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Recent Developments Affecting U.S. Patent Prosecution And Their Impact On Global Portfolios

- **What are ways to avoid/ overcome obviousness-type double patenting (ODP) rejections?**
  - In the US, ODP can arise in "related" continuation applications or applications that do not share priority (requires at least one common inventor, but can have different assignees)
  - Three ways to overcome ODP rejection:
    - Safe Harbor protection under §121 (only for divisional applications)
    - On the merits (claims are nonobvious)
    - File a terminal disclaimer (TD), which requires common ownership for duration of patent term
  - Pre-filing/drafting considerations:
    - Know scope of already claimed subject matter (including dependent claims)
    - Distinguish improvements or selections from prior filings during preparation of new unrelated applications (*e.g.*, unexpected properties of or results produced by a species)
    - Draft and pay for diverse claim set (likely to prompt a restriction requirement)
    - If you think you might need a TD, maintain common-ownership
  - Prosecution strategies:
    - Do not assume Examiner's ODP rejection is proper
    - Same non-obviousness rebuttals as you would use for §103, including secondary considerations
    - Carefully consider risk to patent term before filing TD (and must remain co-owned)
    - If patent issues with large PTA, consider risk of continuation application (*Gilead)*
- **How do you leverage fast-track examination tools to streamline global prosecution?**
  - Goal is reduction in overall cost and efficiency of building patent portfolio
  - Track One Prioritized Examination
    - $4k/$2k USD; no more than 4 independent claims and 30 total claims
    - Months to First Office Action: Track One – 1.8; Traditional – 15.7
    - Months to Final Disposition: Track One – 7.2; Traditional – 24.3
  - Patents 4 Patients (fast-track review for cancer immunotherapy-related applications without fee)
  - Patent Prosecution Highway
    - Accelerate prosecution in related second application based on an allowed first application in another country
    - Applications must share a common priority date; claims must “sufficiently correspond” to the allowed claims
    - Higher allowance rate compared to non-PPH cases; shorter pendency; fewer Office Actions
    - Combine tools to quickly generate global portfolio (Track One; PACE; PPH; PPH-PCT)

- **What prosecution strategies are life sciences companies implementing to create IPR and PGR resilient patents?**
  - Seeking high quality patents: goal is non-institution
  - 7,704 IPR Petitions: 68% institution rate; 76% of claims canceled at FWD; 10% in bio/pharma
  - 110 PGR Petitions: 58% institution rate; 85% of claims canceled at FWD; 27% in bio/pharma
  - Pre-filing: robust patentability searching
    - Know best art before competitors; objective assessment of patentability
    - Help distinguish invention from prior art during preparation; better define claim scope
  - Application drafting considerations:
    - Compelling patentability story in the face of most pertinent prior art (problem/solution)
    - Provide clear definitions for claim terms (glossary)
    - Numerous claims of varying scope and format that are clearly supported by the specification ($15,500 IPR fee up to 20 claims; $300 each additional claim)
  - Prosecution strategies:
    - Get key art on the record and considered by the Examiner during prosecution
    - Well drafted declarations addressing art, claim construction and/or secondary considerations (evidence must be commensurate in scope with claims)
    - Create patent thicket to extent possible around product including separate patents only including claims specifically directed to approved product
    - Expedited prosecution (*e.g.*, Track One) and judicious use of reissue applications to gain additional patents prior to patent owner estoppel; keep pending continuation
- **How do you navigate the narrowing subject matter eligibility threshold in the life sciences?**
  - In the US, product and process claims can be found patent ineligible if directed to laws of nature or natural phenomenon (product and diagnostic claims are more frequently at risk)
  - While addressing different subject matter (diagnostic drug correlations, isolated genes, and algorithms), each of *Mayo/Myriad/Alice* aimed to exclude tools of research from eligibility
  - Considerations for drafting patent eligible products and/or process claims:
    - Include characteristics distinct from the natural counterpart (not just isolated or purified)
    - Add significantly more than what is found in nature (structure and/or functional differences)
    - Once natural phenomenon is removed from the claims, the remaining elements cannot be merely routine, conventional, and well-understood components or steps
    - If all elements of the claim were well known and in common use, consider whether the combination of these elements is inventive
    - Use of diagnostics and/or products in methods of treatment

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