WINSTON & STRAWN LLP

What Are the Patent Litigation Differences Between the BPCIA and Hatch-Waxman Act?

There are fundamental differences between the abbreviated approval processes to obtain FDA approval for biosimilars and generic drugs as those processes relate to patent litigation.

HATCH-WAXMAN ACT	BPCIA
Patents covering the brand name drug are listed in the **Orange Book**.	There is no Orange Book. Instead, patents that cover biosimilars are identified under the provisions of the BPCIA in a process known as the "patent dance."
A generic drug applicant can make certain certifications to the brand name company with its Abbreviated New Drug Application (ANDA) to the FDA for marketing approval. A **paragraph IV certification** indicates that the generic drug applicant believes the Orange Book-listed patents are invalid, unenforceable, or not infringed.	There is no paragraph IV certification. In fact, there is currently no requirement that the biosimilar applicant even notify the sponsor when the applicant submits an aBLA.
Receipt by the brand manufacturer of the generic manufacturer's **notice letter** typically triggers a lawsuit within 45 days.	There is no requirement that a biosimilar applicant provide a notice letter to the sponsor, but patent contentions are exchanged under the "patent dance."

HATCH-WAXMAN ACT	BPCIA
If the brand name manufacturer sues the generic drug applicant within 45 days of receipt of the notice letter, the Hatch-Waxman Act provides for a **30-month stay** of FDA approval of the generic drug applicant's ANDA.	There is no 30-month stay of FDA approval for a biosimilar drug application.
Process patents are not listed in the Orange Book.	Process patent directed to manufacturing biosimilars currently make up a large portion of patents litigated under the BPCIA.

WHAT IS CONSUMER FRAUD?