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New Law Establishes Purple Book Patent Disclosure Requirement

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Signed into law on December 27, 2020, the Biological Product Patent Transparency Act (42 U.S.C. § 262(k)(9)) requires biological reference product sponsors to provide to the US Food and Drug Administration within 30 days of disclosure the patent lists that they serve on biosimilar applicants pursuant to sections (*l*)(3)(A) or (*l*)(7) of the Biologics Price Competition and Innovation Act (BPCIA). The expiry date for each listed patent also must be provided. Disclosed patents will be made publicly available in the Purple Book beginning in June 2021.

The act is a step toward the Orange Book model, which requires identification of covered patents that may be asserted in an Abbreviated New Drug Application. The act therefore may provide efficiencies for some biosimilar applicants:

1. The new disclosure requirements will have no impact on a first biosimilar applicant for a given product. That first applicant will, as before, enter the pre-litigation patent list exchange armed only with information gleaned from its own diligence.
2. For second or later biosimilar applicants, the disclosures somewhat reduce the risk that the patent dance results in the surprise identification of patent rights about which the biosimilar applicant was unaware.
3. The Purple Book's patent lists will be most informative about patents that are difficult to uncover in a freedom-to-operate analysis, such as patents that have been exclusively licensed or that cover manufacturing processes, platform technologies, cell lines or ingredients used in manufacturing.
4. Over time, these Purple Book disclosures may also inform biosimilar program development and launch strategies across biosimilar products where manufacturing processes, inputs or platform technologies overlap.

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