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FTC ENTERS THE DEBATE OVER FOLLOW-ON BIOLOGICS

BACKGROUND

The Hatch-Waxman Act, enacted in 1984, allows generic drug manufacturers to get Food and Drug Administration (FDA) approval by relying on the safety and efficacy data of their competitors—innovators or brand drug manufacturers. The generic drug must be identical to the innovator's drug. The Hatch-Waxman Act established procedures for patent dispute resolution in advance of commercial launch of a generic drug.

Congress is now considering similar regulatory programs for the biotechnology sector. Unlike small molecule drugs, biologics are made from living organisms. As a result, companies cannot typically design and produce identical versions of biologic products. Congress is now considering bills that would allow manufacturers of follow-on biologics (FOBs) or “biosimilar” products to get FDA approval using a competitor's safety and efficacy data.

The Federal Trade Commission (FTC) held hearings on competition policy and biologics, received public comments from industry stakeholders—drug manufacturers, health insurers, pharmacy benefit managers, and consumer groups—and recently published a report.¹

ANALYSIS

The FTC report analyzes the likely market impact of FOBs, the role of patent protection and incentives for innovation, the patent dispute resolution process, and the competitive effects of a marketing exclusivity period for manufacturers of FOBs.

Data Protection Period. The pending biologics bills establish data exclusivity or data protection periods ranging from 5 to 14 years. The data protection period is the time from when the innovator receives FDA approval of a new biologic until a competitor proposing to make a “biosimilar” product can obtain FDA approval by relying on the innovator's safety and efficacy data. In other industries, this information is treated as trade secrets and cannot be used by rivals seeking to replicate a product.

Several empirical analyses conclude that the data protection period of the Hatch-Waxman Act (5 years) may be inadequate for biologics and that the data protection period should be 12-14 years for recoupment of R&D investment. The FTC report questions assumptions behind the empirical analyses calling for a longer data protection period. The report does not, however, recommend a particular time period for data protection.

The R&D economics and marketplace conditions for biologics differ from small molecule drugs. It is important to account for these differences in considering the particular data protection time period.

¹ FTC, Emerging Health Care Issues: Follow-on Biologic Drug Competition, June 2009.

It is also important to account for differences in enforcement of biologic patents relative to small molecule drug patents. FOBs will be similar, but not identical, to the patented product. Thus, designing around to avoid infringement may be easier for similar FOBs compared to identical small molecule drugs. Manufacturing or process patents play a greater role in biologics compared to small molecule drugs and may provide a limited form of protection for certain biologics. These conditions, as well as recent developments at the U.S. Patent and Trademark Office and at the Federal Circuit, have increased uncertainty as to the scope and enforceability of biologic patent claims and may increase the need for a meaningful data protection period.

Patent Dispute Resolution. A key policy underlying the Hatch-Waxman Act is that patent disputes should be resolved in advance of commercial launch of generic products. An at-risk launch can result in large damages liability for the generic drug manufacturer. Certainty in advance of commercial launch also benefits patients, prescribing physicians, and other stakeholders who may suffer from a disruptive product recall.

The comments received by the FTC from a diverse range of industry participants favored advance dispute resolution for FOBs. Commentators, including companies planning to manufacture FOBs, explained that advance dispute resolution is needed to provide certainty, thereby contributing to greater investment in the sector. The biologic bills all allow for advance dispute resolution. Nevertheless, the FTC opposed advance dispute resolution for FOBs, contending that FOB competition will resemble brand-to-brand competition.

Brand-to-brand competition, however, does not involve products determined by the FDA to be “biosimilar” or highly similar to the innovator product. There is likely a greater risk of patent infringement for products found to be “biosimilar” to a patented product than in the case of brand-to-brand competition. A timely patent dispute resolution process may provide certainty and thus increased investment, as has been the experience for small molecule drugs under the Hatch-Waxman Act.

Marketing Exclusivity. The Hatch-Waxman Act provides a 180-day marketing exclusivity period for the first generic manufacturer to apply for FDA approval. The FTC in its report opposed use of a marketing exclusivity period for FOB manufacturers. It found that there are ample financial incentives for FOB manufacturers without a marketing exclusivity period. The FTC further argued that a marketing exclusivity period can create a lottery dynamic, leading to excessive, high risk patent challenges.

NEXT STEPS

Congress is continuing to evaluate a regulatory framework for FOBs. New legislation will likely establish FDA standards for approval of FOB products, the period for protection of innovator data, procedures for timely enforcement of patents covering new biologics, and any marketing exclusivity period for FOBs. The debate should account for the particular characteristics of biologic patents and the need to promote patient welfare through continuous development of safe and effective new products and treatments.

FOR FURTHER INFORMATION:

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