FISH & RICHARDSON

Table: Comparison of H.R. 1427, H.R. 1548, and FDCA §505

Provision	Waxman Bill: H.R. 427	Eshoo Bill: H.R. 1548	FDCA §505
Biosimilarity	"No clinically meaningful differences." Info showing "highly similar molecular structural features" also needed. Based upon non-clinical studies and any necessary clinical studies or other safety studies. The need for any of these studies is at the FDA's discretion. Any clinical studies should be designed to avoid duplicative and unethical clinical testing.	"Highly similar to the reference product." Requires non-clinical studies and clinical studies, including an assessment of immunogenicity. The FDA may waive one or more of these requirements if they are unnecessary, but the clinical assessment of immunogenicity can only be waived if the FDA publishes a guidance supported by data.	Not applicable to biologics. As to small molecule drugs, requires the same active ingredient, plus a showing of bioequivalence.
Pioneer Exclusivity	5 years for a new biologic, 3 years for a supplemental indication or subpopulation, with possible 6 month extensions.	Minimum of 12 years, up to 14.5 years.	5 years for a new chemical entity; 3 years for supplemental indication or subpopulation; 6 additional months for pediatric exclusivity.
Generic Exclusivity	180 days generally but potentially sooner based on the course of patent litigation, awarded to first product to be found interchangeable.	2 years awarded to first product to be found interchangeable.	180 days subject to forfeiture, awarded to the first to file an ANDA with a Paragraph IV certification.
Patent Listings/Notifications	Upon a request of a generic applicant at any time, pioneer must provide a notification of all relevant patents to which it has rights to.	After generic applicant discloses information about its product, pioneer discloses a list of relevant patents. Third parties may also provide notice of their patent rights.	FDA Orange Book.

Provision	Waxman Bill: H.R. 427	Eshoo Bill: H.R. 1548	FDCA §505
Patent Certifications	Optional: Generic applicant may provide a notice that any patent disclosed by the pioneer is not infringed, invalid, or unenforceable. Pioneer may bring suit in 45 days if given such a notice.	Mandatory: At least one type of certification required for each identified patent. Pioneer/third party may bring suit within 60 days for certain benefits.	Mandatory: At least one type of certification required for each Orange Book-listed patent. If the generic applicant makes a paragraph IV certification, the pioneer may bring suit within 45 days to obtain a 30 month stay of approval.
Declaratory Judgment Actions by Generics	Permitted for any patent disclosed by the pioneer in its notification.	Permitted for any patent for which the generic provides an explanation of non-infringement, invalidity, or unenforceability and not more than 3 year before pioneer exclusivity expires.	Permitted.
Stay of Approval of Pending Patent Litigation	None.	Not specified. The FDA may not approve if a court determines patent is infringed before pioneer exclusivities expire.	30 months.
Other FDA Administrative Matters	Certain provisions to prevent delays caused by the filing of citizen petitions with the FDA.	The FDA is required to undertake a scientific review and issue a guidance before making certain interchangeability determinations or waiving certain clinical tests.	N/A