A FOLLOW-ON BIOLOGICS REGIME WITHOUT STRONG DATA EXCLUSIVITY WILL STIFLE THE DEVELOPMENT OF NEW MEDICINES

Biotechnology companies must have some certainty that they can protect their investment in the development of new breakthrough therapies for a substantial period of time in order to secure the necessary resources from venture capital firms and other funding sources. Thus, in order to preserve incentives for biomedical innovation, any statutory pathway for follow-on biologics (FOBs) must include a substantial period of data exclusivity. Such non-patent exclusivity is necessary because, due to the very nature of a FOBs regime, the patent system may not provide innovator biologics with effective protection against follow-on manufacturers prematurely entering the market. For biologics to receive the same length of effective market protection as small molecule drugs receive under the Hatch-Waxman Act, the period of data exclusivity in any FOBs framework must be no less than 14 years. Anything less could skew investment away from biologics research and development.

The similarity standard for FOBs creates a "protection gap" that may allow for abbreviated regulatory approval while eluding an innovator's patents. That likelihood exists because of the confluence of two critical factors not present in the Hatch-Waxman Act construct for generic small molecule drugs. First, unlike a generic drug which must be the same as an innovator product, a FOB may be only "similar' to the corresponding innovator product, and thus the innovator's patents may not be infringed. Second, because of the nature of biologic products – large molecules produced by living cells and organisms – patent protection is often narrower and easier to "design around" than that of small molecule drugs, and the trend is towards increasingly narrow patents.

Strong data exclusivity will preserve the balance that Congress previously found necessary to stimulate innovation in the pharmaceutical industry. In 1984, Congress enacted patent term restoration provisions to provide pharmaceuticals with up to 14 years of patent protection following marketing approval. This time period was selected so that "research intensive companies will have the necessary incentive to increase their research and development activities." H.R. Rep. No. 98-857, at 41 (1984). As a result, the average period of time for marketing a drug product with patent protection now is 11.5 years, and new drugs are, on average, marketed in the U.S. for 13.5 years before the entry of generic competition. Any FOBs pathway should at least guarantee that same degree of effective market protection through data exclusivity. Further, the breakeven point for a biologic occurs after it has been on the market between 12.9 and 16.2 years. Indeed, if the data exclusivity period for biologics is less than the number of years available to drugs under patent term restoration (that is, 14 years), then, because of the patent protection gap and the higher risks of biologics development, it will skew investment away from biomedical innovation.

A 14-year period of data exclusivity serves as an insurance policy that provides innovators with some certainty of protection. Data exclusivity would run concurrently with the patent term for the product. It therefore would create actual protection only in those instances where the follow-on manufacturer would be able to work around the patents held by the innovator but still gain abbreviated approval of its FOB.

Data exclusivity of 14 years is an essential incentive for biotechnology investment. The majority of biotechnology companies are small, private start-ups, heavily reliant on venture capital investment. Yet these companies hold two-thirds of the industry's innovative clinical pipeline. Biologics research and development also is a high-risk endeavor, with higher capital costs, higher material costs, greater manufacturing costs and uncertainties, longer development times, and lower late-stage success rates than compared to small molecule drugs. A failure to include substantial data exclusivity as part of a statutory framework for FOBs would undermine incentives to invest in biomedical innovation and thus would slow progress in the development of breakthrough therapies to improve the health and lives of patients suffering from currently untreatable conditions.