Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaboration: the Role of Intellectual Property

Life Science Patents in Practice

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Technical Minds. Legal Muscle.
Why are life science patents important?

• Encourages disclosure of the workings of inventions to the public (advantage to the public)
• Encourages investment by providing a barrier to entry to those who would copy an innovation
• Can prevent others from using invention as a trade secret
• Encourages collaboration with other patent-holders to cross-license instead of sue you
• Recoup $$ spent on R&D
• Patent exclusivity – allows listing in the FDA’s Orange Book (barrier to generic competitors) for small molecules, or patent dance for biologics
• Can serve as collateral for a bank loan, or sold
Pharmaceutical Drug (small molecule) Approaches

• 505(b)(1) New Drug Application (NDA)
  - New molecular entity
  - New formulation of previously approved drug
  - New combination of two or more drugs
  - New indication for already marketed drug

• 505(b)(2)" application ("Paper" NDA) - modification to an approved drug
  - Relies upon safety and effectiveness data of the reference-listed-drug
  - May be marketed as a “branded” or generic drug

• 505(j) application Abbreviated NDA (ANDA) - duplicate of an approved NDA product:
  - Relies on safety and efficacy studies from NDA
  - Must have identical active ingredient, route of administration, dosage form, strength, labeling and intended use
  - Must demonstrate bioequivalence
Patent Opportunities Under 505(b)(1) NDA

• New Chemical Entity (NCE)
  ○ Polymorphs/crystal forms
  ○ Impurities

• Dosage forms (ex. IR, ER, SR, PR, MR; oral, parenteral, topical, nasal)

• Dosing and/or titration regimen

• Methods of Use
  ○ Methods of treatment
  ○ Methods of dosing and administration
  ○ Methods of inducing physiologic effects

• Pharmacokinetics (Tmax, AUC, Cmax, cytochrome P450)

• Methods of Manufacture

• Subpopulations (clinical trial data mining)

• Diagnostics - subject matter eligibility?
Patent Opportunities Under 505(b)(2) paper NDA

• New Chemical Entity (different salt, ester, complex, chelate, clathrate, racemate, or enantiomer of active moiety)
• New dosage form
• New dosing regimen
• New strength
• New route of administration
• New indication
Patent Opportunities for Biologics (large molecules)

• Nucleotide and amino acid/polypeptide sequences
• Vectors
• Modified organisms (ex. live attenuated virus)
• *Manufacturing methods* (if not kept trade secret)
  – Platform technology
• Formulations
• Methods of Use