National Venture Capital Association

House Committee on the Judiciary
Subcommittee on the Courts and Competition Policy

Hearing on Biologics and Biosimilars: Balancing Incentives for Innovation
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Chairman Johnson, Ranking Member Coble and Members of the Subcommittee, my name is Jack Lasersohn and I am a partner at The Vertical Group, a venture capital firm based in Summit, New Jersey and Palo Alto, California that focuses investment in the life sciences sector. I was originally trained as a physicist and have been an active venture capital investor since 1981. I am also a Board Member of the National Venture Capital Association (NVCA), which represents over 460 venture firms across the country. It is my privilege to be here today and to have the opportunity to share the view of the venture capital community on the crucial role that biosimilars legislation will play in future investment and development of biological products.

As Congress considers the creation of a biosimilars approval pathway at the Food and Drug Administration (FDA), 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.

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, NVCA believes that we must also carefully balance the countervailing need to ensure continued development of and patient access to innovative biologic therapies.

Venture Capital Investing is Critical to Innovation

For the last four decades, the venture capital community has served as a founder and builder of companies, a creator of jobs, and a catalyst for innovation in the United States. This contribution has been achieved through high-risk, long-term investment of considerable time and dollars into small, emerging growth companies across the country and across industry sectors, including information technology, communications, biotechnology, medical technology and more recently the "cleantech" industry. According to the econometrics firm Global Insight 2009 study, venture-backed companies accounted for 12.1 million jobs and $2.9 trillion in revenue in the United States in 2008 representing 11 percent of U.S. private sector

employment. In fact, it was the venture capital industry that created the biotechnology industry including companies like Genentech and Amgen.

In addition to providing early stage funding to young biotech businesses, venture capitalists also take an active role in guiding these companies through their start-up and expansion phases. Accordingly, we have a valuable perspective on the hurdles that these emerging businesses confront and the environments that promote or stifle growth and innovation. Given the role that we play at various points in a biotech company's life cycle, venture capitalists have the opportunity to provide a unique perspective on the importance of providing adequate incentives for innovator products in biosimilars legislation.

My testimony today focuses on the critical role that "data exclusivity" in biosimilars legislation will play in the development of the next generation of innovator biological products. If an adequate period of data exclusivity is not included in the legislation, the "return on capital" (expected return that the provider of capital actually earns on their investment) will be too low to support continued VC investment in the biotech industry. This will stifle, perhaps even cripple, the emerging biotech industry, and delay the development of life-saving therapeutics. This is especially true when one considers that patent protection on biologics is simply too uncertain to sustain, by itself, VC investment in the biotech sector.

The Cost-of Capital for Biotech Drugs Supports a Lengthy Period of Data Exclusivity

The NVCA believes that in determining the appropriate period of data exclusivity, it is critical to understand what factors affect investment in new drug development, including, in particular, the "cost of capital" of the innovation sector of the biotechnology industry. Prior attempts to address this question have failed to recognize two key issues:

First, in contrast to the pharmaceutical sector, the biotechnology industry is overwhelmingly comprised of private, venture capital funded, small, 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. In other words, one must carefully examine the unique circumstances involved in biotech investment and innovation when crafting biosimilars legislation.

Second, one of the most important distinctions between the pharmaceutical and biotech sectors is their respective "cost of capital." The cost of capital is the minimum required return that the provider of capital needs to earn on their investment. Because data on actual cost of capital for the small, privately held biotech companies which comprise the majority of the biotech industry is proprietary, current estimates about the cost of capital in the biotech industry are based on publicly traded companies. 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, and also because such a sample introduces "survivor bias" by excluding from the data all the private companies who do not survive to become public.

A recent study from professors at Harvard Business School and Boston University School of Management found that the cost of capital of the small private biotech VC funded sector is at least 20% and is likely higher. This is in sharp contrast to the 10% assumed in all prior

analyses. The report also found that 44% of VC investments in biotech result in either partial or total loss of capital. Most disturbing, the report concluded that the VC fundraising rate for all sectors has declined by 50% in 2009, but that the VC biotech investment rate has declined by 75% in 2009.

Since the clear goal of any biosimilars system is to produce lower prices for biologics, it follows that such a system will reduce the flow of earnings from an innovator 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. That is obvious and simple.

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 of 10%, based on publicly traded biotech companies, and determined that on average a "data exclusivity" period of seven-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 means that with a seven 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 cost of capital above 10%, including the small, privately owned, VC-backed biotech sector (20% cost of capital), will drastically reduce investments and shift remaining funds to less risky and less innovative opportunities. In other words, VCs will invest in something other than the development of innovative biologics that will be used to treat those with unmet medical needs.

In short, recent studies showing that the cost of capital for the majority of the biotech industry is higher than previously expected indicate that a lengthy period of data exclusivity (at least greater than seven years) is necessary to support continued biotech innovation. For the reasons outlined below, NVCA believes that 12 years of data exclusivity is needed for innovator biologics.

12 Years of Data Exclusivity Protection Is Necessary to Sustain Innovation

NVCA believes that no less than a 12 year data exclusivity period for innovator products is critical to preserving biotech innovation. The recently released Federal Trade Commission (FTC) report entirely 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] However, in the absence of an assured

[1] Brill, Alex M. "Proper Duration of Data Exclusivity for Generic Biologics: A Critique," November 2008.
[2] Federal Trade Commission, Authorized Generics: An Interim Report, June 2009, available at www.ftc.gov/opa/2009/06/generics.shtm.

period of data exclusivity, patent protection is not sufficient to sustain innovation in the biotech sector.

The FTC's 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. The flaws of this logic are obvious: the question is not whether patent protection and market forces have stimulated biotechnology innovation in the past – the question is whether reliance on patents alone continues to be justified even under a new abbreviated biologics approval pathway that completely alters 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 biosimilars 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 and easy to enforce because 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. Long experience under Hatch-Waxman has already demonstrated that existing patent barriers for small molecule drugs delay generic entry 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 rights are less certain, then a 12 year period of data exclusivity will merely protect biologics pioneers for the same 12 years that small molecule drug makers achieve under Hatch-Waxman. For this reason, NVCA strongly supports no less than 12 years of data exclusivity for innovator biologic products.

Moreover, in its discussion of innovator exclusivity, the FTC overlooks the difference between market exclusivity and data exclusivity. Market exclusivity bans all competitor products from being marketed in the U.S., and thus provides the innovator with a virtual monopoly for a period time. In contrast, data exclusivity, which is the concept considered by the pending legislative proposals, delays approval of a biosimilar only if it relies on the innovator's safety and efficacy data rather than on new safety and efficacy data generated by the secondary applicant at its own expense. A data exclusivity period protects the innovator, for a limited period, from the free rider effect of allowing the biosimilar applicant to exploit the innovator's $1 billion investment in developing a pioneering biologic; it is not unrestricted immunity from competition. There is, therefore, a valid public policy served by data exclusivity which cannot be achieved through patent protection alone.

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

Conclusion

The VC community supports the majority of revolutionary biologic drug discovery, thus the innovative biotech industry will be significantly adversely affected by biosimilars legislation which does not adequately incentivize continued investment in this sector. Lack of adequate data exclusivity to ensure a reasonable return on investment means that venture capital funds cannot invest with confidence in promising biotech opportunities. This is a perverse result and cannot be what Congress intends with biosimilars legislation.

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, we must also avoid disincentivizing investment in the development of revolutionary and innovative new biologic drugs. NVCA believes that a 12 year data exclusivity provision will accomplish both goals.