Summary of USPTO’s Biotech/Chemical/Pharmaceutical Partnership Meeting of April 7, 2015

Opening Remarks
Jerry Lorengo, Director of TC1600 gave the welcoming and opening remarks. He commended the SPEs and Examiners in 1600 and 1700 in view of all the increased activity, e.g., 101 issues, in the life sciences.

Patent Quality Initiatives
Valencia Martin-Wallace, Deputy Commissioner for Patent Quality spoke on Patent Quality Initiatives. She started by providing various reasons for the patent quality initiatives and said that the most important reason is “because it’s the right thing to do.”

She then set forth a few internal steps the USPTO has taken to improve patent quality which primarily focus on examiner training. The USPTO is taking measures to reach out to stakeholders for their input. As set forth in the Federal Register Notice, the USPTO would like comments on the following:

- Proposal 1 – Applicant Request for Prosecution Review of Selected Applications
- Proposal 2 – Automated Pre-Examination Search
- Proposal 3 – Clarity of the Record
- Proposal 4 – Review of and Improvements to Quality Metrics
- Proposal 5 – Review of the Compact Prosecution Model and the Effect on Quality
- Proposal 6 – In-Person Interview Capability with All Examiners

The USPTO recently held a Patent Quality Summit in which USPTO personnel and stakeholders discussed various ways the USPTO could improve patent quality.

The video of the Patent Quality Summit will be available on the USPTO website.
Comments in response to the proposals are due **May 6, 2015**. Please submit your comments in response to the above, as well as other recommendations you may have to WordClassPatentQuality@uspto.gov.

Valencia’s PowerPoint slides can be found here.

**A Stakeholder’s Perspective**

Robert “Bob” Stoll of Drinker Biddle & Reath, LLP, provided a stakeholder’s perspective on the patent quality initiatives. Bob said he is a true believer that the patent system creates jobs and economic wealth. He said he does not understand how trolls are defined any more such that he is surprised that time is still being spent on so-called troll issues. With regard to subject matter eligibility, he personally believes that broad subject matter eligibility benefits the United States, and that other patentability requirements, e.g., written description and enablement, should be used as tools to hone in on strong valid patents.

Bob said that the problems of trolls and subject matter eligibility can be minimized by improving patent examination and patent quality.

With regard to enablement (Wands Factors) and written description (Capon Factors), Bob believes that more Examiner training would help improve patent quality as over the last 10 years, the Federal Circuit has invalidated more patents for lack of written description in the biological sciences as compared to other technologies. Bob believes there will be an increasing need to set forth definitions of terms and descriptions of functional motifs (e.g., antigenic epitopes) in the specification. He recommends erring on the side of including as much experimental data as possible.

With regards to obviousness, post- *KSR*, the Federal Circuit has ruled against the patentee in about 50% of biotech obviousness appeals.

Thus, with a view of the trends in written description, enablement, and obviousness, one must draft claims in a more strategic manner. He recommends caution in using patent profanity – some words are not profane when considered in context and how the words are used. He also cautions against blindly incorporating by reference.

In short, Bob believes improving patent quality first begins with practitioners filing and prosecuting better applications.

Bob’s PowerPoint presentation can be found here.

**Recent Updates in Patent Term Adjustment and Patent Term Extension**

*Patent Term Adjustment*

Kery Fries, Senior Advisor, Office of Patent Legal Administration, discussed PTA and noted that there are three different sets of PTA rules. He focused on B “Novartis” delays and C delays. For national phase entries, the 3 year pendency time begins at the time of commencement, i.e., the 30 month PCT time or earlier where all requirements are met.
and an express to request examination is filed. One cannot earn double time, e.g., if earning B time, no C time available.

Kery’s PowerPoint presentation can be found [here](#).

**Patent Term Extension**

Mary Till, Senior Advisor, Office of Patent Legal Administration, discussed Rule 156 Patent Term Extensions. Terminally disclaimed patents are eligible for extension. Correct terminal disclaimer language, according to the USPTO, is that which indicates “…which would extend beyond the expiration term of the full statutory term...” The extended term of a patent can be affected by a terminal disclaimer filed against a later issued earlier expiring patent. Mary stated that it is sometimes recommended that applicants submit more than one 156 extension calculation to account for different interpretations/situations. Best practices include filing a PTE application even if the 156 term calculated at the date of approval is 0 days, if a terminal disclaimer is filed during PTE processing, submit updates to the PTE application pursuing to the duty of disclosure under 37 C.F.R 1.765, and if 154(b) PTA changes after the PTE application is filed, submit updates to the PTE application pursuing to the duty of disclosure under 37 C.F.R 1.765.

