



PABST PATENT GROUP

IP Strategies for Protecting and Commercializing Biotech Inventions

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Outline

- Biotechnology Intellectual Property (IP) Rights
- Protecting Biotech Inventions
 - What is patentable
 - Written Description
 - Enablement and non-obviousness
 - The role of Examples

Notes

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- This presentation is intended to be interactive. Please stop me with questions.

BIOTECH IP RIGHTS

- Patents
 - Protect inventions
 - 20 year term
- Trademarks
 - Protects words and/or symbols used in commerce in connection with goods or Services
 - Source identifier
 - Tylenol® (acetaminophen; Johnson and Johnson)
 - Tamiflu® (Oseltamivi; Hoffman-La Roche)
 - Ozempic® (semaglutide; Novo Nordisk)
- Trade Secrets
 - Protects inventions not disclosed in a patent application
 - Difficult to patent
 - Difficult to enforce
 - Protects know how

What is a patent?

- A business asset
- a legal document
 - the patent owner the right to **exclude** others from making, using, selling, or importing the claimed invention into the patent jurisdiction
- Claims
 - novel and inventive (non-obvious) composition, device or component thereof, method of making or method of using
- Types
 - Utility- protects functionality -compositions, methods
 - Design-protects how an article looks
 - Plants- protects asexually reproduced plants

Patent Claims

- Product Claim

- A clear insulin solution having a pH of between greater than 7.0 and 7.6, consisting of insulin, one or more zinc chelators one or more dissolution agents and one or more excipients,
 - wherein the insulin comprises dissociated insulin monomers produced by chelation of the zinc in insulin hexamers which are not soluble at a pH of between greater than 7.0 and 7.6,
 - the dissociated insulin monomers have bound thereto charge masking agents which stabilize the dissociated insulin monomers,
 - wherein the solution is prepared by raising the pH of an insulin solution from about pH 4.0 to a pH between a pH greater than 7.0 and a pH about 7.6, and
 - wherein the insulin has an enhanced rate of uptake and transport through epithelial cells relative to the solution without the zinc chelator and dissolution agent.

- Method Claim

- A method of treating a diabetic individual comprising
 - injecting an effective amount of the solution of claim 1, into the individual

IP Commercialization- what/how?

- What is IP Commercialization
 - the process of turning products and services into a commercially viable value
- IP Commercialization -how
 - Sale
 - Self-commercialization
 - 3M transformed the “repositionable adhesive” into Post-it notes that they sell
 - Start up, spin-off/spin-out company
 - Licensing
 - For Universities- TLO
 - Assignment
- Why
 - To make money
 - Recoup IP development costs
 - Make profit
 - Sometimes only route to bring any product to market
 - Cost of product development can be prohibitive

IP Commercialization- HOW?

- Build an attractive IP estate
 - Diversify, if possible
 - IP types-must not file a patent on everything; trade secrets are equally valuable
 - Claim types- use to build an estate and increase enforceability
 - Patent Prosecution Strategy
 - Intricately tied to IP value
 - Claim types
 - Some claims types are more difficult to enforce than others
 - Methods vs. products
 - Claim Scope
 - Broad claims vs narrow claims
 - » A composition comprising insulin, a zinc chelator and a diacid
 - » A composition comprising insulin, EDTA and citric acid
 - Claim layering- fall back positions
 - » Broad claims are attractive for commercialization-can block others
 - » Narrow claims are easier to enforce
 - » An application and patent needs both
 - Enablement and written description

Strategies for Protecting IP INVENTIONS

- Patents
 - Multi (US, EP, JP, CN, etc.) vs. one jurisdiction (US only)
 - Fund control- multi can more attractive for commercialization
- Contracts
 - Non Disclosure Agreements
 - Only as good as integrity of the players
 - If possible –PRO filing, then NDA
 - Material Transfer Agreements
 - employees, researchers and collaborators
 - Third party contractors
- Trade Secrets
 - Non Disclosure Agreements
 - employees, researchers , collaborators and potential partners
- Vigilance
 - Review public disclosures (such as technical publications or communications with potential partners) re: confidential information
 - Review licensee’s patent filings- design around licensed IP?

