

Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?

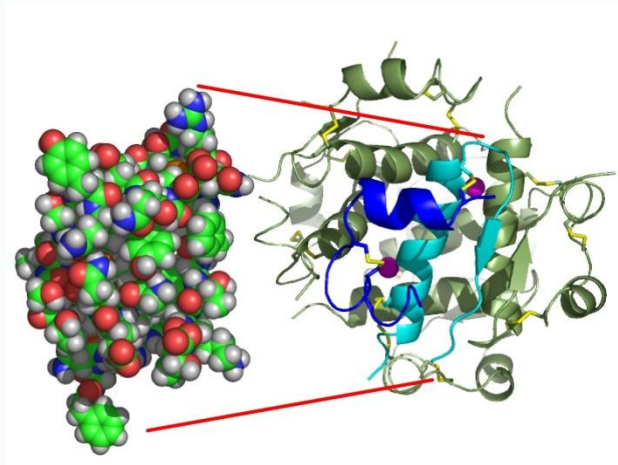
Yaniv Heled



Some Terminology

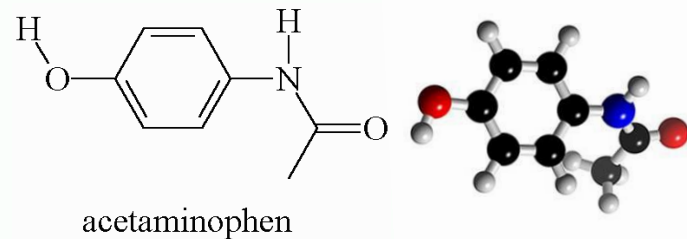
Biologics

- Large/heavy
- Made by living organisms
- Complicated structure
- Difficult to imitate



Small Molecule Drugs

- Small
- Chemically synthesized
- Relatively simple
- Easily reproducible

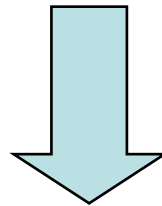


Some More Terminology

- Primary patents: cover the biological product as originally approved by the FDA (usually the active ingredient, methods of making same and the first tested methods of use)
- Secondary patents: later formulations and methods of use
- Statutory exclusivities:
Exclusivities in a product that are the result of legislative bars involving the underlying technology; enforced by executive agencies

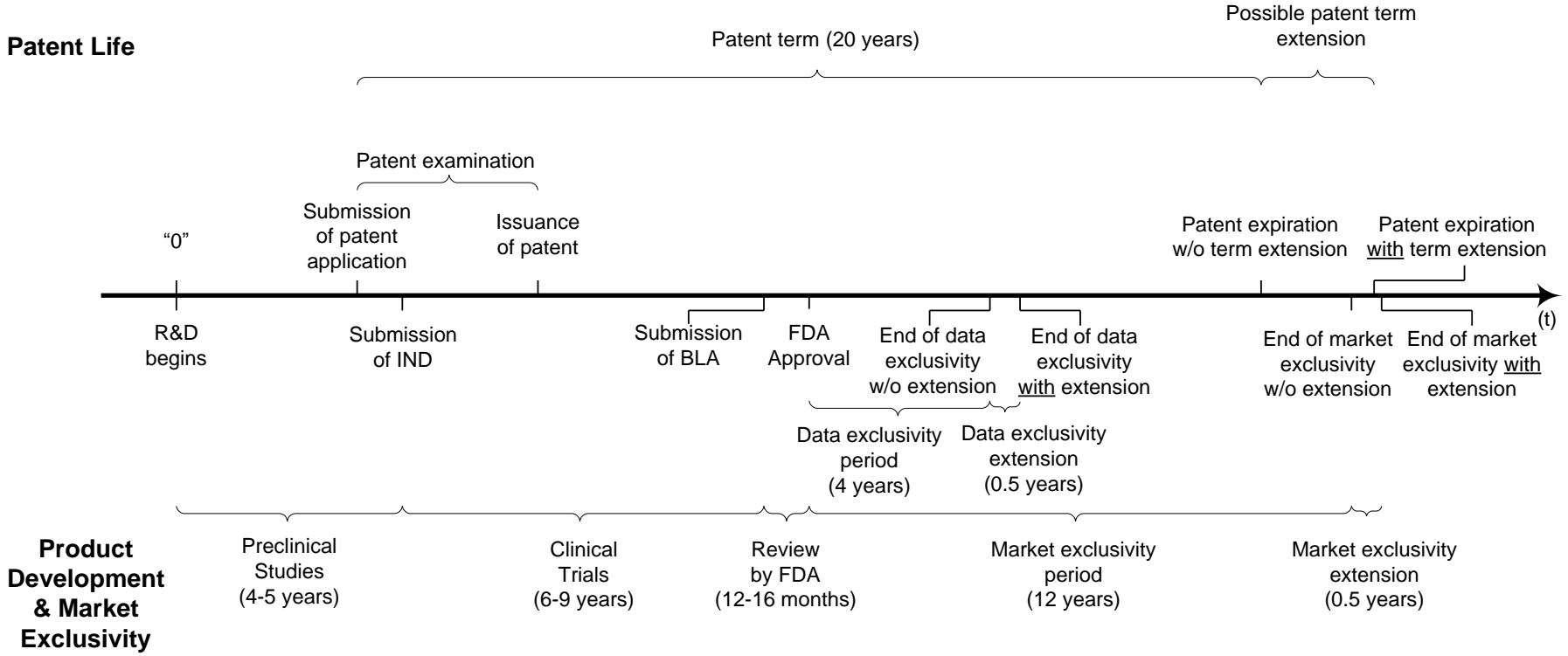
Argument:

1. Biologics will receive a 12 to 12.5 year exclusivity, i.e. no generic for 12 to 12.5 years after approval of original product (42 U.S.C. 262(k)(7), 262(m)).
2. This period is about 5-11 months shorter, on average, than the term of patents covering biologics.
3. Having both patents and statutory exclusivities would lead to waste of societal resources and increase the risk of patent abuse.
4. Statutory exclusivities do a better job at protecting the interests of developers of biologics and promoting “worthy technologies.”



5. Beginning with the onset of the 12-12.5 year exclusivity period, patents covering the subject biologic should be made unenforceable against generic applicants under BPCIA.

**Figure 1:* Patent Term vs. Statutory
Exclusivities in Biologics**



* Not in Scale

Some other issues raised by the proposal (to be discussed in the article)

- Potential loss of 5-11 months of patent protection is justified as payment for insurance
- Primary patents (before) and secondary patents (after) are still essential for promoting innovation

➡ Statutory exclusivities *should not replace* patents

Thank you!