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Hot Topics in Biotech Patent Law

- Patentable Subject Matter
 - Lab Corp Supreme Court Case
 - Monsanto EST Case
- Written Description Requirements
 - UC vs Eli Lilly and its effects
- Inherent Anticipation

Patentable Subject Matter

35 U.S.C. 101

35 USC 101, *Inventions patentable* : Whoever invents or discovers any new and useful **process**, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- **1st purpose**: define categories of patentable inventions (machine, article of manufacture, composition, & process)
- **2nd purpose**: only allow inventions that are useful

Patentable Subject Matter

35 U.S.C. 101

How have the Courts construed Section 101?

In the Supreme Court's landmark 6-5 *Chakrabarty* decision, the Court held that patentable subject matter is:

“[A]nything under the sun that is made by man.”
Diamond v. Chakrabarty, 447 US 303 (1980).

Evolution of the Scope of Patentable Subject Matter

- *Diamond v. Chakrabarty*: Sec. 101 broad enough to encompass living microorganisms.
- 1984: Human cell lines are patentable.
- 1986: Tryptophan overproducing cereals are patentable.
- 1988: Harvard Oncomouse (transgenic animal) is patentable.
- 1991: Human bone marrow stem cells are patentable.
- 2001: New plant varieties are patentable.

Patentable Subject Matter

- What Cannot be Patented:
 - Laws of nature;
 - Natural phenomena;
 - Abstract ideas.
- *Diamond v. Diehr* 450 U.S. 175 (1981)
 - Certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application.

Pending Supreme Court Case Regarding Patentable Subject Matter

Laboratory Corp of America vs. Metabolite

Laboratory Corp. of America

Claim: “A method for detecting a deficiency of cobalamin or folate [Vitamin B] in warm-blooded animals comprising the steps of:

(a) assaying a body fluid for an elevated level of homocysteine; and

(b) correlating an elevated level of homocysteine in said body fluid with a deficiency of cobalamin or folate.”

Laboratory Corp: District Court

- Metabolite sued Lab Corp for patent infringement and won:
 - Double damages
 - Permanent injunction for its test

Laboratory Corp: Federal Circuit

- Reviewed District Court's claim construction under section 112 (not 101).
- Agreed with District Court that “correlating” includes ascertaining a mutual or reciprocal relationship between homocysteine and vitamin deficiency.

Laboratory Corp: Appeal to the Supreme Court

- Federal Circuit holding “extraordinary”
- Construed a patent to bar a doctor from *thinking* about a well known correlation.
- All the patent tells a prospective practitioner is that a person with an elevated homocysteine level may have a vitamin deficiency.

Laboratory Corp: Appeal to the Supreme Court

- Supreme Court asked the Solicitor General to brief the question:
 - “is the patent invalid because one cannot patent laws of nature?”
- Solicitor General urged the Supreme Court to *Not* take the case.
 - Petitioner confused sections 101 and 112
 - 101 issues were not raised in the Federal Circuit and therefore insufficient evidence on record for appeal.

Supreme Court Grants Cert

- Question Presented:
- “Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlat[e]” test results can validly claim a monopoly over a basic scientific research relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result. “

Poor Claim Drafting?

Claim: “A method for detecting a deficiency of cobalamin or folate [Vitamin B] in warm-blooded animals comprising the steps of:

(a) assaying a body fluid for an elevated level of homocysteine; and

(b) correlating an elevated level of homocysteine in said body fluid with a deficiency of cobalamin or folate.”

Patentable Subject Matter

Monsanto EST Case

Monsanto EST Case

Claim:

A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO:5.

- SEQ ID NO: 1- 5 are EST expressed by maize at the time of anthesis.
- Did not have the full length sequences.

Asserted EST Utilities

- Molecular marker for mapping
- Measuring mRNA level via microarrays
- Source for PCR primers
- Use in identifying RFLPs
- Use in isolating promoters
- Use in controlling protein expression
- Use in isolating genes from other plants

Federal Circuit: ESTs Not Patentable

- Patent may not be granted to an invention unless a **substantial or practical utility** for the invention has been discovered or disclosed.
- Substantial utility requires that the asserted use must show that the claimed invention has a significant and presently available benefit to the public.
- Claimed ESTs act as no more than research intermediates that may help scientists to isolate the full length gene and conduct further experimentation on those genes

Federal Circuit: ESTs Not Patentable

- All of the purported uses are merely hypothetical.
- Objectives that any EST could possibly achieve
- No real world uses.
- Holding:
 - Claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent

How is the PTO Applying the EST Law?

- Claims to ESTs themselves not patentable.
- What about claims to methods of using sequences for a novel use?

How is the PTO Applying the EST Law?

- Some Examiners are rejecting method claims even when:
 - cDNAs expressed in a certain tissue and predicted to be useful in predicting a disease.
 - Full length sequence provided.
 - Data in the specification showing some of the predicted cDNAs act as predicted.
 - Data presented to the Examiner in a Declaration showing that other sequences work as predicted.
 - Examiner only willing to allow claims where data is the specification as filed

What if there is no data in the application?

Monsanto EST case refers to a 1983 Raytheon case:

- Proof of utility may be supported when a claimed invention meets with commercial success.
- Submit Declaration with evidence of commercial success to provide proof of utility.

Other Hot Issues in Biotech Patent Law

Written Description Requirement

Written Description Requirement

35 USC §112, First Paragraph

- The specification shall contain a **written description** of the invention, and of the manner and process of making and using it ... as to **enable** any person skilled in the art ... to make and use the invention ... and shall set forth the **best mode** contemplated by the inventor of carrying out his invention.

University of California v. Eli Lilly and Co.

- A patent which included claims directed to mammalian, vertebrate and human cDNA was invalid because there was no written description of the human cDNA.
- Written description of DNA "requires a precise definition, such as by structure, formula, chemical name or physical properties."
- Merely describing a method for preparing cDNA or describing the protein coded for by the cDNA not enough.

Practical Effects of UC vs Lilly

- If you clone a novel sequence, the PTO is allowing increasingly narrow claims:
 - Percentage identity claims
 - High stringency hybridization claims
 - The sequence itself
 - Easy to design around

How To Get Broader Claims

Data is king

- Identify homologs and orthologs and test them
- Identify core regions and show that they are critical and required.
- Importance of partnering to generate data.
- Set up Examiner Interviews

Other Hot Issues in Biotech Patent Law

Novelty Issues Anticipation by Inherency

Novelty Issues in Plant IP

- Invention is a drought resistant transgenic plant resulting from over-expression of gene X
- Prior art describes 50,000 plant sequences (including gene X) and suggestion to make a transgenic plant with each of the sequences
- Prior art does not suggest drought resistance.

Claim Analysis

- Claims to drought resistant transgenic plants comprising a sequence described in the prior art rejected as inherently anticipated by the prior art.
 - Try subset argument: not all transgenic plants expressing gene X are drought tolerant due to position effects
- Method of making drought resistant transgenic plants found to be patentable.

Summary

- Patentability standards only increasing.
- Requirements for data increasing.
- Prior art issues becoming more challenging.