

LATIMER, MAYBERRY & MATTHEWS

USPTO REPORT

Your Connection To The USPTO Customer Partnership Meetings

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USPTO Holds Second Biotech/Chem/Pharma Customer Partnership Meeting Of 2007

On 13 June 2007, the USPTO held a full-day Biotech/Chem/Pharma Customer Partnership Meeting at the USPTO facility in Alexandria, VA. The USPTO panel included John LeGuyader, Bruce Kisliuk, and Chris Low, Directors of Technology Center (TC) 1600; Jack Harvey, Director of TC2100; Andy Faile, Director of TC2600; Bruce Campell, SPE of Art Unit 1648; Larry Helms, SPE of Art Unit 1643; James Schultz, SPE of Art Unit 1635; and Jean Witz, tQAS of TC1600.

TC1600 Administration Changes

Dr. LeGuyader began the meeting with a summary of changes in TC1600 since the last meeting. He stated that George Elliott had temporarily taken on a detail assignment to the House of Representatives, and had been replaced by Christopher Low. Other changes within SPE and Quality Assurance Specialist (QAS) positions had taken place to fill vacancies created by retirements and promotions.

Dr. LeGuyader further stated that interim guidelines for examination in view of the *KSR* decision had been implemented, and the overall instructions to TC1600 examiners was to continue to examine applications for obviousness as they had before. New training materials are almost complete and will be provided to examiners by the end of the month. As a general matter, Dr. LeGuyader indicated that practitioners should expect changes in examination only in predictable arts.

USPTO Implementing A Peer Review Program To Improve Exam

Mr. Harvey discussed the new USPTO Peer Review program, which has been implemented to allow the public to assist examiners in identifying relevant art. While it is currently a pilot program limited to the computer arts, if it is successful, the USPTO should implement it office-wide. In essence, the program allows up to 250 applicants to voluntarily permit the public to submit up to ten pieces of prior art, to be considered by the examiner in determining patentability. The public sub-mission will supplement the examiner's search and will be limited to the ten most relevant references (as selected by the public). In exchange, the application will be given "priority" status and examined quickly. The program will be limited to TC2100 and applications published in the last two months or published during the pilot period. Evaluation of the program should be complete by October 2008, at which time a decision will be made as to whether to expand it to other technologies or to conclude the program.

Suite Of New Patent Products To Be Considered

Mr. Faile spoke to the audience about a new USPTO outreach initiative, which has a goal of identifying weaknesses in the US patenting system, and ultimately devising solutions to improve the system. The initiative is broad in scope, looking for all comments on the US patent system, from those relating to statutory concerns,

rules implemented in the CFR, and examination guidelines and training materials, to those relating to particular specific issues, such as ease of use of PTO forms, phone systems, and the like. Mr. Faile indicated that there would be a series of town-hall type meeting over the next several months, and that the USPTO was also soliciting direct comments from practitioners and applicants. The initiative will be a long-term process with wide-ranging changes possible.

Obviousness Rejections For Routine Optimization Might Rise

Ms. Witz discussed implementation by TC1600 of the standards for obviousness where optimization of a known technology is claimed. She summarized case law holding that, even though a prior art reference was completely limited in its disclosure of parameters for achieving a goal, unless one achieves an unexpected result, it is obvious to vary the parameters outside of the ranges disclosed in order to optimize the parameters. She further summarized case law holding that the changes to the prior art must be critical to achieving the unexpected result. As general guidance, she concluded that TC1600 will apply the following examination guidelines: when all claimed elements are present in the prior art but differ in specific values, an obviousness rejection may be made; evidence that an element is result-effective may be important and should be closely considered by the examiner; evidence of unexpected results should always be considered by the examiner, but that assertions of applicants should not be taken on face value; and finally, the examiner should verify that the scope of the claims are commensurate with evidence of unexpected results. The ease with which the USPTO will make such rejections is likely to increase with the *KSR* decision; however, Ms. Witz did not make any specific statements on changes that can be expected.

Interfering RNA Claims Require Extensive Support

Doug Schultz discussed patenting of interfering RNA (iRNA). Mr. Schultz discussed the focus of examination: utility, enablement, and written description. Mr. Schultz stated that knowledge of gene function sufficient to warrant target inhibition is required to have utility for a claim to iRNA or its use. The rationale used by the USPTO is that, if the function of the target is unknown, there can be no readily apparent use for the iRNA. This rationale, of course, fails to recognize the use for determining the function of the gene, which is a real-world use. With regard to enablement, Mr. Schultz stated that TC1600 finds iRNA to be an unpredictable technology, and thus requires a relatively great amount of data to support enablement. The USPTO conclusion is apparently based substantially on the *in vivo* success rate of antisense technology and the lack of FDA approval of iRNA and treatment methods using them. With regard to written description, the USPTO will not allow claims to iRNA technology that recite function, but no structure, unless an adequate number of species having that function are disclosed. The rationale is that one must at least disclose a structure, and preferably the key structural elements, of a representative number of species in order to obtain a claim reciting function only. In general, the USPTO believes that the probability of finding an iRNA for a particular gene is high, but the probability of any particular iRNA working is low. To improve the probability, the USPTO will accept bioinformatics data. Regarding anticipation, the USPTO expects the prior art to specifically disclose a molecule as being an iRNA molecule; however, for obviousness, the state of the art is considered to be important. That is, other types of nucleic acid knock-down technologies may be used to assert that a claimed iRNA is obvious.