USPTO Biotechnology,
Chemical, and Pharmaceutical Customer
Partnership Meeting
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Stakeholder's Perspective on Patent Quality Initiative

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Medical Center

Who Are We?

- UT Southwestern is a world class medical university engaged in biomedical education, research, development, and patient care
- Our 2,100 faculty generate an average of 160 new biomedical inventions per year, operating under a research budget of about $430M per year

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What's Our Role in the Patent System?

- The Office for Technology Development manages the University's inventions, patents, product development, licenses, and start-up formation
- After evaluating an invention disclosure received from our faculty, we decide on the most sensible course of action

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How We Pursue Invention Protection

- If we decide to file a patent application, we file a US provisional application
- We don’t draft applications in-house, we rely on outside patent attorneys
- If we license an invention, the licensee takes over responsibility for the rest of the prosecution, domestic and foreign

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What Matters To Us

- Cost
  - Attorney's Professional Fees
  - Application Filing Fees
  - Time spent on the matter-this is where the USPTO's quality initiatives impact us the most
- Defensibility/Enforceability

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EPQI Programs Considered

- Search And Training Enhancement Programs
  - Automated Pre-Examination Search Pilot
  - Scientific and Technical Information Center Awareness Campaign
  - Clarity of Record Training
- Prosecution Enhancement Programs
  - Quality of Record Pilot
  - Interview Specialist
  - Reevaluation of After-Final Consideration Pilot
- Post-examination Enhancement Programs
  - Design Patent Publication Quality
  - Post Grant Outcomes
- Evaluation Enhancement Programs
  - Clarity and Correctness Data Capture
  - Quality Metrics
  - Topic Submission For Case Studies

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General Observations

- Appreciation that metrics have been selected and are being gathered and analyzed
- Positive impression from the number of initiatives created

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Other Useful Programs

- Programs used most often:
  - **(1) After Final Consideration Pilot 2.0;**
  - **(2) the pre-appeal brief; and**
  - **(3) the QuickPath Information Disclosure Statement (QPIDS)**.
- These 3 programs have greatly reduced the cost to the client, generally improved the communication between examiner and attorney, and streamlined the prosecution process (the QPIDS is great when there is foreign prosecution-greatly aids the attorney they keep getting more references from foreign prosecution that we must cite to the USPTO).
- Programs are good-continue them.

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Subject Matter Eligibility Examples (& 2014 Interim Guidance on Subject Matter Eligibility)

- Guidelines do not appear to align with relevant case law, especially in view of the Supreme Court's refusal to grant *cert* in the case of *Sequenom v. Ariosa*
  - Net effect is that attorneys must advise clients that two inconsistent outcomes are possible, i.e. pursue allowable claims vs. obtain enforceable claims

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Subject Matter Eligibility Examples (& 2014 Interim Guidance on Subject Matter Eligibility)

- In all fairness, we recognize that the USPTO is confronted with a lack of clarity in the case law
- Continued uncertainty from the courts is expected
- ‘It’s a huge mess”

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Eligibility Examples

- Examples would benefit from avoiding unduly narrow fact patterns, which are seen to lead Examiners to perform excessively rigid examinations
  - E.g. Example 28, cl.7: the microneedle array that forms part of the claim limits the scope of the claim so severely that the usefulness of the example is diminished
- It is a relief to see examples to diagnostics- possible path back to diagnostic patents again

Eligibility Examples

- An inconsistency in the examples: Example 29 claim 1 vs claim 2
  - Why does the addition of a limitation on "diagnosing" render cl. 2 eligible, compared to cl. 1 ?
  - It is not doctrinally sound to take an ineligible claim and make it eligible through the addition of a limitation, since limitations determine patentability over prior art

Another Metric to Consider

"I really think what is missing is more training and quality control of the supervisory examiners. We still get huge variability between examiners and sometimes it seems there is no supervision whatsoever. We have had a few cases where the examiner did not even have a supervisor for 6 months! So, the time taken to fill vacancies for supervisors and training of supervisors would seem to be another metric the PTO should look into measuring."

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Here's an Idea:

- "In my practice, I have found that having lunch on a frequent basis with a current patent examiner (who happens to live in Dallas, and before whom we do NOT practice as we don't have any cases in his art unit) has been (very) helpful. We tend to get a preview for what initiatives supervisory examiners are going to start pushing forward, the type of training the examiners are getting, the pressure they are under, we get great tips about how an examiner views the art and claims, and get explanations for actions from the PTO that do not otherwise make sense! Not sure the PTO has a pilot program for his, but its made a positive difference in how we practice in our office."

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By The Way…

- The Formalities process has really improved with a definite decrease in the extent seen of the human error problems

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