Oral Statement of Commissioner Pamela Jones Harbour

Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
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"Emerging Health Care Issues: Follow-on Biologic Drug Competition"

Introduction

Chairman Pallone, Ranking Member Deal, and members of the Subcommittee, I am Pamela Jones Harbour, a Commissioner of the Federal Trade Commission. I am joined by Michael Wroblewski, Deputy Director of FTC's Office of Policy Planning. Thank you for inviting us to testify today.

I appreciate this opportunity to provide an overview of the Commission's recently released report, *"Emerging Health Care Issues: Follow-On Biologic Drug Competition."* A primary goal of our report is to examine how competition is likely to evolve in biologics markets – in particular, between pioneer biologics and follow-on biologics, or FOBs. The report sets forth our findings regarding the competitive dynamics of FOBs, and we hope that our recommendations will inform the legislative debate.

I note that the report does not address any specific bills. The Commission recognizes that legislators are balancing many different objectives, as they seek to craft a solution that best protects the public interest. The Commission has limited its recommendations to competition issues, which are our core area of expertise. We believe, of course, that this competition perspective is of critical importance in the FOB debate – which is why we are grateful to have been given, literally, a seat at this table today.

If Congress can create a balanced pathway for FOBs, and also pass legislation to eliminate "pay-for-delay" patent settlements between branded and generic companies in small-molecule markets, Congress will have taken substantial steps to ensure that all Americans have access to affordable, life-saving medicines. On behalf of Chairman Leibowitz, I commend the Committee for moving legislation to ban these patent settlements through the Consumer Protection Subcommittee last week.

Overview of Testimony

The report's basic premise is that competition between pioneer biologics and FOBs is likely to look much more like current competition between two or more branded drugs that

treat the same medical condition – for example, Enbrel and Remicade, which both treat rheumetoid arthritis. It will look less like current competition between branded and generic versions of a drug.

I will explain why the Commission reached this conclusion, and I will also identify some implications for legislation seeking to create an abbreviated regulatory approval pathway for FOBs.

Key Characteristics of the Biologics Marketplace

But first, I will begin by highlighting some important characteristics of the biologics marketplace.

As you know, the emergence of biologic drugs has dramatically improved the lives of thousands of Americans over the past few decades. For example, the biologic "*Herceptin*" is used to treat breast cancer, and an annual course of treatment costs about $48,000.

One way to reduce the costs of biologics would be to authorize the Food and Drug Administration (FDA) to permit follow-on biologics, or FOBs, to enter the market once a biologic drug's patents expire. However, there is no statutory or regulatory pathway to allow abbreviated FOB entry without the FOB applicant having to duplicate existing knowledge about safety and efficacy. This duplication represents an inefficient use of limited R&D resources. Also, as the FDA has explained, repeating all of the clinical trials raises ethical concerns associated with unnecessary human testing.

Elements of the Hatch-Waxman Act provide a model for reducing FOB entry costs and addressing ethical concerns. Hatch-Waxman does not require generic applicants to duplicate the clinical testing of branded drugs that already have been proven safe and effective. Hatch-Waxman has successfully reduced drug prices, broadened access, and hastened the pace of innovation. And if pay-for-delay settlements are prohibited, these benefits of Hatch-Waxman will be preserved.

But as the report describes, according to the FDA, there are key scientific differences between biologic and small-molecule drug products. Most notably, under Hatch-Waxman, the generic applicant must show that its product is "bioequivalent" to the branded drug product. This is important because it means that the product is identical.

In stark contrast, according to the FDA, biologic products cannot be perfectly duplicated – at least not based on current science. Technology is not yet robust enough to determine whether an FOB product is "interchangeable" with the pioneer product.

Current FOB legislative proposals reflect the complexities of biologics. They would permit FDA approval of an FOB drug that is *similar* to, but not an exact replica of, the pioneer biologic product. Under these proposals, the FDA could rely on its previous findings regarding the pioneer biologic drug's safety and efficacy, to the extent those findings also would be relevant to the FOB. An FOB manufacturer likely would save on some clinical testing expenses, which would reduce entry costs.

The Commission's Study Objectives

With that background in mind, let me turn to the Commission's report. The purpose of our study was to evaluate how FOB competition is likely to develop and evolve, paying particularly close attention to the differences between small-molecule and biologic drugs.

The study was coordinated by an interdisciplinary FTC team (headed by Mr. Wroblewski) that included not only pharmaceutical industry experts, but also patent lawyers and economists. As part of its inquiry, the Commission solicited two rounds of public comments, which attracted submissions from approximately 30 industry participants and other stakeholders.

In November 2008, the Commission conducted a public roundtable discussion that included over 30 panelists. The Commission also has examined European markets where FOB entry has occurred.

The Commission's Findings Regarding FOB Competition

In the interest of time, let me briefly summarize the four major reasons why FOB competition will not be like generic drug competition.

- First is the extraordinary cost and time necessary to develop an FOB, which will sharply limit the number of competitors who can afford to enter, and also will limit the discounts the FOB can offer in relation to the pioneer price.
    - FOB products are likely to take eight to ten years to develop, and their development likely will cost between $100 and $200 million each.
    - In contrast, small-molecule generic drugs typically take three to five years to develop, with product development costs of between $1 and $5 million, and much lower manufacturing costs as well.
    - In addition, it is expected to cost between $250 million to $1 billion to build a new biologic manufacturing plant.

