



National Venture Capital Association

The Importance of Evaluating the Cost of Capital for Early-Stage Biotechnology Ventures to Preserve Innovation

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As Congress considers the creation of a new “biosimilars” FDA approval process, the central question is how to balance the public’s interest in lower prices for biological drugs, with continued vigorous investment in the development of new medical treatments and cures for patients suffering from debilitating diseases such as cancer, Parkinson’s, and multiple sclerosis.

The National Venture Capital Association (NVCA) supports the principle of a biosimilars approval system to reduce excessive costs of biologic drugs, particularly arising from inflated earnings streams extending far beyond the reasonable expectations of market exclusivity. However, in seeking this result, we must avoid excessive damage to the system that produces the majority of revolutionary and innovative new biologic drugs. NVCA believes a data exclusivity period of at least 12 years for innovator products is a critical fulcrum in the effort to balance cost with the preservation of biotech innovation.

In developing legislation Congress has appropriately sought to understand the factors affecting the investment in new drug development, including, in particular, the “cost of capital” to the innovation sector in the biotechnology industry. Unfortunately, prior attempts to address this question have failed to recognize several key issues:

1. In contrast to the pharmaceutical sector, the biotechnology industry is overwhelmingly comprised of small, private, venture capital (VC) funded, entrepreneurial companies. Thus, conclusions about how a biosimilars system will affect innovation in this sector cannot be drawn directly from experience with Hatch-Waxman in the pharmaceutical sector.
2. One of the most important distinctions between these two sectors is their respective “cost of capital.” Current estimates about the cost of capital in the biotech industry are based on publicly traded companies – not the small, privately held companies that comprise the majority of the biotech industry. Data on actual cost of capital for venture-backed biotech companies is proprietary and is not accessible to the academic community. As a result, all prior analyses have included information from large publicly traded biotech companies.
3. While understandable, this substantially understates the cost of capital for the small public and privately held firms because large public companies are intrinsically more mature and less risky than the average private VC funded company. Such a sample also introduces “survivor bias” by excluding from the data all the private companies who do not survive to become public.

The NVCA asked two noted academic scholars, Professor Iain Cockburn, Boston University School of Management, and Professor Josh Lerner, Harvard University School of Business, in the field of entrepreneurial finance and capital formation to analyze the cost of capital of the small, privately held biotech sector. To assist in this study, the NVCA provided them unprecedented access to proprietary venture capital databases.

The report's primary conclusions are as follows:

1. The cost of capital of the small, private biotech VC funded sector is at least 20% and is likely higher.
2. 44% of VC investments in biotech result in either partial or total loss of capital. This substantially increases the variance risk of these investments resulting in a high "beta" (risk) of at least 2.5.
3. The VC fundraising rate for all sectors has declined by 50% in 2009.
4. The VC biotech investment rate has declined by 75% in 2009.

Why is the "cost of capital" important?

Since the clear goal of any biosimilars system is to produce lower prices for biologics, it clearly follows that such a system will reduce the flow of earnings from a biologic as compared to what it would be in the absence of a biosimilars system. If the reduction in the expected flow of earnings reduces the value of the earnings stream below the "cost" of inventing the drug, no one will invest to invent the drug in the first place.

Unfortunately, the question of "cost," how one values a future earnings stream, and most importantly, how one assesses and discounts risk, is extremely complex and far beyond the scope of this report. However, as a general rule, investments are made if the expected "return on capital" is higher than the "cost of capital" and more important, that investments are not made if the return is less than the cost.

For example, if an investor can borrow \$100,000 from a bank at 10% interest per year (her "cost of capital,") it could be rational for her to buy an apartment building costing \$100,000, if the cash flow from all the tenants in the building was \$11,000 per year (11% "return on capital.") In this case she would make \$1,000 per year. It would obviously not be rational to buy the same building if its cash flow was only \$9,000 per year, because in this case she would lose \$1,000 per year (absent appreciation of the value of the building for some other reason, which would also be considered part of her "return on capital.")

If the biosimilars legislation has the intended result of reducing the stream of earnings from a future biological product, the key question is whether the value of that "return" has been reduced below the relevant investor's cost of capital, in this case the biotech segment of the venture capital industry. In its recent report on follow-on biologics drug competition, the Federal Trade Commission never even raised this question, let alone attempted to answer it. However, this question is the central issue in this debate. The cost and return of capital analysis has been examined in numerous academic studies, including one commissioned by the generic drug industry,¹ a strong supporter of the proposed biosimilars system. That study assumed a biotech cost of capital, based on publicly traded biotech companies of 10% and determined that on average a "data exclusivity" period of 7 years would permit an investor with a 10% cost of capital to make a positive return on its investment in the development of new biologics. That

¹ Brill, Alex M. "Proper Duration of Data Exclusivity for Generic Biologics: A Critique," November 2008.

means, that with a 7 year data exclusivity period an investor with a cost of capital of 10% or less, would continue to make investments in new drug development. Unfortunately and more importantly, it also means that investors and companies with a cost of capital above 10% would not rationally make that investment. In that scenario the entire VC biotech sector, with an estimated 20% cost of capital, will drastically reduce such investments and shift remaining funds to less risky and less innovative opportunities – i.e., they will invest in something other than the development of innovative biologics that will be used to treat those with unmet medical needs.