Can you get a Patent?

Patentable Subject Matter

- **Criteria for obtaining a patent**
 - **Must fall within one of 4 categories**
 - Things
 - processes, machines, manufactures
 - actions" (i.e., inventions that consist of a series of steps or acts to be performed).
 - Processes
 - Must not be directed to subject matter the courts have found are exceptions
 - Abstract ideas,
 - laws of nature
 - natural phenomena (including products of nature).
 - basic tools of scientific and technological work", monopolizing these tools by granting patent rights may impede innovation rather than promote it.

Can you get a Patent?

- Abstract ideas
 - Mathematical concepts – mathematical relationships, mathematical formulas or equations, mathematical calculations
 - Certain methods of organizing human activity – fundamental economic principles or practices
 - Mental processes – concepts performed in the human mind (including an observation, evaluation, judgment, opinion)
- laws of nature
- natural phenomena (including products of nature).
 - A method of diagnosing julitis in a patient, said method comprising:
process
 - a. obtaining a plasma sample from a human patient; routine
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 (porcine) antibody and detecting binding between JUL-1 and the antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected. Correlation/rel btwn Jul-1 and julitis => consequence of a natural process => laws of nature; can be performed using mental processes

What are you protecting

- You start with an idea- you test the hypothesis
 - Method or Composition?
 - Should you file a patent application?
 - Expand it to cover what you hope your partner or a licensee can market- adds value
 - Imagine an egg- promise of more to come
 - Describe the idea in an expanded (not narrow) fashion (to tech transfer/attorney)
 - A composition comprising insulin, a zinc chelator and a diacid
 - » Covers any zinc chelator, and diacid
 - » Test more than; no requirement to test all
 - A composition comprising insulin, EDTA and citric acid
 - » Easy to design around

How are you protecting?

- **Provisional**

- Stake in the ground
- Fund raise
 - Not ready to commit funds
- Still experimenting
- Meeting with potential partners

- **Non- Provisional**

- U.S national application
 - Can claim priority to provisional
- PCT application
 - Filing in countries of interest follows
- **Design**

Patent Application

- **Parts of a Utility Patent Application**
 - Specification
 - Describes and Enables the invention
 - Examples or none
 - Claims
 - Products; methods of making, methods of using etc.
 - Abstract
 - Drawings
- **Parts of a Design Application**
 - **One claim**
 - We claim the ornamental design for a flexible heat sink , as shown and described .
 - **Drawings**

Claim Scope Considerations-Prior Art

- **Patentability Search?**
- **Novelty**
 - Draft around known prior art
 - Express disclaimers of elements the prior art requires as fall back
 - Establish how invention differs
 - Inventors typically are aware of the close prior art and are in a good position to establish at filing how they differ
 - In a telephone conversation
 - Inventor disclosed more than one year ago?
 - **STOP**
 - Duty of disclosure in US => no patent
 - No duty in foreign jurisdictions, however, potential licensee will uncover disclosure/patent cannot withstand a challenge=> not enforceable
 - Non-enforceable patent is not attractive to potential buyers
- **Inventive step**
 - Even if you are novel why are your different?
 - Comparative data in the application is invaluable during prosecution
 - shows advantages of invention
 - Shows invention is enabled as broadly claimed

PUBLIC DISCLOSURE By Inventor

- Claims were directed to methods of preparing foods containing extruded soy cotyledon fiber (“SCF”), which lowers serum cholesterol levels while raising HDL cholesterol levels.
- Two years before applying for a patent:
 - Inventors presented the method at a meeting of the American Association of Cereal Chemists. During the meeting, the presentation, which disclosed every limitation claimed in the application, was displayed on poster boards for two and a half days.
 - Also displayed for less than a day, at an Agriculture Experiment Station at Kansas State University.
 - The presentation consisted of fourteen slides, including a cover page, an acknowledgement slide, and four slides presenting experimental data.
- The Court found that the presentations were sufficiently “publicly accessible” to constitute a “printed publication.”



