



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