Comparison of the Hatch-Waxman Act and the BPCIA

Many attorneys are familiar with provisions of the Hatch-Waxman Act but not with the Biologics Price Competition and Innovation Act (BPCIA). The chart below compares key provisions of the two acts and should prove useful to many.

	HATCH-WAXMAN ACT	BPCIA
Patents identified	Orange Book listing of patents (no process patents), certified against by generic applicant (Para. IV certification)	No patent listing, but private exchange of patent information ("patent dance"), which is optional
Application types	ANDA or § 505(b)(2) "paper NDA"	Biosimilar license application/biosimilar interchangeable license application
FDA stay	Automatic 30-month stay of FDA approval upon filing suit	No automatic stay of FDA approval
Sponsor exclusivity	Five-year marketing exclusivity for new active moiety commencing on FDA approval	Twelve-year marketing exclusivity for new biological structures commencing on FDA approval: ▪ But if application is filed by same Sponsor or manufacturer of the Sponsor's product (or a licensor, predecessor-in-interest or a related party), the changed biological structure must also result in: – A change in indications, route of administration, dosing schedule, dosing form, delivery system, delivery device or strength, or – A change in safety, purity, or potency
Sponsor exclusivity	Three-year marketing exclusivity for new indication or dosage form	No additional exclusivity for same biological structure
Generic exclusivity	ANDA—First to file and to certify under Para. IV (challenging Orange Book patents) receives 180 days of market exclusivity against later-filed ANDAs ▪ Can be forfeited under various conditions ▪ § 505(b)(2)—no 180-day exclusivity	No exclusivity for biosimilar. First interchangeable biosimilar receives exclusivity against any subsequent interchangeable license application for any condition of use in the Sponsor's product until the earlier of: ▪ One year after commercial marketing by first biosimilar; ▪ Eighteen months after court decision (appellate court, if appealed) on all patents or dismissal of action against first biosimilar; or ▪ Forty-two months after first biosimilar approval if litigation is still pending, or 18 months after first biosimilar approval if no suit is filed (i.e., where first biosimilar fails to market)
Pediatric exclusivity	Pediatric exclusivity adds 6 months to all exclusivities	Same
Filing limitation	ANDA cannot be filed until 5 years after Sponsor's FDA approval of new active moiety, but can be filed after 4 years if accompanied by a Para. IV certification	Biosimilar application can be filed 4 years after Sponsor's FDA approval

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