Why is data exclusivity protection necessary to sustain innovation?

The recently released Federal Trade Commission (FTC) report dismisses the need for data exclusivity by concluding, in part, that existing patent protection will provide equivalent or even stronger barriers to entry for biological drugs as compared to small molecule pharmaceuticals.²

This conclusion is largely based upon past examples of biologics innovator-on-innovator patent litigation where patents have been successfully asserted. The report acknowledges that there have been examples to the contrary but concludes that, on the whole, substantial data exclusivity is not needed because there is no evidence that past biologics patents have been designed around more frequently than those claiming small molecule drugs. Also, the FTC found no evidence that biologics have suffered from a lack of patentability, or that market forces have been insufficient to incentivize the development of new biologics in the past. However, the question the FTC should have addressed is not whether patent protection and market forces have stimulated biotechnology innovation in the past. Rather, the question is whether reliance on patents alone continues to be justified even under a new abbreviated biologics approval pathway that completely changes the business incentives for pioneering developers and subsequent competitors alike.

With no abbreviated approval pathway today, biologics developers have little incentive to incur staggering development costs only to create me-too biologics that are marketed as merely “similar” to existing products with no opportunity for product differentiation. The creation of an abbreviated approval pathway would change that – it would create powerful incentives for biologics competitors to identify and exploit gaps in each others’ patent portfolios that could be filled with “similar” products, developed at a fraction of today’s costs. In other words, “patent pressure” will increase by orders of magnitude – pressure on originators to develop only those biologics that have the best patent protection, and pressure on subsequent competitors to tear down or design around these same patents. Thus, it is by no means assured that a patent system that enables abundant biotechnology innovation today will continue to do so under a follow-on biologics system that incentivizes biologics competitors to invade rather than avoid each others’ patent space, and to develop similar rather than different products. The answer to whether reliance on patents alone is justified under such a new system allows no margin for error.

In concluding that patents alone are sufficient, the FTC glosses over the most relevant point with respect to patent protection for biologics under a biosimilars system. Unlike under Hatch-Waxman, biological biosimilars will *not* need to be identical to the pioneer drug. As a result, composition of matter patents are less likely to protect against biosimilars competition as they do in the case of Hatch-Waxman. In the small molecule drug space, composition of matter patents are usually extremely strong (because they are narrow) and easy to enforce because

² Federal Trade Commission, Authorized Generics: An Interim Report, June 2009, available at www.ftc.gov/opa/2009/06/generics.shtm.

proof of infringement is rarely an issue. This most potent patent protection is much more easily avoided in the biosimilars context because the biosimilar developer has more design alternatives, i.e., greater opportunities to modify the innovator's molecule in ways that avoid the patent but are still similar enough for abbreviated approval. Regardless of how one weighs all the other intangible patent questions, it is clear that this factor alone will make the patent rights of pioneer developers much less certain compared to their rights under Hatch-Waxman.

Even if one could conclude that the increased uncertainty of patent rights is somehow offset by the greater diversity of typical biotechnology patent portfolios, as the FTC seems to do, the FTC conclusion that this eliminates the need for data exclusivity completely ignores the fact that the proposed exclusivity is not additive to patent protection, it is merely a parallel right. The patent rights and data exclusivity terms would run concurrently. In other words, if patents are strong and cannot be designed around, data exclusivity would not matter. Years of experience under Hatch-Waxman has already demonstrated that existing patent barriers for small molecule drugs delay generic entry for 12 years. The Senate's proposed data exclusivity will run for 12 years. If the FTC is correct that patent rights for biologics will be at least as strong as those of small molecule drugs facing generic challenge, the data exclusivity will be irrelevant because it will provide no exclusivity beyond that provided by patent rights. But if the FTC is wrong and, as most experts expect, the patent's rights are less certain, then the data exclusivity will merely protect biologics pioneers for the same 12 years that small molecule drug makers achieve under Hatch-Waxman.

Considering the financial vulnerability of the biotech industry, and the difficulty of predicting exactly how the balancing of patent rights will evolve, data exclusivity is a prudent effort to insure against undermining this nation's entire system of new biological drug discovery and innovation.

Conclusion

If legislation is enacted without an adequate data exclusivity period founded upon an appropriate cost of capital, the venture industry's ability to support revolutionary biologic drug discovery will be compromised.

The NVCA has strongly supported the principle of a biosimilars approval system to reduce excessive costs of biologic drugs, particularly arising from inflated earnings streams extending far beyond the reasonable expectations of market exclusivity. However, in seeking this result, we must avoid excessive damage to the system that produces the majority of revolutionary and innovative new biologic drugs. NVCA believes that a 12 year data exclusivity provision will accomplish both goals.