

Generic Biologics: Possible ? Desirable? How?

Venture Capitalists, Start-ups, and Biogenerics: Current Activities and IP Strategy Impacts

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New Laws = New Business Opportunities

- Hatch-Waxman Act → Generic & Specialty Pharmaceutical (505(b)(2)) Start-ups
 - Much of the low-hanging fruit has been taken
- Biosimilar Act → Biosimilar & Specialty BioPharma Start-ups
 - Great new investment opportunities with ripe fruit
- Innovator Biologics Start-ups
 - Respond or die
 - Fast-follower Biologic Start-ups

Innovator Biologic Companies

- Relative to small molecule companies, innovator biologics face challenges
 - more uncertain regulatory environment
 - manufacturing challenges
 - **IP challenges can be insurmountable except with most narrow coverage**
 - And now the biosimilar challenge?
- If not a clear platform technology, most investors will pass: investment profile is too long and uncertain

Innovator Biologic Companies Investor-Friendly IP Strategies

- Tough for the NewCo, Great for the OldCo
- Narrow patent claims, followed by expanding circles in a contracting universe → weak NBE protection?
- Best positioned to use Biosimilar Act as a Shield:
 - Manufacturing
 - QC
 - Mode of action
 - Immunogenicity
- Large Shield

Fast-Follower Biologic Companies Investor-Friendly IP Strategies

- Potential big winner in NewCo space in short and long run
 - IP regime favors smaller innovator patents
 - Resulting in: more IP space around validated scaffolds
- However,
 - IP regime may disfavor fending off biosimilars using the Biosimilar Act as a shield
 - Obvious? Manufacturing, QC, etc
 - ▶ Best scenario: if innovator has not yet grabbed that territory
- Medium shield

Specialty BioPharma Companies Investor-Friendly IP Strategies

- Short term winner in NewCo space: investor friendly
- New dosage forms, new routes of administration, new combinations of approved biologics → rely on safety and some efficacy data, but still require Phase II or III clinical trials
- IP challenge → once low-hanging fruit has been taken, only weak potential IP barrier. However, pharmacokinetics, stability and the like, should always offer an IP opportunity.
- Small shield: susceptible to Biosimilar challenge

Biosimilar Companies Investor-Friendly IP Strategies

- Very tough for NewCo; great for OldCo
- Medium sword → look for weakly protected biologics
- Patent design-arounds?