



FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE COMMISSION D'ÉTUDE ET DE TRAVAIL (CET)

7. The reference product the applicant is relying on has been withdrawn because safety issues existed
8. Untrue statements or facts have been included in the application

In view of the fact that interchangeable biological products generate the greatest benefit in regards to reductions in costs; this bill would provide incentives to promote development of interchangeable products. These incentives include permission for product labels to state that the product is interchangeable with the reference product, and some market exclusivity if the applicant is the first to develop a product that is interchangeable with the reference product.

The Secretary has eight months after submission of the application, or 180 days after the application has been accepted for filing, to either approve or disapprove the application. The bill has provisions to prevent applicants who file frivolous petitions from delaying the approval of the comparable drugs by forcing the Secretary to take action by the final action date regardless of whether or not a third party has made a request. The bill also prevents a Court from entering an order enjoining the Secretary from taking final action. Additionally, the Secretary must report to Congress any failure to take final action by the due date or any extension of the final action.

To ensure early resolution of patent disputes, this bill adds disincentives for late patent suits through the limitation of infringement actions and remedies (this is done on a case by case basis). Within 60 days upon a request from an applicant of a comparable product, the owner of the reference product must provide a list of all patents related to their product and must update the list for the next two years within 30 days of issuance of a new related patent or license. The owner of the reference product may demand payment up to \$1,000.00 for providing this service. If the comparable biological product applicant elects to notify the owner of the reference product that they intend to challenge any patents from the list they must provide a statement, which includes the facts and legal basis for the invalidity claim. Through this bill, the laws would be amended to deem any

patent not disclosed in response to a request, unenforceable against the applicant.

Major Critiques from the Biotechnology Industry

The Biotechnology industry is concerned that the bill is lopsided towards the FOB applicants for several reasons. They argue that the bill should incorporate provisions to ensure substantial data exclusivity that is concurrent with the patent term of the biologic product to ensure that the biologic product innovators are able to receive an appropriate return.

First of all, they point out that the "same" under the 1984 Hatch-Waxman Act, to a more lax "highly similar" standard. As a result, a FOB may be similar enough to receive the abbreviated regulatory approval while different enough to avoid a patent infringement claim. A FOB product may get on the market well in advance of expiration of the patent of the reference product, thus undermining the incentives to invest in innovations. Biologic products are especially susceptible to the laxer standard because most biologic products are large and large molecules allow more possible ways of altering the products themselves or the process of manufacture.

Second of all, because of current limitations on patentability of naturally occurring substances, many biological products are protected by process patents that may be easier to get around.

Third of all, while patents on small molecules pertinent to generic drugs affected by the 1984 Hatch-Waxman Act can be protected by a claim covering a whole class of related molecular structures, patentable biotechnology inventions usually are narrowly claimed by specifying a single protein or nucleotide sequence.

The currently proposed bill does not include a data exclusivity protection while the



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1984 Hatch-Waxman Act does. Congress recognized in the passage of the Hatch-Waxman Act that patent protection alone is not enough to provide innovators with sufficient market exclusivity to serve as an incentive for continued innovation. Furthermore, without adequate data exclusivity protection, biologic product innovators, which are mostly small privately funded start-ups, may not be able to afford expensive advanced development, which is critically important to preventive healthcare and the U.S. economy.

Attached are:

- 1) A detailed outline of the Act available from the website of Representative Waxman
- 2) A copy of the proposed legislation.
- 3) A copy of each of the following from the Biotechnology Industry Organization (BIO):
 - a. BIO White Paper
 - b. BIO press release
 - c. BIO fact sheet