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## The Role That Sequence Searches Play in Patent Prosecution and FTO Analyses

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# The Role That Sequence Searches Play in Patent Prosecution and FTO Analyses

- Why perform sequence searches?
  - Patent Prosecution
  - Evolution of genomics based patent applications.
  - Freedom to Operate (FTO)



# Patent Prosecution

# Patent Prosecution

- Filing a new genomics application
  - Novelty assessment - review prior art.
    - Caveats: a) 18 month period of time between filing and publication; b) pending U.S. applications filed prior to November 29, 2000 (in U.S. only); c) requests for non-publication (U.S. applications); d) homeland security; and e) database entry issues.
  - Drafting application - written description, enablement and utility requirements.
  - Claim drafting.
- Filing Information Disclosure Statements (IDS')
  - Duty of disclosure – documents identified by applicant or by examiner in a foreign counterpart.
  - IDS is not a representation that (1) a search was made, or (2) cited information is material.

# Patent Prosecution

- Patent examiner
  - Examiner reviews documents cited in applicant's IDS.
  - Examiner performs own sequence search.
  - Examiner may rely on any document(s) cited in IDS or identified by the examiner to reject the applicant's claims.
  - Novelty rejection will usually include a percent identity between the subject and the query (over a specified length) and may additionally include a sequence alignment.

# Patent Prosecution

- Overcoming examiner's rejections
  - Novelty:
    - Verify statement made by the examiner by performing sequence alignment or sequence search.
    - Argue that cited document is inadmissible as prior art (establish priority date; argue that cited document is not entitled to its priority date; swear behind).
    - Amend claims to overcome novelty rejection (if possible)
  - Utility:
    - Perform sequence search to identify post-filing publications confirming asserted utility.

# Evolution of genomics based patent applications



# Evolution of genomics based patent applications

- Gold Rush Days (mid to late 1990's)
  - Patent Applications Filed on:
    - Expressed Sequence Tags (ESTs);
    - Un-annotated sequences;
    - Non-vector trimmed fragments;
    - No asserted utility or lack of credibility;
    - No data or data with questionable real-world utility;
    - Voluminous applications.



# Evolution of genomics based patent applications

- Revised Interim Utility Guidelines (2001)
  - The U.S. Patent and Trademark Office (USPTO) released new guidelines in 2001 regarding utility requirements specifically targeting genomics based patent applications.
    - Guidelines stated that in order for a DNA sequence or protein sequence to be patentable, the specification must include a specific, substantial, credible and well established utility for the molecule.

# Evolution of genomics based patent applications

- How have the Utility Guidelines affected genomics based applications?
  - Pre 2001 applications:
    - Difficulty in obtaining patents – lengthy arguments from both sides.
    - Abandonment of many applications.
  - Post 2001 applications:
    - Most applicants try to include data (i.e., differential expression data).
    - Difficulty in obtaining patents – data does not necessarily confer specific, substantial, credible and well established utility to molecule.
    - Potentially narrower claims, i.e., claims will sometimes be limited to a molecule comprising a particular sequence having a particular function.

# Evolution of genomics based patent applications

- Revised Interim Written Description Guidelines (2001) The USPTO released new guidelines in 2001 regarding written description requirements.
  - Guidelines stated that in order for a DNA sequence or protein sequence to be patentable, the subject matter being claimed must be described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)

# Evolution of genomics based patent applications

- How have the Written Description Guidelines affected genomics based applications?
  - Prior to written description guidelines:
    - Examiners allowed broad claim scope, i.e., “A nucleic acid sequence comprising a nucleotide sequence which is 70% identical to the nucleic acid sequence of SEQ ID NO:1”.
  - Post written description guidelines:
    - Examiners argue that the recitation of one sequence does not provide written description support for the genus of sequences which would be encompassed by, for example, the claim above.
    - Difficulty in obtaining patents with broad scope (i.e., <95% identity).

# Evolution of genomics based patent applications

- Genomics Based Patent Applications and the European Patent Office (EPO):
  - Industrial Applicability Requirement (EPO) = Utility requirements (US).
  - Written description requirements: EPO has stricter written description requirements (explicit basis required), but less strict on allowing broad sequence patents.
  - Inventive Step Requirements.



# Freedom To Operate Analyses

# The Role That Sequence Searches Play in FTO Analyses

- Reasons to perform sequence searches when doing FTO analyses
  - Identify patent landscape surrounding target
    - Composition of matter: Nts; AA; Abs
    - Methods of using target (i.e., screening claims, therapeutic purposes, diagnostic purposes, etc)
    - Methods of making target (i.e., use of vectors and host cells comprising nucleic acid sequence for production of polypeptide or antibody)
    - Diligences (i.e., acquisitions, in/out-licenses)
  - Identify patent landscape surrounding components used in manufacturing processes
    - Use of vectors containing specific promoter sequences

# The Role That Sequence Searches Play in FTO Analyses

- Considerations when performing FTO analyses
  - Does client have patent position?
    - If so, what is priority date and are they entitled to their priority date from a utility, written description and enablement perspective?
    - Are there other parties who have filed on the same (or substantially the same) sequence within a close period of time (i.e., +/- 3 months).
      - If so, are they entitled to their priority date?
      - If so, can client swear behind other party (if needed)?
      - How likely is it that other party may be able to swear behind client's position? Has molecule been deposited with the ATCC?



# The Role That Sequence Searches Play in FTO Analyses

- Considerations when performing FTO analyses
  - Why is the client requesting a search?
    - Use of reagent for experiment
    - Potential interest in pursuing a target
    - Development candidate
  - Scope of search and client's risk tolerance will likely vary depending on why the search is requested.
  - Where is the client performing activities (U.S. and/or worldwide)?

# The Role That Sequence Searches Play in FTO Analyses

- What about the hits?
  - Issued Patent(s)
    - Valid?
    - Perform additional searches to look for art that could be used to invalidate the patent(s).
    - Is the specification enabling and does it meet written description and utility requirements?
    - Does client infringe issued claims?
    - Review file history. Equivalence? File history estoppel?
  - Published Application(s)
    - What is likelihood of issuance?
    - Perform additional searches to look for prior art.
    - Is the specification enabling and does it meet written description and utility requirements?

# The Role That Sequence Searches Play in FTO Analyses

- What then?
  - Is there a possibility of working around IP issues? What is risk tolerance?
  - If invalidating art identified or if client believes that there are grounds for patent to be invalidated, obtain written opinion.
  - Obtain license (if available)

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