- Second, follow-on entry will not radically erode the pioneer's market share.
  - In the small-molecule space, when lower-cost interchangeable generics enter, the branded firm soon loses most of its share as patients switch to generics.
  - But in biologics, a pioneer is likely to retain significant market share after FOB entry, largely due to the pioneer's first-mover advantage, the lack of interchangeability, no automatic substitution, and a smaller price discount.
- Third, the specialty pharmaceutical characteristics of FOBs are likely to further constrain the FOB entrant's ability to gain market share.
  - Specialty drugs are primarily injected or infused, and they are combined with ancillary medical services and products that require specialized training for proper handling and administration.
  - These factors will make it more difficult to switch from a pioneer to an FOB alternative.
- Finally, because biologics are provided in clinic-type settings as part of medical treatments, they are not purchased and reimbursed in the same manner as small-molecule drugs.

As a result of all of these factors, the Commission's report predicts that FOB markets are likely to develop with the following characteristics.

- FOB entry is likely to occur only in biologic drug markets with more than $250 million in annual sales.
- Only two or three FOB manufacturers are likely to attempt entry in competition with a particular pioneer drug product.
- These FOB entrants likely will not offer price discounts larger than 10% to 30% off the pioneer product's price. Although this discount is not as steep as with small-molecule generic drugs, it does represent millions of dollars in consumer savings for these very expensive products.
- Pioneer manufacturers are expected to respond by offering competitive discounts to maintain their market share. This price competition likely will increase consumer access and further expand the market.

- Without automatic substitution, FOB market share acquisition will be slowed. Pioneer manufacturers likely will retain 70% to 90% of their market share. This means that a pioneer firm will continue to reap substantial profits for years, even after entry by an FOB.

FOB market dynamics will contrast sharply with the market dynamics of generic drug competition, where lower-cost generic entry plus automatic substitution lead to rapid erosion of the branded drug's market share. When the first generic drug enters the market, it generally offers a 25% discount off the branded drug's price. As additional generic firms enter – and often there are eight or more of them – the price discounts reach as high as 80%.

Incentives That Support Innovation and Competition: Patent Protection Plus Market-Based Pricing

Given these likely dynamics of FOB markets, the Commission next asked whether any additional incentives will be needed to encourage FOB competition and foster ongoing biologics innovation. The report concludes that existing incentives – the same ones that motivate branded biologics – are sufficient. These two incentives are patent protection and market-based pricing.

Through patent protection and the resulting exclusionary rights – biotech firms increase their expected profits from investments in R&D. Patents thus foster innovation that would not otherwise occur.

Market-based pricing allows firms to charge prices that reflect the value of the drugs to consumers. By pricing at market rates, firms can recoup their substantial investments in biologic drugs. Prices also enable firms to receive accurate market signals about the value of developing particular biologic drugs.

Currently, pioneer drug manufacturers race against other firms to bring products to market, in both pharmaceuticals and biologics. This competition benefits consumers by accelerating the pace of innovation, and also through eventual price competition. Given that FOB competition is likely to resemble competition by another brand, FOB competition is likely to promote the same consumer benefits, without the need for any additional incentives.

Implications for FOB System Design

These findings have several implications for the design of an abbreviated approval system for FOBs. In the interest of time, I will briefly summarize three key implications. Mr. Wroblewski and I are happy to elaborate further during the question period.

- First, pioneer manufacturers are unlikely to need additional incentives to continue to innovate in the face of FOB entry, beyond existing patent protection and market-based pricing.

  - It appears that pioneer biologics are capable of being covered by numerous and varied patents, including manufacturing and technology platform patents.

  - There is no evidence that patents claiming a biologic drug product have been, or are likely to be, designed around more frequently than those claiming small-molecule products.

  - Market-based pricing – especially during the period of exclusivity granted by the patent system itself – provides strong incentives to innovate.

  - In light of these existing patent incentives, the Commission report concludes that no additional period of branded exclusivity is needed to spur the development of new drug products.

  - To the extent that drugs are unpatentable, an exclusivity period could be used to incentivize their clinical testing.

- A second implication is that it is unnecessary to implement special procedures to resolve patent issues between pioneer and FOB drug manufacturers.

  - The Hatch-Waxman procedures to trigger an early start of patent litigation made sense in the generic drug context, where there was a concern that generics would not be able to pay post-entry patent infringement damages.

  - But looking at the cost and complexity of bringing FOBs to market, it is likely that only well-funded firms will seek FOB entry, which will mitigate concerns about the enforceability of patent infringement judgments.

  - Moreover, special procedures are unlikely to succeed in raising and resolving all pertinent patent issues prior to FDA approval, and may create competitive problems.

- Third, FOB drug manufacturers are unlikely to need additional incentives to develop interchangeable FOB products, such as a marketing exclusivity period for the first FOB.

- If FOB competition will closely resemble brand-to-brand competition, then the incentives provided by market-based pricing should be sufficient, and there is no reason to risk delaying the entry of subsequent FOBs that are ready for market.

Conclusion

Again, thank you for the opportunity to present the Commission's report. Mr. Wroblewski and I will do our best to respond to your questions.