Patents & Patenting in the Life Sciences

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Patent Fundamentals

- What is a patent?
- What makes an invention patentable?
- The patent process.
- Patent strategy.
What Is a Patent?

- A legal monopoly
- Based on the Constitution: Congress shall have the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”
What Is a Patent?

- **Quid pro quo**
  - Exchange of disclosure of idea for a legal right

- Legal monopoly
  - An incentive system
  - Exclusion of competition/market power
  - Reward for disclosure of invention

- Right to exclude
  - A mere “right to exclude others from making, using, offering to sell, or selling the invention throughout the United States”
  - Only right that a patent grants is the right to sue others
Considerations in the Life Sciences

- **Patentability of Inventions.**
  - Patents prevent competitors from copying your invention
  - Particularly important in biotech industry where cost of development (research, regulatory approval) is extremely high.

- **Freedom to Operate**
  - Need to ensure that business model is not impeded by third party patents.
  - If a blocking patents exist:
    - Is there a work-around available?
    - Could the patent be licensed?
    - Is the patent valid?
Patent Nuts & Bolts

Specification

- Includes the drawings and text of the application.
- Must provide a “written description” of the invention and “enable” the invention to be made and used.
- The specification does not change during prosecution of a patent application.
Claims

- Define the boundaries of the legal monopoly provided by the patent
- Often change during prosecution of the patent
- Claim changes must be “described” and “enabled” by the specification as filed.

1. An isolated human antibody, or an antigen-binding portion thereof, that dissociates from human TNFα with a $K_d$ of $1 \times 10^{-8}$ M or less and a $K_{off}$ rate constant of $1 \times 10^{-3}$ s$^{-1}$ or less, both determined by surface plasmon resonance, and neutralizes human TNFα cytotoxicity in a standard in vitro L929 assay with an IC$_{50}$ of $1 \times 10^{-7}$ M or less.

2. The isolated human antibody, or antigen-binding portion thereof, of claim 1, which dissociates from human TNFα with a $K_{off}$ rate constant of $5 \times 10^{-4}$ s$^{-1}$ or less.

3. The isolated human antibody, or antigen-binding portion thereof, of claim 1, which dissociates from human TNFα with a $K_{off}$ rate constant of $1 \times 10^{-4}$ s$^{-1}$ or less.

4. The isolated human antibody, or antigen-binding portion thereof, of claim 1, which neutralizes human TNFα cytotoxicity in a standard in vitro L929 assay with an IC$_{50}$ of $1 \times 10^{-8}$ M or less.

5. The isolated human antibody, or antigen-binding portion thereof, of claim 1, which neutralizes human TNFα cytotoxicity in a standard in vitro L929 assay with an IC$_{50}$ of $1 \times 10^{-9}$ M or less.
The claims alone define the monopoly, just as a deed defines a piece of physical property.

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Lifecycle of a “Typical” Patent

- Conception
- Provisional Application
- PCT Application
- Utility Application
- Patent Issues
- Post-Grant Proceedings
- Enforcement

Negotiation with Patent Office

1 Year
18 Months

Prosecution
Patent Term

- Filed before June 8, 1995: 17 years from issuance
- Filed after June 8, 1995: 20 years from earliest non-provisional filing
  - Patent term may be lengthened to compensate for delays at USPTO or FDA
To be patentable, an invention must:

- Encompass “patentable subject matter”
- Be useful
- Be new
- Be non-obvious
Patentable Subject Matter

“Anything Under the Sun Made by Man”

- Processes
  - In U.S., this includes therapeutic and diagnostic methods
- Machines and Manufactures
- Compositions of matter
  - chemical compounds, proteins, antibodies, artificial nucleic acids, transgenic cells, transgenic organisms
However, the following are not patentable:

- **Products of nature**
  
  1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

- **Abstract concepts**
  
  1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
     (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
     (b) determining a level of 6-thioguanine or 6-methylmercaptopurine in said subject having said immune-mediated gastrointestinal disorder,
     wherein a level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
     wherein a level of 6-thioguanine greater than about 400 pmol per $8 \times 10^8$ red blood cells or a level of 6-methylmercaptopurine greater than about 7000 pmol per $8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.
Inventions are Patentable Only if Useful

- Low standard for utility.

