



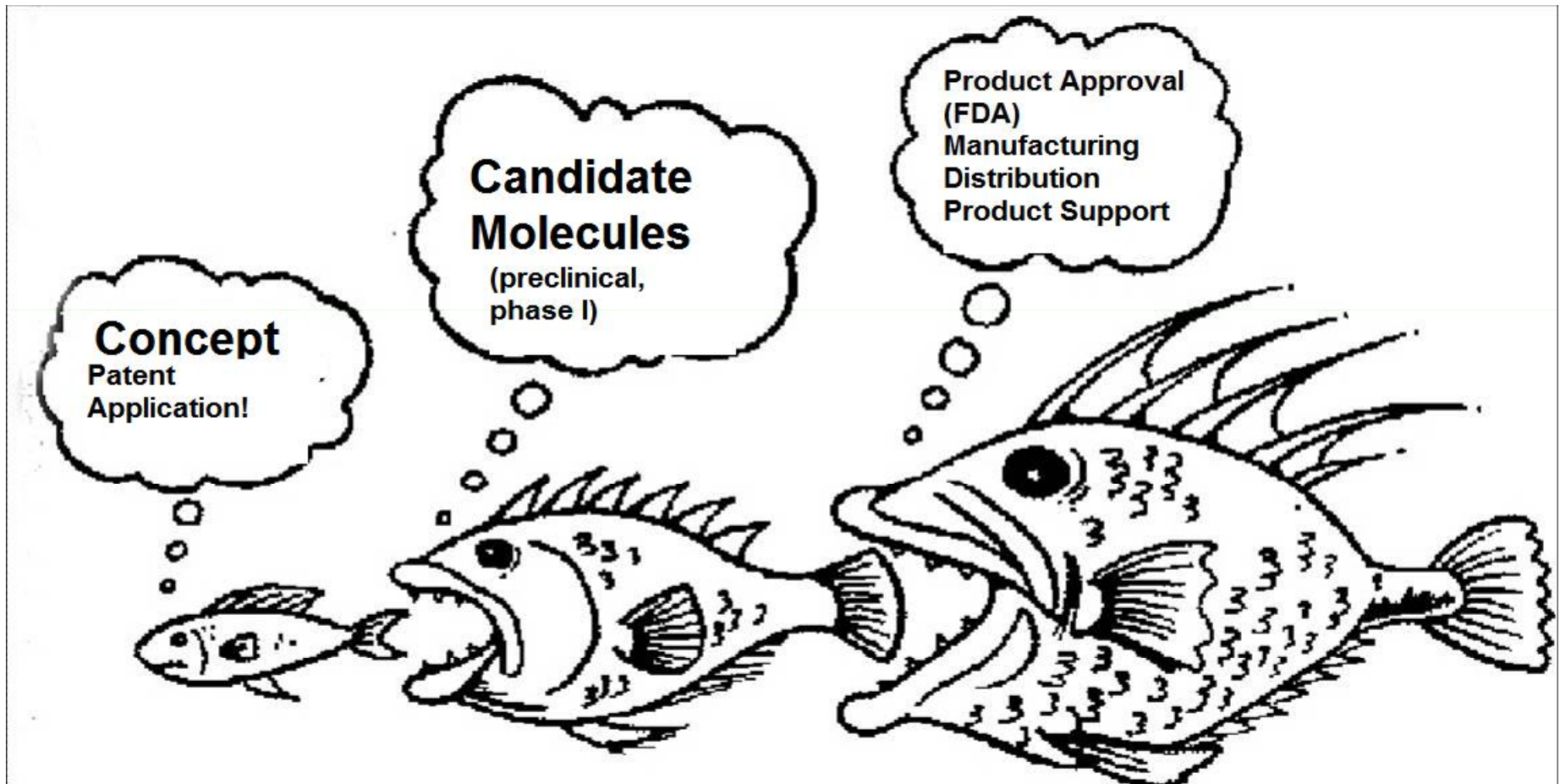
BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE TOKYO WASHINGTON, D.C.



