results
- Teaching away
- Long felt but unresolved needs
- Failure of others
- Commercial success
- Recognition of problem
- Failures to solve problem
- Competitors’ prompt copying
- Licensing of patent to industry
- Disbelief and incredulity
Claim 4
A diphosphonic and acid compound, or pharmaceutically-acceptable salt or ester thereof, which is 2-(3-pyridyl)-1-hydroxyethane diphosphonic acid.
Procter & Gamble Co v. Teva: Analysis

- “[E]ven if 2-pyr EHDP was a lead compound, the evidence does not establish that it would have been obvious to a person of ordinary skill at the time of the invention to modify 2-pyr EHDP to create risedronate.”
- Bisphosphonates determined to be inherently unpredictable
  - 3-pyr EHDP less toxic than 2-pyr EHDP
  - 4-pyr EHDP totally inactive
Claim 21
A compound according to claim 1 which is 2-[(3,4-dimethoxy-2-pyridyl)methylsulfinyl]-5-(1,1,2,2-tetrafluoroethoxy)-1H-benzimidazole or a pharmacologically-compatible salt thereof.
• One of skill in the art would have narrowed the prior art to 18 exemplary compounds, including compound 12.

• Prior art taught methoxy group at 3-position of pyridine ring would have lower pKa value than methyl at that position.

• Prior art taught that it was desirable to lower the pH of proton pump inhibitors
Ortho-McNeil v. Teva et al.
(Fed. Cir. 2009)

Claim 6
A composition comprising tramadol and acetaminophen in an about 1:5 ratio.
Ortho-McNeil v. Teva: Analysis

• Only difference between claim 6 and prior art is weight ratio (prior art disclosed p-acetamino-phenol)
• “Ortho-McNeil’s problem, however, is that its own evidence indicates no perceptible difference in synergy between [the claimed weight ratios and the prior art weight ratios].”
• “Thus, Ortho-McNeil has failed to create a material dispute of fact regarding whether ‘the claimed range achieves unexpected results relative to the prior art range.’” (emphasis in original)
CLAIM 73

An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

- Appellants claim DNA molecules encoding a protein known as the Natural Killer Cell Activation Inducing Ligand ("NAIL").
- Claim specific to CD48-binding region of NAIL.
- Natural Killer ("NK") cells are a class of cytotoxic lymphocytes that play a role in fighting tumors and viruses.
In re Kubin: Prior Art

- The Valiante patent: discloses the NAIL protein, and suggests way to isolate NAIL cDNA.
- The Matthew article: discloses the nucleotide sequence of the mouse version of the NAIL protein.
Appellants used conventional techniques, as taught in Valiante and Sambrook, to isolate a gene sequence for NAIL.

Applicant references “standard biochemical methods” of Sambrook in specification.

Matthew is “exemplary of how routine skill in the art can be utilized to clone and sequence the cDNA of a similar polypeptide.”
The Invention Must Be Adequately Described

Test:

• Would a person of ordinary skill in the art, reading the application as filed, understand that the inventor(s) was “in possession” of the invention set forth in the claims?

  • Note that “in possession” means invention is “complete,” not necessarily “made.”
Enablement

Must enable one of ordinary skill in the art to make and use the claimed invention

Test:

• Would a person of ordinary skill in the art be able to make and use the claimed invention without undue experimentation?
  • Well-described experimental procedures are important.
• **Claim 92**
  
  A method of treating neurofibrosarcoma in a human by administering an...antibody...secreted from a...hybridoma derived from the neurofibrosarcoma cells.
• The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method.

Claim was enabled, but not described
• This sparse description of antibody structure in the claim stands in stark contrast to the detailed method of making the antibodies found in the specification.
• Must set forth the inventor’s view of the best mode of carrying out the invention at the time application is filed.
• Best mode must be disclosed, but need not be identified as such.
• Patent Offices assume that one of the embodiments disclosed is the best mode.
  - What is the best way to make invention?
  - What is the best way to test whether the invention works?
Determination of inventorship is a strictly legal determination.

A patent can be invalidated due to an incorrect inventorship listing.

Inventorship depends on the significant intellectual contribution made towards developing a specific and sufficiently precise approach to a particular problem.

If the collaborator merely conducts experimentation dictated by another's specific idea, he is not an inventor, even if the tasks he undertakes require skill and some creative thought.
Since the U.S. has a “first to invent” system, proving that an inventor was first (i.e., conceive/reduce to practice) can be especially important.

- Lab notebooks
- Invention disclosures
The Patent Process: Documenting the Invention

• The laboratory notebook
  • Documents the inventive process
  • Serves as the source of experimental data for patent claims, patent examples, proof of concept, etc.
  • Can provide evidence of the date of invention.
• Standard good laboratory notebook-keeping practices should always be followed.
Recording conception. Clearly record in your notebook the facts surrounding the invention. Each page should be signed and dated and signed by a witness.

Record continuity. Intervals in your research, if any, should be noted.
• Witnessing.
• Recording disclosures to others.
• Speculation as to other embodiments of the invention, possible other uses, *etc.* should be recorded as this will assist in sizing up and fleshing out the invention. (In fact, speculation may lead to other inventions!)
Procedure for a Well-Prepared Patent Application

• Prepare and file an invention disclosure.
• Talk to CVIP to describe the invention, its novel aspects, and the prior art.
• Drafting of application.
Guidelines for Scientists

- Report all discoveries internally ASAP
  - new invention disclosures
- Avoid public disclosure prior to patent filing
  - articles
  - presentations (e.g. posters, lectures)
  - other exchanges/collaborations
- Pre-clear ALL public disclosures
Responsibilities of Inventors

- Participate fully in the patent process
- For example:
  - Disclose invention fully
  - Perform preliminary literature search
  - Help write applications: Review drafts
  - Help prepare responses to examiners
  - Provide “prior art” references
Thank You

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