- However, a patent is not a hunting license -- you cannot patent small molecules, genes, proteins, etc. if they have no known utility.
Inventions are Patentable Only if New

You will not get a patent if:

- Someone else files a patent application disclosing your invention before you file.
- Someone else publishes or publicly discloses “your” invention before you file a patent application.
- You publish your own invention more than a year before you file a patent application.
- You sell your invention more than a year before you file a patent application.
Inventions are Patentable Only if New

Situation:
- Your company discovers a chemical compound that can be used to treat cancer.
- The chemical compound has previously been publicly used to waterproof boats.

*Can you patent your invention?!*
Inventions are Patentable Only if New

Situation (cont’d):

- Cannot get a patent on the compound itself - not new.
- However, you may be able to get a patent on:
  - Methods of using the compound to treat cancer
  - Pharmaceutical formulations containing the compound
Inventions are Patentable Only if Not Obvious

- Not patentable if it would have been “obvious” to combine previously known elements to arrive at your novel invention.

- Example:

  Invention is the treatment of a form of cancer by administering both **Compound A** and **Antibody B** to a patient.

  **Reference 1** is a scientific paper that teaches that **Compound A** can be used to treat cancer.

  **Reference 2** is an earlier filed patent application that claims the use of **Antibody B** to treat cancer.

  *Invention is likely obvious (i.e., not patentable)*

  *in light of References 1 and 2*
Some ways to show an invention is nonobvious:

- The combination of known elements produces unexpected results
  - The combination of Compound A and Antibody B results in unexpected efficacy – synergy!

- The art taught away from the invention
  - A prior art paper taught that administration of Compound A to a patient taking Antibody B resulted in potentially lethal side-effects.

- “Secondary” Considerations
  - Long-felt need
  - Commercial success
  - Acclaim of others
  - Failure by others
  - Copying by others
  - Licensing
First Steps Following Conception:

- Inventor drafts an Invention Disclosure – document used to describe invention
- Inventor may be asked to perform a preliminary patentability search – informal search of prior art to determine whether invention is really new
- Preliminary commercial evaluation – getting a patent is expensive, not all inventions are worthy of patent protection
Drafting a Patent Application:

– Usually should be done by a qualified patent attorney.
– It is important to ensure that the application covers both the *broad invention* and the *commercial embodiment*.
– In addition to being a legal document, a patent application is also an *advertisement for your technology*.
– Make sure *inventorship is correct*. 
Filing Options

– U.S. utility Application
  • Fastest way to get your application before the examiner.
  • Starts the patent clock.

– Ex-U.S. Application
  • Can establish priority for a U.S. utility application filed within 1 year.
  • Can not be used to overcome a statutory bar.
  • Does not start the patent clock in the U.S.

– U.S. Provisional Application
  • Can establish priority for a U.S. utility application filed within 1 year.
  • Does not publish.
  • Is not examined
  • Does not start the patent clock.

– PCT Application
  • International application
  • Delays examination
  • Starts patent clock
Patent Prosecution is a *negotiation* with the patent office where the Applicant negotiates with the Examiner to obtain claims that are as broad as possible.

Prosecution may entail written arguments and examiner interviews.

The claims often change during patent prosecution, but the specification remains the same.

After issuance patents can be subject to challenge.
WHAT YOU CAN DO WITH A PATENT

- **Tout it:** A strong IP position can be critical in obtaining investment.
- **License it:** Collect royalties by allowing others to practice the invention.
- **Enforce it:** Bring infringement suits against others practicing the invention.
- **Sit on it:** There is no requirement in U.S. law to practice a patented invention.
Do You Really Need a Patent?

- **Patents are Expensive**
  - Obtaining a patent costs many thousands of dollars.

- **Patents take a long time to obtain**
  - Depending upon the technology, it may take several years before a patent examiner even looks at your application.

- **Patents require you to disclose your invention**
  - Patent applications require you to disclose how to make and use your invention.
  - Applications publish 18 months after filing

- **Some patents are difficult to enforce**

- **All patents are expensive to enforce**
  - Enforcing a patent can cost many hundreds of thousands of dollars.
The Value of a Patent

- Patents are critical for technologies that require long and costly development and/or that require government regulatory approval. Examples: pharmaceuticals, biologics or diagnostics.

- Patents may not be worthwhile for technologies that can be developed quickly, rapidly become obsolete, and/or can be used confidentially. Examples: manufacturing processes or software.