MPEP 2128

PUBLIC DISCLOSURE By Inventor

- BioRxiv, et al.
 - Immediate publication
 - Ensures Loss of foreign rights in absolute novelty jurisdictions
 - Shrinks patent estate
- Constant Communication with TLO/attorney is key
- Must disclose prior disclosures to TLO/attorney



Novelty

- Every claim element is expressly or inherently found in a single reference
 - Composition comprising A + B + C components
 - Reference must disclose A + B + C
 - Cannot combine two references
 - Inherent disclosure – the element is necessarily present even if not expressly disclosed
 - Need not be recognized by prior art/ person of ordinary skill in the art
 - Claims to hemihydrate compound
 - inherently anticipated by prior art patent to an anhydrous form of the compound
 - practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate

Obviousness

Applicant has tools

- Are the elements really present in the combined references?
- Did the Examiner provide a reason why one would combine them?
 - Rational reason for the combination avoids hindsight analysis
 - Hindsight is impermissible as a basis for concluding obviousness
- Did the Examiner pick and choose portions of prior art references while ignoring others so as to arrive at the claims
 - Cannot use Applicant's specification as a roadmap and look for elements in the prior art
 - Inventions are almost always putting together known elements in novel and unexpected ways
- Unexpected results/Superior properties/Properties not present in the prior art
 - Evidence based

Obviousness

- A patent for a claimed invention may not be obtained...
 - if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious
- Can combine multiple references
 - Pharmaceutical composition comprising A +B + C
 - Reference A discloses a composition with A and B and does not mention C
 - Reference B discloses that component C can be added to pharmaceutical compositions
 - An Examiner can correctly allege that the combination of A + B+C is obvious over the combination of Reference A and Reference B
 - Inherent property
 - Claims to a method of making a hemihydrate compound
 - Reference A discloses an anhydrous form of the compound
 - practicing the process in the prior art to manufacture the anhydrous compound "inherently results in a hemihydrate form"
 - Reference B discloses that hemihydrate forms have superior properties and methods of purifying them are known
 - Examiner, one would be motivated to modify the method in reference A to provide the hemihydrate form

Obviousness

Applicant has tools

- Modification cannot change the principle of operation of a reference
- Modification cannot make a reference unsuitable for its intended purpose
 - prior art patent to an anhydrous form of the compound
 - practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate
 - Cannot modify the method in prior patent to provide a hemihydrate compound where the whole purpose of the patent is to provide an anhydrous compound to solve a specific problem
- Long felt but unmet need
 - Evidence based
- Prior art teaches away from the claims
 - Leads one in a path different from one Applicant took

Patent Drafting Considerations-What could go wrong

- OVERLY Narrow Description of the invention
 - Claims can be limited only to the narrow description
 - Are you converting fibroblasts to liver cells using Forskolin or cAMP activators?
- Overly broad description of the invention- too ambitious?
 - Enablement problems when the Examiner can show some claimed subject matter does not work
 - Nanoparticle loading of up to 50% max – remarkable
 - Inventors prior application disclose up to 99% loading –then inventor says this was not possible
 - Fraud on the patent office
- No fall back positions
 - Ranges- they may all die together during prosecution
- Use terms that are not art recognized with no definitions
- Use subjective terms with no objective description

Claim Scope -Description

- the "specification shall contain
 - a written description of the invention“
 - in sufficient detail
 - that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention
- words, structures, figures, diagrams, and formulas
- Discovery- cancer patients with upregulated levels of phosphorylated p53 do not respond well to chemo
 - Method of improving cancer treatment by administering to a subject a specific inhibitor of p53 phosphorylation
 - No such inhibitor exists
 - Delivering cells therapy compositions with Forskolin improves their survival in vivo
 - Described 6 examples of cAMP activators, but no forskolin analogs; cannot later claim a specific analog you find works best

