

BioTech Customer Partnership Meeting at USPTO

The most recent Biotech Customer Partnership Meeting was held at the USPTO on March 7, 2006. Highlights of this meeting included a discussion of the new web-based e-filing system for most PTO papers, an update on the PTO's proposed rules packages with John Doll, a discussion of §101 guidelines, and examination in the antibody arts. Slides presented at the meeting are available at www.cabic.com/bcp.

Web-Based e-filing

This month, the USPTO rolls out its new web-based e-filing system for patent applications and other papers. The new system is a PDF-based system. Documents prepared as usual are converted into PDF file format and submitted to the PTO. Electronic transmittal documents are provided on a "fill in" basis and simplify submissions. No digital certificate is required to use this system, but it confers some advantages. For example, with a digital certificate, Private Pair can be immediately checked to confirm that e-filed papers were received and are accurate. Private Pair will also have a new feature in April. SCORE provides digital certificate holders to view an Examiner's search strategy and results through Private Pair.

Merchant & Gould participated in beta-testing the new e-filing system and found it very easy to learn and to use. One caveat is the time for e-filing: Transmission must be received by midnight East Coast time. For those filing in California, e-transmissions must be received at the PTO by 9:00 p.m. Pacific time to get the date

New Rules Packages

John Doll fielded a discussion on the proposed rules packages for continuations, double patenting, and number of claims. He indicated that the PTO is seeking comments and especially creative solutions to the PTO's workload problem. Statistics presented showed 40% of pending applications are continuations or RCEs applications, with 20% of those 2nd continuations/RCEs or more. A higher proportion of these cases are in biotech art units. Despite the fact that the new rules may only affect 5-10% of pending cases, John's

view is that **any decrease is better than no decrease**. An alternative that John discussed included a **tiered examination system** that would allow different levels of examination and deferral of examination. Comments and discussion are requested on this suggested alternative. Merchant & Gould is in the process of preparing comments to the proposed rules packages, and is participating in the preparation of comments by the AIPLA and IPO. Please forward to us any helpful ideas or comments.

More New Rules

John briefly introduced new PTO rule packages soon to be released relating to Information Disclosure Statements and Markush groups. The new rules will limit the number of references that may be submitted in an IDS and also contains provisions for attorney characterization of cited references.

Interim §101 Guidelines

Audin Marchel reviewed the PTO's current/interim §101 guidelines. These guidelines will be used by the PTO at least until the *Metabolite v. Lab Corp.* case is decided by the Supreme Court. According to the Guidelines, claims are reviewed under §101 under a standard process. Claims are examined

- 1) to see if they fall within a **statutory category**
(machine, manufacture, composition of matter, process);
- 2) do not fall within a **judicial exception**
(laws of nature, natural phenomenon, abstract ideas); and
- 3) produce a **useful concrete tangible result**.

A tangible result is one where there is a physical transformation (e.g. curing of rubber) or data transformation that is then used to actively do something. The active step must be in the claim. If the claim contains only calculating or mental steps the statutory requirements are not met.

Obviousness for Genus/Species

Examiner Padmanabhan discussed obviousness in the context of genus/species, centering on polymorph claims. The Examiner analyzed subgenus claims using a Baird analysis, looking to the size of the genus; express teaching of the reference disclosing the genus, teachings of structural similarity, similar properties or uses, predictability, and any other teaching that supports selection of a species or subgenus.

Examination of Antibody Claims

Examiner Helms discussed two cases concerning antibody technology as well as the term “specifically binds”. In particular, he discussed written description support for humanized antibodies in view of *Chiron v. Genentech*. In that case, the Court found that Chiron was not able to reach back to its earlier filing date to support claims to humanized antibodies, as the **technology was not known at the time** of the earlier filing date. He also discussed *Noelle v. Lederman*, where the court found that as long as Applicant had disclosed a **fully characterized antigen** by structure, formula, chemical name, or by deposit, claims to an antibody binding to that antigen were supported.

Cross reactivity and “specific” binding of antibodies was also discussed. In the case where prior art discloses a protein having 99% sequence identity to the protein disclosed by Applicant, this prior art would support a rejection under 102 because this level of sequence identity is substantial evidence of cross reactivity. Examiner Helms and Bonnie Eyler indicated that the exact cutoff of % sequence identity would vary from case to case, depending on whether any domains of the protein were highly conserved.

The next PTO Partnership meeting will be about the third week of June.

Katherine M. Kowalchyk
Merchant & Gould P.C.