

FTC Follow-on Biologics Report Takes Hard Line against Exclusivity Periods and Patent Protection for Pioneer Products

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On June 10, the Federal Trade Commission (FTC) released its report, “Emerging Health Care Issues: Follow-on Biologic Drug Competition” (the Report). On June 11, Commissioner Pamela Jones Harbour testified on behalf of the FTC before the Subcommittee on Health of the U.S. House of Representatives Energy and Commerce Committee and presented the findings and recommendations in the Report. The Report examines the competitive effects of introducing similar versions of pioneer biologics, known as follow-on biologics (FOBs), and provides the Commission’s recommendations for legislation to create an FDA pathway for approval of FOBs.

The Report, issued by the Commission rather than only by FTC staff, is lengthy and detailed, comprising nearly 100 pages including appendices with more than 350 footnotes. It provides a detailed analysis of the likely functioning of an FOB market and its effects on biologics market competition. Notwithstanding the length and detail of the Report, its analyses lack depth in certain areas. Specifically, its analysis of the rationale for an exclusivity period, as well as of the absence of any need for special patent procedures to resolve disputes, and of the absence of the need for protection of investment in new biologics, are surprisingly cursory. The Commission’s predominant focus on the potential for cost savings of an FDA regulatory approval pathway for FOBs, and the absence of a balanced discussion of the impact on innovation of the absence of exclusivity protections, may well result in the Report having less influence on eventual Congressional resolution of these issues than may have been expected.

The FTC strongly favors an abbreviated FDA approval process for FOBs. In evaluating the future FOB market, the FTC contrasted the differences between FOBs and generic versions of small-molecule drugs, for which an FDA regulatory approval pathway has been in place since the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act in 1984. The Report suggests that competition between the pioneer biologic and an FOB is more likely to resemble the dynamics of brand-to-brand competition than that of the brand-generic competition that currently exists for small-molecule drugs. As a result, the FTC concluded that current patent protection and general market incentives will continue to provide innovation incentives for pioneer biologics and that an extended exclusivity period of 12 to 14 years is unnecessary. Further, the FTC did not support any special procedures to resolve patent disputes or any special incentives for FOB drug manufacturers to enter the market, such as the 180-day exclusivity period provided to the first filer for a generic drug.

The Report provides a detailed outline of the FTC’s view of the likely nature of competition in a biologics market with FOBs. The Report concludes that the high entry costs associated with developing

FOBs will limit the number of competitors in the market to likely only two to three competitors for a particular pioneer biologic drug, compared to 10 or more generic entrants seen in many markets for conventional drugs. The Report states that FOBs are likely to take eight to 10 years to develop, and will likely cost between \$100 and \$200 million. In contrast, generic drugs take three to five years to develop and cost only between \$1 and \$5 million. It is unclear how the FTC derived its time or cost estimates, since the FDA's testing requirements for approval for FOBs have yet to be established and can be expected to vary widely in complexity depending on the therapeutic class involved.

The Report predicts that FOBs will gain only 10%–30% of the market from the pioneer biologic when they enter the market because FOBs will not be designated as therapeutically equivalent to the pioneer biologic. As a result, there will be no automatic substitution and FOB manufacturers will have to market and negotiate sale of their products separately with purchasers. Further, the lack of therapeutic equivalency may also raise concerns about safety and efficacy differences with the pioneer, presenting additional difficulty in gaining market share from the pioneer. Share may also be limited because most biologics tend to be specialty drugs that are primarily delivered to patients in hospitals and other supervised settings. The costs of switching to an FOB, such as restocking inventory and retraining hospital staff, will likely also be a barrier to entry.

Based on these predicted dynamics of competition between pioneer biologics and FOBs, the FTC concluded that the market-based pricing and patent protection incentives that currently protect competition among pioneer biologics would be sufficient, and that additional provisions to delay FOB entry or restrict competition are not necessary to foster pioneer drug innovation.

The FTC specifically rejected a 12- to 14-year exclusivity period as unnecessary to protect innovation by pioneer biologics manufacturers, asserting that market-based pricing and patent protection offer sufficient incentives to develop new biologics. The FTC relied on its conclusion that FOBs are unlikely to be sold at steep discounts or to take significant market share from the pioneer biologics.

The FTC argued that: “The potential harm posed by such a period is that firms will direct scarce R&D dollars toward developing low-risk clinical and safety data for drug products with proven mechanisms of action rather than toward new inventions to address unmet medical needs,” and that such an extended period thus “risks overinvestment in well-tilled areas.” The Commission's assumptions are dubious, however, in view of both the nature of biologics products, the diseases and conditions against which they are primarily targeted, and the high costs of their development. The cost for development of pioneer biologics products was estimated by the Tufts Center for the Study of Drug Development to be on average \$1.2 billion per product in 2006. Considering this, the absence of a sufficient exclusivity period and other protections may well result instead in underinvestment and a consequent reduction in innovation, to the detriment both of consumers and the competitiveness of one of the nation's leading knowledge-based industries.

The FTC also takes the position that special procedures to resolve patent disputes between pioneer and FOB manufacturers prior to receiving FDA approval are unnecessary to encourage FOB entry. Although special processes are provided under the Hatch-Waxman amendments to resolve patent infringement litigation regarding generic drugs, the FTC views such protections as unnecessary in the biologics context, stating that, since FOB manufacturers are likely to be many of the same companies that manufacture pioneer biologics, “they will have the expertise and resources necessary to assess whether to launch their product before any patent infringement litigation is resolved, just as they do with a branded pioneer drug.” The FTC noted further that “FOB manufacturers are highly unlikely to offer

steep discounts that could jeopardize their ability to pay patent damages.” The Commission fails to consider, however, that disputes over patentability of pioneer drugs have been both widespread and uncertain in outcome. It also does not consider that the incentive to innovate is reduced when patent challenges are thus made easier to pursue in the biologics context as compared to that for generic drugs.

The Report provides considerable information and useful analyses of the likely structure and competitive dynamics of a future marketplace with FOB products. However, the Commission’s cursory assessment of the dangers to continued innovation of pioneer biologics by not providing an adequate period of exclusivity, or appropriate special procedures regarding patent challenges, likely will not help bridge the gaps between the two bills being debated by Congress to establish a pathway for FDA regulatory approval for follow-on biologics.

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