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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)
  • 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

  • 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

  – 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)
Breakthrough science. Breakthrough medicine."