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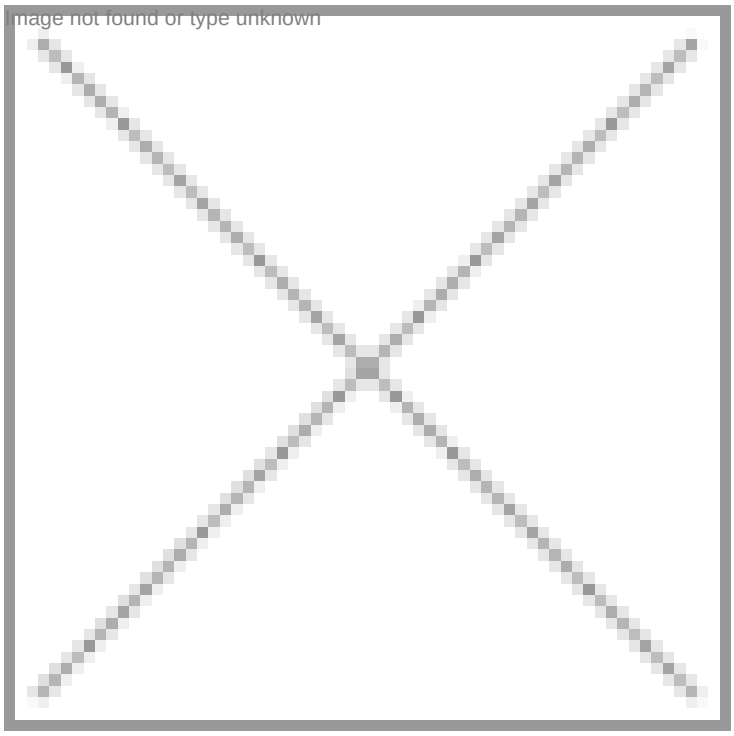
06 May 2009 | News



Waxman Biosimilars Bill, implications for the biotech industry

On March 11, 2009, Henry A Waxman (D-Calif.), chairman of House Committee on Energy and Commerce; Frank Pallone (D-N J), Nathan Deal (R-Ga), and Jo Ann Emerson (R-Mo), introduced the bipartisan "Promoting Innovation and Access to Life-Saving Medicine Act" (H R 1427) that is intended to give the US Food and Drug Administration (US FDA) the authority to approve biosimilar versions of biotech drugs.

The bill provides the approval of biosimilar products that are defined as "no clinically meaningful differences between the biological product and the reference product" as well as "interchangeable" biosimilars, defined as a product that can be "switched one or more times" with the reference product "without an expected increase in the risk of adverse events". The bill also provides incentives for brand companies to develop new therapies. Specifically, similar to the current structure for approved drugs, the bill would provide five years of exclusivity for a novel molecular structure before any biosimilar could be approved. The bill also provides three-year exclusivity for certain modifications of a previously approved product (such as a new condition of use) and a six-month pediatric exclusivity period. These exclusivity provisions are a change in direction for Waxman, as his biosimilar bill put forth in the 2007 Congress (H R 1038) provided no exclusivity for brand biologic products. Finally, Waxman's bill also provides first biosimilar applicants with at least six-month exclusivity period if an interchangeable biosimilar product is approved. Senator Susan Collins (R-Maine) announced that she will co-sponsor the senate version of the bill, expected to be introduced soon by Senators Charles Schumer (D-N.Y.) and Sherrod Brown (D-Ohio). The bill provides the approval of biosimilar products that are defined as "no clinically meaningful differences between the biological product and the reference product" as well as "interchangeable" biosimilars, defined as a product that can be "switched one or more times" with the reference product "without an expected increase in the risk of adverse events". The bill also provides incentives for brand companies to develop new therapies. Specifically, similar to the current structure for approved drugs, the bill would proviKiran.gifde five years of exclusivity for a novel molecular structure before any biosimilar could be approved.

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Patent disputes addressed

The bill would establish a procedure for resolving patent disputes before a biosimilar is approved, and would establish penalties for failure to litigate patents in a timely manner. It also presents patent dispute provisions similar to those proposed in H R 1038.

Under the current bill, a biosimilar applicant has discretion to send a written request for patent information to the BLA holder. Within 60 days, the BLA holder must provide the applicant a list of all patents relating to the approved product, including patents claiming the biological product, formulations, and methods of using and manufacturing the product, even if the claimed methods for manufacturing are not used to make the reference product. The BLA holder must update the patent list for two years after receiving the request. At any time thereafter, the biosimilar applicant may provide notice of the biosimilar application with respect to one or more patents, either listed by the BLA holder or not. This notice, which the applicant sends to the BLA holder, patent owner, and the Federal Trade Commission (FTC), must include a detailed statement of the factual and legal basis for applicant's belief that the listed patents are invalid, unenforceable, or not infringed.

