

Innovation, Biotechnology and Patent Protection in the USA

Nathan P. Letts, PhD, JD

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Public Policy: To protect innovators in a free market environment

- In general the US is a free market system believing unencumbered competition is in the public interest.

Public Policy: To protect innovators in a free market environment

Exceptions exist, e.g.,

- Anti-trust laws to prevent abuse of a dominant position
- Government funding of basic research
- Patent laws
 - Patents encourage publication of new discoveries while providing protection from copycat drugs
 - Every FDA approved drug requires \$500-800 MM US in R&D expenditure

Patents

- In the U.S. originates in the Constitution, Art. 1, Sect. 8, clause 8.
- “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?

- A legal document that creates a negative right and provides the owners with the right to exclude others from making, using, offering to sell, or selling, that which is covered by a claim of the patent.

WHAT is a patentable invention?

- NEW? Easy, it can't be known.
- USEFUL? Generally easy, but for nucleic acid related inventions utility must be specific, substantial and credible.
- UNOBVIOUS? Typically, use an indirect proof, commercial success, long felt need, failure of others, unexpected results.
- WRITTEN DESCRIPTION? Actual examples are not required. Must be sufficient for a person in the field to make and use the invention. For US must disclose the best mode.

WHY patent an invention?

A patent provides:

- Means to capture and exploit the value from technology;
- Incentive for investment of \$\$\$ to develop and commercialize an invention;
- Barriers to entry and the cornerstone of a strong proprietary position;
- Publication provides recipe for others to build on;
- Recognition in the field;
- Drafting may reveal additional ideas or uses not previously considered.

Ownership vs. Inventorship

- U.S. rewards inventors. If there were no other contractual obligations, a sole inventor would own the entire patent and a joint inventor is part owner of the entire patent.
- As part of your employment, employers own all of your inventions (and notebooks). Inventors must assign their patent rights.
- To be an inventor you must contribute to either the conception or the reduction to practice of an invention. Someone following a protocol to validate will not be an inventor.

