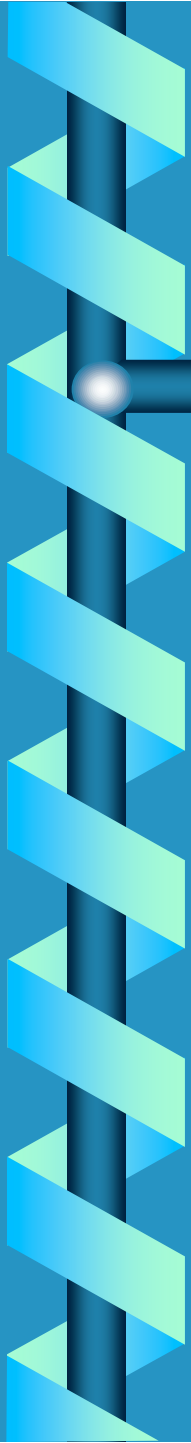


NAPP 2004 Short Course-July 10, 2004
The Nuts and Bolts of Patent Prosecution Practice

BASIC CLAIM DRAFTING

Biotechnology Patents as a Model System

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- ⊗ Hypothetical
 - ⊗ Brainstorming on subject matter to be claimed and claim drafting
 - ⊗ Tips on claim drafting



Hypothetical

- The technology transfer director at HiTech University has contacted you about Dr. X's latest invention. You have been provided with the following invention disclosure:
 - Cow sour milk syndrome affects cows throughout the US. Those cows afflicted produce sour milk. The causative agent to this date has not been isolated. Our laboratory has discovered the causative agent from cow (bovine) mammary glands. It appears to be a rhabdovirus-like virus and has been named cow sour mild syndrome virus (CSMSV). The viral genome has been isolated and sequenced and is depicted in SEQ ID NO: 1 (see attached). Five potential coding regions have been deduced and the amino acid sequences of these coding regions are depicted in SEQ ID NOS: 2-5 (see attached).



Hypothetical (cont'd)

- ⦿ Determine subject areas that may be claimed. Review attached Supplemental Materials
- ⦿ Draft claims



Claim Drafting Steps

- Review Disclosure
- Determine statutory patentable subject matter under 35 U.S.C. 101 in disclosure
- Put yourself in the shoes of a potential infringer- think about how as the infringer you would design around the disclosure.
 - For example, if nucleic acid and protein sequences disclosed, a potential infringer may design around by producing a variant DNA with similar activity or inhibitors.



Claim Drafting Tips (cont'd)

- ⊗ If composition disclosed, think of possible uses.
- ⊗ Look at issued patents and pending applications in the subject area
- ⊗ Make a preliminary list of possible independent claims
- ⊗ Determine if there are any prior art issues
 - For method of use claims, consider inherency
 - Obviousness-consider if common assignee

Claim Drafting Tips (Cont'd)

- ⊙ Determine if 112 requirements have been met
 - (a) Enablement- Consider number of examples disclosed in the specification; nexus of in vitro and in vivo results
 - (b) Written description-Has subject matter been sufficiently characterized?
- ⊙ Draft claims of varying scope. Be sure to include preferred embodiment.