

Biotechnology Partnership Meeting
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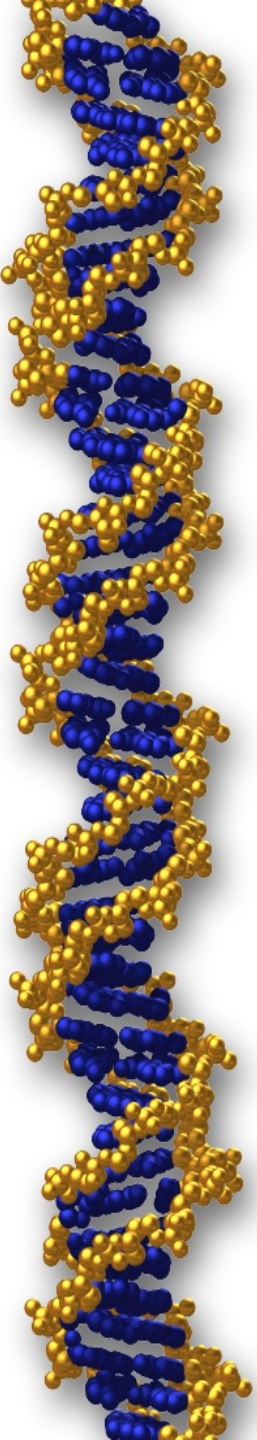
Technology Center 1600



**UNITED STATES
PATENT AND
TRADEMARK OFFICE**

Topic

- Deduction of sequences of putative proteins, the existence of which is inferred through discovery genetics, attribution of a putative protein to an extant protein family, and determination of compliance with the utility requirement of 35 U.S.C. § 101.





35 U.S.C. §101

Patentable Inventions

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.



Specific and Substantial Utility

- **Brenner v. Manson, 383 U.S. 519 (1966)**
 - **The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.**



Specific and Substantial Utility

- The famous quote from
Brenner v. Manson:
 - “But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

Utility Guidelines

- Federal Register
 - (http://www.access.gpo.gov/su_docs/aces/aces140.html)
 - Utility Guidelines
 - 66 FR 1092 (January 5, 2001)
 - 1242 Official Gazette 162 (January 30, 2001)

Raising the Bar

- Old Test
 - Two-pronged
 - Specific
 - Credible
- New Test
 - Three-pronged
 - Specific
 - Substantial
 - Credible

And Well Established (*i.e.* readily apparent) Utilities that are Specific, Substantial and Credible





Specific Utility - Definition

A utility that is **specific** to the subject matter claimed.

This contrasts with a **general** utility that would be applicable to the broad class of the invention.



Substantial Utility - Definition

A utility that defines "real world" use

A utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

Credible Utility - Definition

An assertion is credible unless

(A) the logic underlying the assertion is seriously flawed,

or

(B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion

A *credible* utility is assessed from the standpoint of whether a person of skill in the art would accept that the recited or disclosed invention is currently available for such use.





Well Established Utilities - Definition

An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.



Discovery Genetics

Genes are

PATENTABLE

SUBJECT MATTER

in the United States



Discovery Genetics

- Expressed Sequence Tags (ESTs)
- Genomics
 - Genome sequencing
 - Bacterial
 - Viral
 - Mammalian
 - Single Nucleotide Polymorphisms (SNPs)
- Directed cloning



The “Generations”

- *Applies equally to all nucleic acids*
- 1st generation
 - partial sequences, no Open Reading Frames (ORFs)
- 2nd generation
 - ORF disclosed with putative function only
- 3rd generation
 - Fully characterized nucleic acid including expression of any encoded protein and full functional analysis of said protein.



Scope of this Presentation

- This presentation is limited to 2nd generation DNA applications



Claim Analysis

- Consider the following claim:

A nucleic acid comprising SEQ ID NO 1.



Question

- What does the application disclose?
 - Full ORF
 - 2nd generation. A full open reading frame (ORF) is disclosed
 - Application further asserts that the encoded protein is a member of a family of proteins that is already known based upon amino acid sequence homology (*i.e.* comparison of entire sequence or determination of a consensus sequence).



2nd Generation

- Search the protein
- Question
 - Would one of skill in the art accept that the protein has been placed in the correct family of proteins as is asserted?



2nd Generation

- “The” Protein
 - **Two possibilities**
 - The search does not reveal any evidence that the family attribution made in the application is either incorrect or may be incorrect.
 - The protein either more likely belongs to a family other than that asserted in the application or likely does not belong to the family asserted in the application.
 - The search shows that the attribution is likely correct .



Example I (a)

- Example I (a):
 - Applicant asserts that the protein is an interleukin receptor because it is 85% identical at the amino acid level with other IL-receptors.
 - Search results are consistent with the asserted identity and that the next closest match is a 50% identity to beta-actin.
 - **No reason to doubt assertion that the protein is an IL-receptor.**

Example I (a)

- Utility
 - Is there a well-established utility for IL-receptors?
 - No. Different receptors would have different functions and the artisan would have to determine such.

Example I (a)

Is the asserted utility specific?

Maybe. The use would be particular to a general class of receptors, but the limited amount of information present would apply equally to all IL-receptors.





Example I (a)

- Is the asserted utility substantial?
 - No. The artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation on the protein itself would be required before it could be used.



Example I (a)

- With these facts, the claimed invention would be rejected under 35 U.S.C. §101 as failing to have patentable utility.



Example I (a)

Is there a utility as a probe?

- It is possible that there is utility under 35 U.S.C. §101 for a DNA found in organisms that encodes the protein as a probe, provided that the result of the assay using the probe has some specific, substantial, and credible utility.

Example I (b)

- A search of the prior art reveals the next closest match is an 85% identity to β -actin.
 - In this case, there is reasonable support for the conclusion that the protein may not be an IL-receptor, but a β -actin.



Example I (b)

Therefore, rejections under 35 U.S.C. §101 and 112, first paragraph, as failing to be supported by specific, substantial, and credible utility or a well-established utility are appropriate. This rejection may be rebutted by appropriate argument and/or evidence.

If there is an alternative utility disclosed such a use as a probe, then utility may be established as in Example I (a).



Example II

- Application asserts protein function is as a DNA ligase and the search and analysis indicate that this is reasonable (i.e., based on sequence homologies).
- Utility
 - DNA ligases have well-established and readily apparent uses in the art based upon their enzymatic activity at least *in vitro*.

Example II

- Scope of enablement
 - Applicant may rely upon the property of encoding a protein with a readily apparent and well-established utility. Open claim language is appropriate.

Summary

- Considerations limited to 2nd Generation DNA claims
- Utility is based upon sequence homology.
- If there **is** reason to doubt that the application attributes the putative protein to the correct protein family, utility cannot be extrapolated from family, 101/112 rejection is proper.
- If there **is no** reason to doubt that the application attributes the putative protein to the correct protein family but the utility **cannot** be extrapolated from family, 101/112 rejection is proper.
- If there **is no** reason to doubt that the application attributes the putative protein to the correct protein family and if the utility **can** be extrapolated from family, 101/112 rejection is not proper.