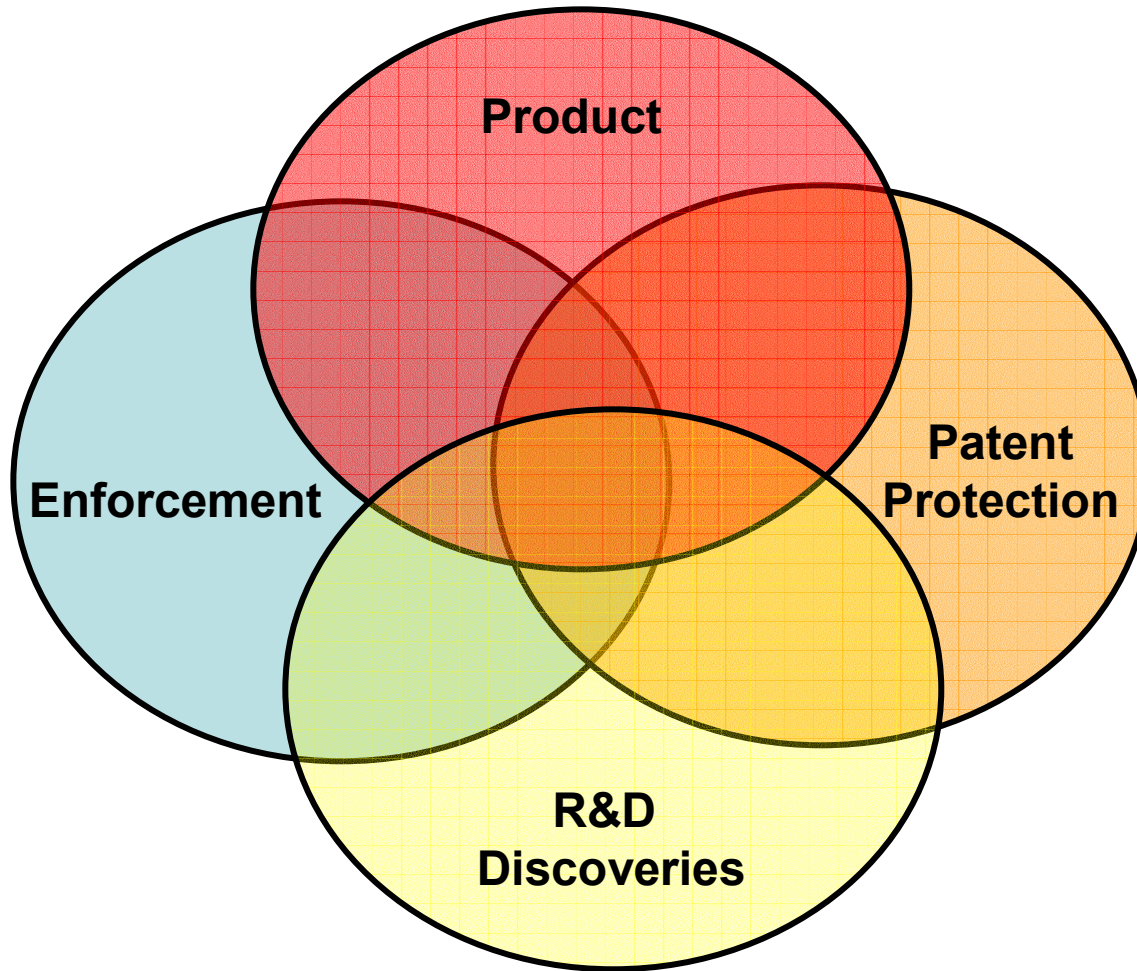
US Gov't Funding

- Most academic/university discoveries are supported in part by federal funds.
- Prior to 1982, in a slow and onerous process inventors could petition the NIH/NSF for rights to an invention.
- In 1982, Bayh-Dole act passed granting universities the right to own inventions made by researchers. In exchange US gov't gets rights (march-in rights, research non-excl, patent notification, annual updates regarding commercialization...).

Types of biotech claims

- **cDNA, mRNA, SYNTHETIC DNA**
- **PROTEINS, PEPTIDES, FRAGMENTS**
- **MONOCLONAL ANTIBODIES**
- **VECTORS**
- **HOST CELLS, CELL LINES**
- **TRANSGENIC ANIMALS**
- **DIAGNOSTIC KITS**
- **PHARMACEUTICAL COMP.**
- **PRODUCTION METHODS**
- **METHODS OF USE, RX**
- **METHODS OF USE, DX**
- **METHODS OF USE, IMAGING**
- **GENE THERAPY PROTOCOLS**
- **COMPUTER PROGRAMS, ALGORITHMS**

Proprietary Product Wheel



In re Kratz

- Inventors discovered chemical compound responsible for natural strawberry flavor.
- In 1979 a patent granted for “substantially pure” 2-methyl-2-pentanoic acid and even a food to which the substantially pure compound has been added.
- The court ruled that that the substantially pure form did not exist in nature, therefore both composition and food were patentable.

In re Chakrabarty (1)

- In 1972 Ananda Mohan Chakrabarty working for General Electric filed for a patent on a crude oil eating bacteria and uses of the bacteria to clean up oil spills, etc.
- The patent office granted claims to the uses but denied the bacteria *per se* because it was a life form.

In re Chakrabarty (2)

- The case was appealed to the Supreme Court.
- Briefs opposing the patent argued that
 - “genetic research may pose a serious threat to the human race”
 - “the dangers are too substantial to permit such research to proceed”
 - “may spread pollution and disease”
 - “may result in a loss of genetic diversity ...and depreciate the value of human life”
- The Court ruled that one may patent “anything under the sun that is made by man” and ruled life forms meeting patentability criteria are patentable subject matter.
- Interpreting the patent law, the Court found it does not provide a basis to bar patents on new life forms. The public policy concerns should be addressed to Congress and the Executive.

Rochester v. Searle (1)

- In 1992 Rochester filed a patent appn. based on discovery of Cox-2 and uses.
- In 2000, a patent issued with claims to use of a compound to “selectively inhibit” Cox-2 with a non-steroidal inhibitor.
- They filed a suit for infringement by Celebrex® and Bextra®.

Rochester v. Searle (2)

- In 2003, the District Court ruled the patent was invalid for failure to provide an adequate written description.
- The claimed method requires “a person of ordinary skill in the art . . . to engage in undue experimentation, with no assurance of success.”
- In 2004, the CAFC affirmed the lower courts ruling.
- The CAFC and Supreme Court denied Rochester’s request to review the case.

State Street Bank v. Signature Financial

- 1993 Signature received a patent for method of balancing mutual fund portfolios.
- 1996 State Street sued to have patent invalidated because it was “a business method.”
- The district court ruled in favor of State Street.
- In 1998 the CAFC overturned the lower court decision and ruled ‘business method’ exception was “no longer an applicable legal principle.”

The Aftermath of State Street

- Several questionable software/business method patents have issued and been litigated.
- One the Amazon “one-click” patent for expedited online purchases.
- Amazon sued Barnes & Noble for their “express line” service. The district court granted Amazon an injunction.
- In 2001, the CAFC overturned the injunction and the case settled.

Summary

- Balancing of public interest/protecting innovators for biotech discoveries in the US
- Requirements & types of biotech patent claims
- Case law biotech/pharmaceutical R&D and products (Kratz, Charabarty, Rochester, State Street)

About the Presenter

Dr. Letts has over thirteen years of practice in biotechnology patent law. In 1991 he received a PHD in Organic Chemistry from Columbia University. He then joined Cooper & Dunham LLP as a scientific advisor/patent agent. In 1996 he received a JD from Fordham Law School and joined Pennie & Edmonds as an associate. At the Practising Law Institute he taught several biotechnology patent classes and wrote chapters for the corresponding textbook. For the last four years he has been with diaDexus, Inc. in South San Francisco, CA as the only in-house lawyer and responsible for intellectual property protection and licensing. He may be reached at 650.246.6409 or nletts@diadexus.com.