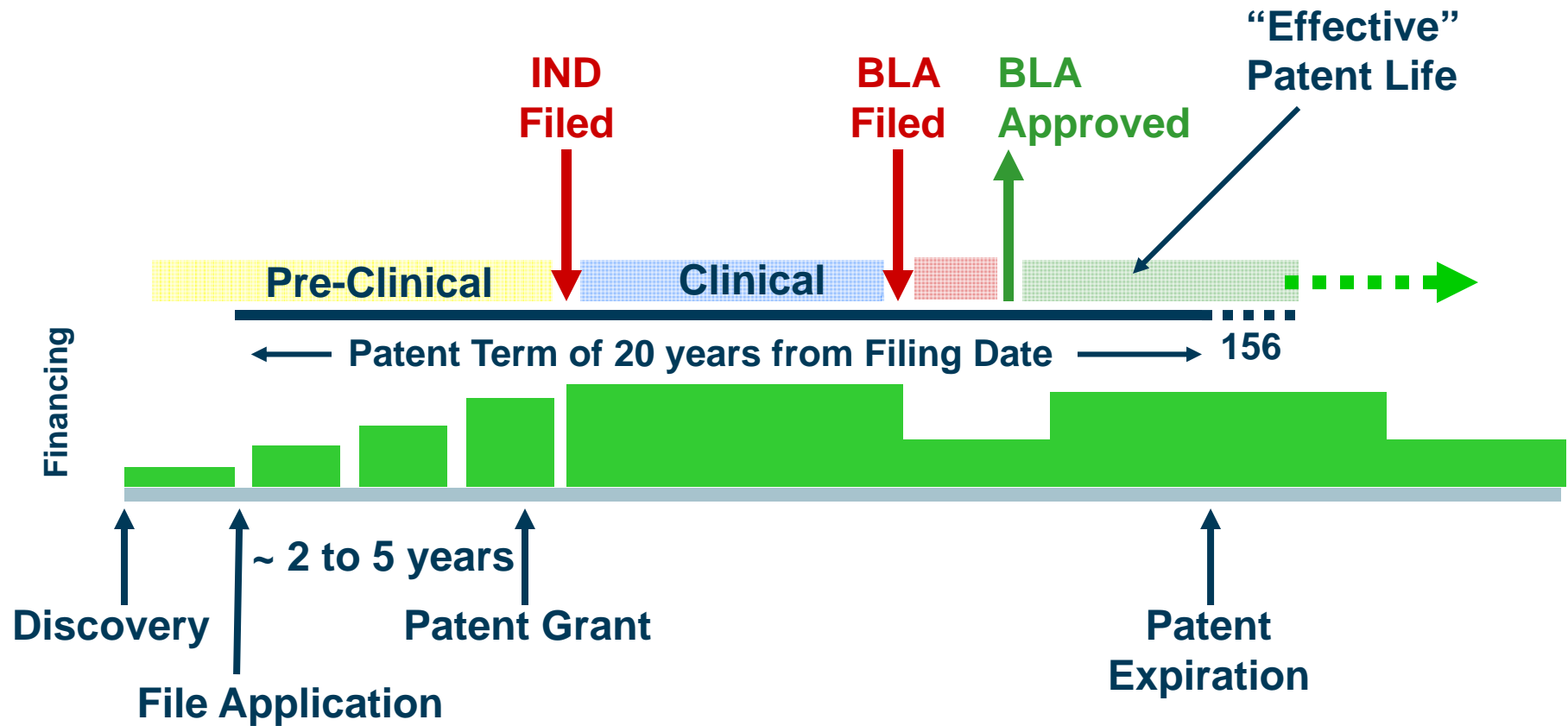
Patent Issues for Biotechnology Products

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The Biotech Business Model



Patent Application vs. Product Development Timeline



Systemic Needs for an Innovation Market

- Strong incentives to innovate and continue development of a BLA product
 - Many drugs target cellular mechanisms and can be used for variety of therapeutic applications
 - Better for patients, more choices, more capacity to meet unmet medical needs
- Tolerance must exist in the system for failures and gaps in progressing innovation
 - Funding is a critical parameter, and is not consistent or 'predictable'
 - Need to capture future commercial potential to drive immediate funding decisions

Why Fourteen Years?

- Biotech investment decisions are made by forecasting and probabilities
 - Assume high risk of failure
 - But, also assume that successful new biologic will be able to maximize all of the regulatory and statutory incentives available
 - One important target is a maximized patent term of a successful new biologic under 35 USC 156
 - Caps patent life at 14 years from market launch (effective patent term)

Patent Issues Are Distinct from ANDAs

- Follow on “active” ingredient will not be identical to innovator molecule
 - Even with same amino acid sequence, differences exist due to different manufacturing process and conditions
- More embodiments of innovator technology are implicated
 - Nucleic acid, protein, host cell claims historically have been divided by PTO into separate patents
 - Narrower claims linked to particular sequences
 - Manufacturing processes are linked to product approvals
- More patent owners - small biotech, universities own many patents that dominate products

What Needs to be Different?

- “Orange book” patent listing will not work
 - Follow-on will not be “identical” to innovator product
 - Only follow-on producer has product information necessary to identify relevant patents
 - Manufacturing patents important to approval
 - Need to identify patent owners other than BLA holder to resolve all key patent issues pre-launch
- Litigation is not “assured” for every relevant patent
 - Many dominating patents on manufacturing techniques are non-exclusively licensed
 - Mechanism should permit resolution of relevant patents, either by licensing or litigation, as appropriate

What Needs to be the Same?

- Patent certainty before launch of follow-on product
 - Patent certifications need to state position of follow-on for each identified patent that will not be licensed
 - Once positions known, innovators need ability to enforce all relevant patents
 - Litigation should commence with ample time to resolve dispute before FDA approval of follow-on granted
 - Use incentives of concluding litigation before FDA approval
 - If valid patents are infringed, follow-on should not be able to launch product
 - District court decision of infringement should block FDA approval of the follow-on product

Issues in Discussion

- Senate HELP bill adopts an unnecessarily complex patent litigation structure
 - Should simply require identification of relevant patents, require patent certifications on those, and that patent owners commence suit by date certain
 - If adequate data protection period provided, unnecessary to require FDA to stay approval of FOB
 - Longer data exclusivity period means also means fewer patents need to be litigated
 - Should allow third parties to identify relevant patents and commence suit as necessary
 - Declaratory judgment authority can be used by FOB producer to “quiet title” on unasserted patents

Issues in Discussion

- Special patent sanctions unnecessary
 - Loss of right to assert patents is a severe sanction
 - Complexity of patent identification and litigation process will risk loss of rights due to administrative errors
 - Strong incentives already exist already for owners of relevant patents to assert them
 - Appropriate sanction for patent owners to consciously delay litigation is to lose patent linkage benefit!
- Don't create "patent windfall" for FOB producers
 - Using the complexity of patent litigation and PTO examination practices to create opportunities for follow-on products to launch early will seriously erode incentives for innovation!