SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
1501 K STREET, N.W.
WASHINGTON, D.C. 20005
(202) 736 8000
(202) 736 8711 FAX

jkushan@sidley.com
(202) 736-8914

BEIJING GENEVA SAN FRANCISCO
BRUSSELS HONG KONG SHANGHAI
CHICAGO LONDON SINGAPORE
DALLAS LOS ANGELES TOKYO
FRANKFURT NEW YORK WASHINGTON, DC

FOUNDED 1866

August 7, 2009

The Honorable Henry C. Johnson, Jr.
Committee on the Judiciary
Subcommittee on Courts and Competition Policy
United States House of Representatives
B-352 Rayburn House Office Building
Washington, D.C. 20515-6216

Dear Chairman Johnson:

I write in response to your letter of July 22, 2009 presenting follow up questions to the Subcommittee's July 14, 2009 hearing on "Biologics and Biosimilars: Balancing Incentives for Innovation." The answers in this letter are provided on behalf of the Biotechnology Industry Organization (BIO), on whose behalf I testified at the July 14 hearing.

Questions from Chairman Johnson:

1. *How much do you estimate it costs to bring a new biological pharmaceutical to market? How does this compare with the costs of bringing a pharmaceutical product regulated under the FDCA to market?*

A: In a peer reviewed paper by Henry Grabowski and Joseph DiMasi, the authors find that the cost of bringing a new biologic product to market is approximately $1.24 billion.[1] They also found that, in comparing the cost of bringing to market a new pharmaceutical product regulated under the Federal Food Drug and Cosmetic Act (projected using past growth rates) to the cost of bringing a new biologic product to market, the "total capitalized cost per approved new molecule was nearly the same." In a subsequent paper, the authors clarified that this estimate did not include a significant additional cost attributable to biologic products, observing:

> "It is important to note that the costs of constructing a new manufacturing facility or retrofitting an existing plant for large-scale commercial production are not included in the R&D cost estimate. The cost of a new multi-product manufacturing plant is substantial in the case of biologics. In particular, it has been estimated that a new manufacturing plant can take 3–5 years to build, and cost US$250 million or more. Even retrofitting an existing plant can cost between $50–100 million."[2]

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1 Grabowski et al., The Cost of Biopharmaceutical R&D – Is Biotech Different?, *Managerial and Decision Economics* 28(4-5) (2007).

2 Grabowski et al., Follow-on biologics: data exclusivity and the balance between innovation and competition, *Nature Reviews* 7(479-488) (2008).

BIO also observes that the $1.24 billion Grabowski and DiMasi estimate assumes a conservative cost of capital figure of 11.5%. More recent studies have shown a much higher actual cost of capital for biotech firms, particularly for those privately-held companies that make up the bulk of the biotech industry. For example, Vernon and Golec reported that the real cost of capital for publicly-traded biotech firms was approximately 13.25%,[3] while in a recently released paper by the National Venture Capital Association, the cost of capital for privately-held biotech firms was reported to be approximately 20%.

In both cases, does the cost include direct marketing and advertising to consumers and health care providers? If so, what percentage of these costs is dedicated to such marketing and advertising?

The cost figures reported by these authors do not include either marketing or advertising to consumers and health care providers. These estimates also do not take into account any post-approval R&D costs, which are needed to seek FDA approval for new indications or to comply with post-marketing studies or other requirements imposed by the FDA as a condition of approval of the biological product.

If such marketing and advertising isn't already included, how much on average do you estimate is spent to market a new biological pharmaceutical product to consumers and health care providers?

BIO, as a trade association, does not collect such information.

Questions from Rep. Goodlatte

2. *Commissioner Harbour testified at the hearing that data exclusivity is "above and beyond" patents. Your testimony seems to say otherwise. Can you clear up that confusion for me?*

Commissioner Harbour's testimony appears to be based on a misunderstanding about how data exclusivity and patent rights relate to innovator and biosimilar products, and the role that data exclusivity will play in a system where patent rights may not prove effective to prevent marketing of a biosimilar product.

Data exclusivity and patents are independent mechanisms. Data exclusivity prevents "free riding" on an innovator's investment in clinical research by deferring the date that the FDA can use an innovator's clinical data to approve a biosimilar product. Data exclusivity does not provide market exclusivity – another company can always get approval of its "biosimilar" product by conducting independent clinical research. Of course, allowing the biosimilar to free ride on the innovator's clinical research significantly reduces the time, cost and unpredictability of obtaining approval of the biosimilar product. This means that a biosimilar producer will have a choice: either incur the costs and risks of independent product development, or wait until expiration of the data exclusivity period for the innovator.