Within 45 days of receiving the biosimilar applicant's notice, the BLA holder or patent owner may sue for patent infringement, but only with regard to patents listed in the notice. If the BLA holder or patent owner does not file suit within 45 days, the biosimilar applicant may bring an action for declaratory judgment that the patents are invalid or not infringed. If the BLA holder or patent owner sues after 45 days, the BLA holder or patent owner is entitled to damages only in the form of reasonable royalties in the event that a court finds infringement by the applicant. The bill also states that if a patent owner or licensee fails to disclose a patent in response to an applicant's request for patent information in a timely manner, the patent owner or licensee may not bring an action "under this title" for patent infringement.

Major battle looms

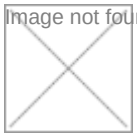
The Waxman bill has broad support from varied groups, including the Generic Pharmaceutical Association (GPhA), which "applauded" the introduction of the bill; Consumers Union, American Association of Retired Persons (AARP), National Organization for Rare Disorders, Coalition for a Competitive Pharmaceutical Market, General Motors, Express Scripts, Inc., National Business Group on Health, American Federation of Labor and Congress of Industrial Organizations(AFL-CIO), and Service Employees International Union (SEIU). However, the Biotechnology Industry Organization (BIO) described the Waxman bill as "filled with potholes," and has previously stated its position that a 14-year exclusivity period is necessary to provide adequate protections for continued research and development of novel biologic products.

Other competing bills

Representative Anna Eshoo (D-Calif.) and House Committee on Energy and Commerce ranking member Joe Barton (R-Texas) are expected to reintroduce the legislation, the "Pathway for Biosimilars Act" (PBA), that would award brand companies 12 years of protection from generic competition and an additional two years of protection for an approved new indication, which is a "significant improvement" over other marketed products. The PBA also would provide six-month exclusivity for study in pediatric populations. The PBA does permit FDA to determine interchangeable products, and would grant at least two years of exclusivity for the first approved interchangeable biosimilar product. The PBA places requirements on FDA to issue proposed guidance documents for public review, issuance of final guidance prior to waiving clinical trials for immunogenicity of any biosimilar, prior to the approval of any interchangeable biosimilar; and initiate a proceeding for issuance of a guidance with respect to a product class prior to accepting a biosimilar application for review. Further, such application may not be approved until such final guidance is completed. Publication of such guidance would likely have the effect of slowing the submission and review process of biosimilars.

The PBA differs from the current Waxman bill in several respects as it relates to patent dispute provisions. For example, in the PBA, relevant patents include those having claims directed to the biosimilar product, material used in the product manufacture or methods of treatment, but not methods of manufacturing the product. In addition, the biosimilar applicant does not have discretion to act under the PBA, but instead must provide the bond ledger account (BLA) holder a copy of the biosimilar application and product and production information. Within 60 days of receiving the application and information, the BLA holder must provide the applicant a list of relevant patents. The PBA also requires FDA to publish a notice within 30 days of accepting a biosimilar application. Any time after FDA publishes its notice, a third party patentee may provide notice to the biosimilar applicant identifying at least one patent. Within 30 days of receiving that notice, the biosimilar applicant also must send the patentee a copy of the patent application and product or production information. Within 90 days thereafter, the patentee must provide a list of relevant patents to the applicant. The BLA holder or patentee must explain in writing why a listed patent would be infringed. Within 45 days of receiving the list, the biosimilar applicant must send a written statement regarding each listed patent that either states that the applicant will not market until after the patent expires, or provides an

explanation why the patent would not be infringed, or is invalid or unenforceable. Within 60 days of receiving the patent list the BLA holder or patentee may sue for patent infringement.
Also in contrast with the Waxman bill, the biosimilar applicant may only bring a declaratory judgment action on the date thatis either three-year before the 12-year exclusivity period for the brand company or 120 days after the submission of explanation by the applicant.



A look ahead
Given the broad disagreement on major components of the bill between both industry and congressional members, negotiation and compromise will still be necessary in order to pass this complex legislation. With other pressing issues before the House Committee on Energy and Commerce, including universal health care and climate change, it remains to be seen when this bill will gain the full attention of the committee. In addition, H R 1427 was referred to the House Committee on the judiciary, so there is more than one committee playing a role. On the senate side, compromise on a bill will be essential, as procedural hurdles in the senate ensure that passage will require 60 votes. Thus, although there appears to be a consensus that biosimilar legislation will pass this congressional session, this is simply the first, albeit important, step in the process. Obama administration has voiced support for biosimilar legislation, and as a candidate, Obama supported shorter exclusivity periods for branded biologics than those proposed by BIO, but has yet to weigh in on specifics involving the bills.

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