



Panel Discussion:

**BIOLOGICS, DRUG PATENTS and the 2010
BIOSIMILARS LEGISLATION**

Petrie-Flom Center Harvard Law School

by
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Drug Patents and the 2010 Biosimilars Legislation*

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I. SOME RELEVANT BACKGROUND ABOUT ME

I am currently Executive Chairman of Tigris Pharmaceuticals, Inc., Chairman of ParinGenix, Inc., and a Founder and Principal of Leviathan Biopharma Group, LLC.

I was the Vice Chairman of IVAX CORPORATION, an International generic and brand pharmaceutical company, until it was sold to Teva in 2006 for \$10 billion.

I was also the Senior Vice President and General Counsel of SYNTEX CORPORATION, an International, research-based, brand Pharmaceutical Company, until it was sold to Roche in 1994 for \$5.3 billion.

I was also Chairman of the Life Sciences Legal Practice Group of Heller Ehrman White & McAuliffe.

Harvard College (Phi Beta Kappa, Magna Cum Laude) and Law School (Magna Cum Laude).





II. What is really at stake if we unduly delay follow-on biologic competition?

A. Many more \$ Billions each year in healthcare costs – which is not sustainable.

B. Many more people not receiving the best available (rather than the cheapest) medicine – which is intolerable. Some examples.

C. Contrast the Waxman-Hatch approach with EU price controls.





III. The 12-year (plus possible additional 12-year)* data exclusivity provided by the new law is much too long!

A. The Waxman-Hatch brilliant compromise:

1. A regulatory pathway to generics in return for significant patent term extensions.
2. Advocates for The Biotechnology Industry Organization (“BIO”) overstate the cost of new biologic drug development.
3. BIO’s advocates understate the time, cost and risks of the development of biologic follow-on products.
4. BIO’s advocates overstate the impact the launch of follow-on biologics will have on brand biologics.

B. The Amgens, Genentechs, Genzymes are crying wolf, and Venture Capital investors do not need 12(+12) years.

For “structural” modifications of the brand biologic which change safety, purity or potency.





IV. The 12-year (plus possible additional 12-year) data exclusivity provided by the new law is the wrong kind of market exclusivity.

- A. Unlike patent term extensions, the extended data exclusivity period(s) will provide money to biotech firms, but will not provide the incentive to innovate.
- B. Although the patent system is flawed, it has provided such incentive.
- C. 12 (+12) year data exclusivity will misdirect research efforts to lower risk, less innovative areas, and away from higher risk, innovative cures for cancer, heart disease, Alzheimer's, Diabetes, etc.
- D. Consider the impact of massive Direct-To-Consumer drug promotion.

V. CONCLUSION