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3 Vernon et al., NBER Working Paper No. 13604 (November 2007).

Patents provide exclusive but defined rights in inventions. These rights prevent unauthorized use of the patented technology and, for all patent applications filed on or after June 8, 1995, run 20 years from the date the patent application was filed.[4]

Patents and data exclusivity co-exist under today's Hatch-Waxman system. Certainly, each will have the capacity to defer the date that a biosimilar product may reach the market in a future system. For example, if no patents cover the biosimilar product, data exclusivity will dictate when the biosimilar producer can gain approval for its product via reliance on the innovator's clinical research. If the innovator's patent covers the biosimilar product, and has a term that extends past the date that data exclusivity expires, then the patent will dictate when the biosimilar product may reach the market.

In my testimony, I explained that valid patent rights in biological products may not prove effective in preventing the marketing of a biosimilar product. This is the result of two factors. First, the biosimilar product will not be required to have an identical structure as the innovator product. Second, the PTO is very strict in granting patent rights in biological products. This combination of factors makes it possible for a biosimilar developer to design a biosimilar product that is similar enough to the innovator's product to permit use of the innovator's clinical data, but different enough to avoid the innovator's patents.

This scenario is not possible under the Hatch-Waxman system for small molecule drug products. Under Hatch-Waxman, the generic drug must have an identical structure as the innovator's product. This means that patents that cover the innovator's product necessarily cover any generic product. Research has shown that these patent rights, on average, last until 12 to 14 years past the date of approval of the drug product. The incentive provided by these patent rights has proven effective in stimulating the investments and efforts to bring those products to market.

With this background, I believe Commissioner Harbour's testimony that data exclusivity is "above and beyond" patents reflects a confusion about how these two mechanisms function and relate to an innovator product.

As I noted above, if the patent system works as it is supposed to (and does for small molecule drugs), patents should deliver up to 14 years of protection from competition by biosimilar products following approval of the innovator's product. In this scenario, data exclusivity will have no impact at all, as the period of patent exclusivity will extend past the expiration of a 12 year period of data exclusivity. Of course, if valid patents do not prove effective in blocking market entry by a biosimilar, the only protection the innovator will be able to count on will come from data exclusivity. In this scenario, data exclusivity will serve a critical role of providing the incentives necessary for encouraging development of the biosimilar product.

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[4] For those patents filed before this date, patent term runs 17 years from the date of issuance.

Accordingly, a more accurate way to refer to the interplay between these two systems is that data exclusivity will serve as a backstop to patent protection, and will have an effect only in those situations where a biosimilar producer has managed to evade the valid patent rights of the innovator. Given the need for the biotechnology industry to have effective incentives to develop new biological products, and to continue to clinically develop those products, this backstop will play a critical role.

3. *The FTC report says that data exclusivity is available for small molecule pharmaceuticals when the drug is not patentable, i.e., in the public domain. Is that the only instance where you can get data exclusivity?*

The FTC is incorrect in suggesting that data exclusivity is available only for small molecule drugs that are not patentable. Under current law, data exclusivity is provided to small molecule drugs regardless of whether those drugs are also covered by patents. In fact, this has always been the law, and is actually reflected in the design of the Hatch-Waxman system.

For example, under § 505(j), a generic drug applicant may submit an Abbreviated New Drug Application a year early (i.e., 4 years after NDA approval instead of 5) if it includes in its application a statement contesting patents that have been listed by the innovator as covering the innovator's drug product. In addition, if the NDA holder proves that generic drug applicant infringes a listed patent that the generic applicant contested, FDA will defer final approval of the generic drug until the valid and infringed patent covering the drug expires. In fact, one of the three elements of the Hatch-Waxman package expressly recognizes that patents will cover drugs that also are provided data exclusivity; namely, the provisions that permit an NDA holder to secure a patent term extension for a new drug to compensate for the regulatory review time needed to obtain approval of the drug. If Congress in 1984 thought that data exclusivity would only apply to unpatentable drugs, it would not have included any of these patent-related measures.

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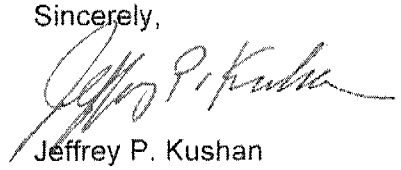
Thank you again for permitting BIO to provide its views on this important subject. If you have any further questions, please do not hesitate to contact me.

Sincerely,



Jeffrey P. Kushan