



PROPER DURATION OF DATA EXCLUSIVITY FOR GENERIC BIOLOGICS: A CRITIQUE

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Highlights from the Paper:

“This paper discusses the importance of an appropriate duration for data exclusivity and critiques the recent work by Duke economist Henry Grabowski on this subject (Grabowski 2008)....Results presented here indicate that seven years is a reasonable duration to balance incentives for innovators with the market benefits of competition.”

“This paper provides an analysis of the Grabowski model and its assumptions. It demonstrates that with more plausible assumptions regarding the cost of capital and the contribution margin, the “break-even” period is considerably shorter.”

- “Grabowski’s model discounts future cash flows and capitalizes R&D costs using the market-driven cost of capital as the appropriate discount rate. While this approach is valid in theory, we doubt the 11.5 percent and 12.5 percent real discount rates assumed by Grabowski.... Taken together, a real cost of capital in the biopharmaceutical industry is reasonably 10 percent.”
- “Contribution margins vary over time and to focus only on 2001, a year in which the U.S. economy was in recession, fails to provide an accurate and current estimate of the contribution margin for the biopharmaceutical industry....we calculated contribution margins for each of the six largest biotechnology companies in each of the years 2001 through 2007, in a manner similar to CMS (2003). Therefore, we find that 50 percent is too low and consider a contribution margin of 60 percent a more plausible assumption.”

“The new results range from just less than nine years to 12 years. Based on assumptions we view as most plausible, a 10 percent discount rate and 60 percent contribution margin, the best estimate of a “break-even” point is at just less than nine years.”

“Furthermore, this paper explains that, as a general matter, the “break-even” point should be interpreted as an extreme upper bound for data exclusivity and not as an estimate of optimal duration of data exclusivity. In the case of the biologic drug industry, because innovator drugs can be expected to continue to earn economic profits in a market open to biogeneric competition, optimal data exclusivity will always be less than the “break-even” point. Many readers of Grabowski (2008) falsely interpret that paper’s results.”

- “Assuming that prices and market shares decline according to the assumptions laid out by the Congressional Budget Office (CBO 2008), we find that seven years of data exclusivity would result in a break-even point of 10 years, beyond that point the portfolio continues to earn profits in excess of the required rate of return.”

“Important other factors, including other patent protection issues and the aforementioned evergreening issue, not modeled here will affect incentives to innovate and affect the ability of biogeneric competition to improve access to drugs.”