Mary’s PowerPoint presentation can be found [here](#).

**Filing Sequence Listings in International and National Stage Applications**

Susan Wolski, International Patent Legal Administration (and The One Who Knows All About Sequence Listings) reviewed the requirements for filing a sequence listing in an international (PCT) applications compared to sequence listings in regular utility applications. Note the need for this talk is relatively soon after the last time... meaning many are still filing sequence listings wrong.

A table containing sequences, even if entitled “sequence listing”, is NOT a sequence listing (something that looks like that generated by using PatentIn).

If filing a PCT application in the US/RO, the recommended way to file the sequence listing is in text format via EFS-Web on the international filing date. This results in the sequence listing being considered both part of the international application and the Computer Readable Form (CRF), no page fees, and no sequence listing statement. Conversely, filing a pdf or hard copy of the sequence listing will result in extra page fees and a CRF and sequence listing statement are required. Additionally, the text copy of the sequence listing does not form a part of the international application (such that when entering the National Phase, the USPTO will not automatically obtain the sequence listing meaning Applicants must provide a CRF of the sequence listing and sequence listing statement in the US national phase application).

Failure to identify the text copy of the sequence listing as forming a part of the international application on the Request 101 form can result in a **fatally defective application**.
There are two different 101 Request forms (checklists) – one is for paper filings and one is for EFS-Web filings. If you do not use PCTEasy, make sure you use the correct checklist.

If a substitute sequence listing is filed in the PCT, e.g., in response to a PCT/ISA/225, when entering the national/regional phase, the application must be amended to incorporate the substitute sequence listing. Corrected/Substitute Sequence Listings should be filed in the chosen International Searching Authority (ISA). So if one sees a “defective” sequence listing in PAIR, but the US was not chosen as the ISA, do not submit a corrected sequence listing to the US/RO. Instead, wait for such a requirement from the chosen ISA.

In WIPO’s PatentScope®, a sequence listing provided under the “Related Documents” means that the sequence listing does not form part of the international application. The best practice is to check this information after publication of the PCT. If the sequence listing is indicated in PatentScope® as forming part of the international application, it will be transmitted to the USPTO upon national phase entry in the US.

If the sequence listing was not part of the international application, one must submit the CRF of the sequence listing along with a preliminary amendment and sequence listing statement to make it a part of the national phase application. If the sequence listing was part of the international application, one need not resubmit the text file upon US national phase entry. If, however, the sequence listing was part of the international application and one uploads a text copy of the sequence listing, submit with a sequence listing statement explaining what exactly it is, e.g., if it is the same as that submitted in the PCT, contains amendments, is a translation, etc.

Patent term adjustment will be reduced if the sequence listing is not in compliance within 8 months from the date of commencement of the national stage application.

See the slide deck for how to download a text copy of a sequence listing from PAIR and WIPO and edit it.

Three best practices – 1) Avoid doing Transfer Requests; 2) Avoid doing Transfer Requests; and 3) Avoid doing Transfer Requests.

Contact STIC-SSSCHelpdesk@uspto.gov with questions to avoid receiving a telephone call from Sue.

The next sequence listing standard (XML standard) is still in the works. Stay tuned.

Sue’s PowerPoint presentation can be found here.

Interim Guidance on Patent Subject Matter Eligibility

Paul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, spoke on the Interim Guidance at the Denver Office. The beginning of Paul’s presentation is essentially the same as the USPTO’s discussion at the January 2015 Forum on the Interim Guidance which summarized the differences between the Mayo/Myriad Guidance and the Interim Guidance. The second part of his presentation focused on
how to analyze nature-based products which followed many of the examples set forth in the Nature Based Product Examples and the Examiner training module on Analyzing Nature-Based Products.

The USPTO is currently reviewing the comments received in response to the Interim Guidance and hope to provide further clarifications and examples which will be provided on the USPTO’s 2014 Interim Guidance webpage here.

Diagnostic examples are expected sometime after Ariosa v. Sequenom.

If you have 101 eligibility questions relating Group 1600, you can email them to Myriad1600@uspto.gov.

Paul’s PowerPoint slides can be found here.

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