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Client Alert

House Introduces Legislation On Generic Biologics Approval Process

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On March 11, 2009, House Energy and Commerce Chairman Henry Waxman (D-CA) and Representatives Frank Pallone (D-NJ) and Nathan Deal (R-GA), Chairman and Ranking Member of the Energy and Commerce Subcommittee on Health, introduced H.R. 1427, the Promoting Innovation and Access to Life-Saving Medicines Act. If passed, this legislation would create an abbreviated process for the Food and Drug Administration ("FDA") to approve generic biological products, similar to the process that the 1984 Hatch-Waxman Act provides for an abbreviated approval process for generic versions of traditional small molecule or chemically-synthesized pharmaceutical drugs.

Biosimilars and Biogenerics

The proposed legislation distinguishes between "biosimilar" and "biogeneric" products. An applicant for approval of a biosimilar product would need to demonstrate that there are no clinically meaningful differences between the branded and the generic biologics. The applicant also would be required to demonstrate that the two products are highly similar in molecular structure and, if known, share the same mechanism of action. Additionally, the applicant would have an opportunity to establish that a product is a biogeneric, that is, "interchangeable" with the originally approved product. If the FDA agrees, the generic biologic drug could be substituted for the approved product, subject to state law requirements. The FDA would have discretion to determine what clinical studies would be required to establish safety, efficacy and interchangeability, and to require post-market studies. The first applicant to demonstrate interchangeability would be granted 180 days of marketing exclusivity.

The legislation also would allow an applicant to submit an abbreviated application for a product that is different from, or incorporates a change to, the original product if the applicant is able to demonstrate that the product is safe and effective. The legislation also would impose user fees on generic biologic drug applicants.

Data Exclusivity

Similar to the Hatch-Waxman Act, H.R. 1427 would provide data exclusivity periods of five years for an original product with a novel molecular structure and three years for a modification of a previously approved product. These exclusivity periods could be extended for up to one year if an applicant conducts pediatric studies or demonstrates that the product can be used for a new indication.

Patent Infringement, Rights and Remedies

With respect to patents, rather than an Orange Book-type listing as required under the Hatch-Waxman Act, the legislation would permit the biosimilar applicant to send a request for patent information to the holder of the

approval for the reference product. The approval holder would then be required to provide a list of patents that relate to the product within sixty days. The applicant could provide notice to the approval holder, the patent owner, and the Federal Trade Commission of the factual and legal bases for a belief that one or more of the patents are invalid, unenforceable or would not be infringed by the commercial sale of the product for which approval is sought. The proposed legislation is clear that these procedures are within the discretion of the applicant for the approval of the generic biologic product. The applicant would not be required, and could not be compelled, to send the request for patent information or the notice.

Within forty-five days of receipt of the notice, the holder of the approved application or the patent owner could bring an action for infringement. If the action is brought after forty-five days, or within the forty-five day period but is not prosecuted in good faith, the sole and exclusive remedy upon a finding of infringement would be a reasonable royalty. If a patent is not timely disclosed in response to a request for patent information, the patent owner or licensee would be precluded from bringing an action for infringement of the patent.

The legislation also would preclude the holder of the approved application from bringing a declaratory judgment action against the applicant with respect to any patent not identified in the notice. With respect to patents identified in the notice but for which suit has not been brought with forty-five days, the applicant could bring an action for declaratory judgment that the patent is invalid or would not be infringed by the biologic product for which approval is sought.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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