Claim Scope -Description

- No aptamer structures described in the specification
 - => no structure function relationship described
 - 17. A kit for performing a non-competitive assay for an analyte selected from the group consisting of a hormone, drug, or drug metabolite having a molecular weight of less than 2,000 Daltons,
 - wherein the kit comprises a membrane strip comprising an application point, a capture zone, and an absorbent zone,
 - wherein the capture zone comprises an aptamer **that selectively binds to a binding agent-analyte complex but not free analyte**, immobilized in or on the membrane strip, and
 - wherein the aptamer comprises nucleic acid aptamer, or peptide aptamer.
- Structure function relationship
 - A method of treating Alzheimer's Disease in a subject, the method comprising administering to the subject a therapeutically effective amount of an anti-prion protein (anti-PrP) antibody **having the complementarity determining sequences** (CDRs) DYNLD (amino acids 50 to 54 of SEQ ID NO:4), NVYPNNGVTGYNQKFRG (amino acids 69 to 85 of SEQ ID NO:4), YYVDVSY(amino acids 118 to 124 of SEQ ID NO:4), SASSSVSYM (amino acids 46 to 55 of SEQ ID NO:6), DTSKLAS (amino acids 71 to 77 of SEQ ID NO:6), and HQWRSNPYT (amino acids 110 to 118 of SEQ ID NO:6).
 - Complementarity-determining regions (CDRs) are part of the variable chains in immunoglobulins (antibodies) and T cell receptors, where these molecules bind to their specific antigen.

Claim Scope - Enablement

- The specification shall
 - describe how to make and how to use the invention
 - ensure that the invention is communicated to the interested public in a meaningful way
 - must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention
 - The inventor must meet their end of the bargain for a patent
- Test for Enablement
 - (A) The breadth of the claims;
 - (B) The nature of the invention;
 - (C) The state of the prior art;
 - (D) The level of one of ordinary skill;
 - (E) The level of predictability in the art;
 - (F) The amount of direction provided by the inventor;
 - (G) The existence of working examples; and
 - (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim Scope -Enablement

- The breadth of the claims
 - a broader claim is more likely to overlap with prior art or lack adequate support or enablement and is therefore a more vulnerable target for patentability and validity attacks
- The level of one of ordinary skill
 - Less is needed when the level of skill in the art is high
 - Can we use mRNA in vaccines? Today, level of skill in the art is high

Enablement

Working/prophetic Examples

- The existence of working examples
 - Not needed, however...
- Unpredictable arts
- Undeveloped arts
- Correlation between *in vitro* and *in vivo*
- Claims to a genus
 - representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient

Can you get a Patent?

Obviousness-Type Double Patenting (ODP)

- **Cannot obtain claims to obvious variants**

- **Cited Patent Claim-** owned by Eidgenössische Technische Hochschule Zürich and Universität Zürich- Caltech Inventor moved here

- A fusion peptide, **comprising**



- (i) a first domain; (ii) a second protein domain; and (ii) an enzymatic or hydrolytic cleavage site between the first and the second domains;
- Wherein the first domain is a growth factor selected from the group consisting of the platelet derived growth factor superfamily and transforming growth factor superfamily;
- Wherein the second domain is a crosslinking factor XIIIa substrate domain----etc
PDGF and TGF = Growth factor => it is a species of GF (genus)

A species anticipates a genus- this is the law.

- **-Rejected Claim-** owned by Cal Inst of Technology

- A composition **comprising**

- a matrix and a bidomain protein or peptide having an amino acid sequence that comprises a transglutaminase substrate domain and a polypeptide growth factor, wherein the protein or peptide is covalently bound to the matrix by the transglutaminase substrate domain.

- **Solution- Contract (Assignment)**





QUESTIONS?