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An Early Holiday Present for Generics? Legislation Requiring Greater Disclosure by Brands Passes the Senate

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Earlier this month, two bills intended to promote generic competitiveness by presenting a clearer idea of the patent landscape covering reference products passed the full Senate, albeit with amendments. These laws, if enacted, will require brand pharmaceutical companies to submit more information about their innovator products.

Potential Changes to Orange Book Listing Requirements for Non-Biologics Drugs

As part of its current obligations, an innovator product manufacturer must submit to the FDA the patent number and expiration date of any patents that claim the drug or a method of using the drug. The FDA then performs the ministerial function of listing the information in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the Orange Book. The Hatch-Waxman Act permits generic manufacturers to file a counterclaim to delist a patent that they believe is improperly listed. Over the years, FDA has issued technical regulations expanding on the requirements, which under statute, are relatively sparse. However, there has been some uncertainty regarding what patents must be listed—especially in the case of drug products with innovative delivery systems.

The Orange Book Transparency Act of 2020, H.R. 1503, seeks to codify certain existing regulations and bring some certainty to the process. First, the Orange Book Act provides greater clarity on the types of patents a brand company must list. Currently, the relevant statutes require submission of patent information for "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug" that could be asserted based on the manufacture, use, or sale of the drug. The Orange Book Act would alter that language to require submission of patent information for patents that claim the drug substance (active ingredient), the drug product (formulation or composition), or a method of use that is included in the application (*i.e.*, a method of use that corresponds with an approved indication/use code). All other patents—*e.g.*, patents that cover off-label use—must not be listed.

Second, the FDA would be responsible for "specify[ing] any exclusivity period that is applicable," including the 180-day exclusivity period for first-to-file applicants.

Finally, the Orange Book Act codifies certain existing agency requirements. Under current FDA

regulations, brand manufacturers are required to promptly request delisting if they determine that a patent no longer qualifies or its relevant claims are invalidated, and within 14 days if court-ordered. The Orange Book Act would codify the duty on brand manufacturers to remove listed patents within 14 days—rather than "promptly"—when any claim of a listed patent "has been cancelled or invalidated pursuant to a final decision" by the Patent Trial & Appeal Board or a court once it is unappealable. This quick turnaround time of communicating to the public which patents have been found invalid will be key to giving generics an advantage in developing generic products and patents covering branded drug products invalid. The Orange Book Act includes a 30-day period for a brand manufacturer to list a patent after issuance; this requirement mirrors already existing FDA regulations.

While commentary surrounding the bill has suggested that the Orange Book Act will bring major changes in transparency to help generic brands, in reality, it appears unlikely to have a significant impact on either brand or generic companies. As currently drafted, the new language implements minimal changes, instead largely codifying existing regulations. The new 14-day requirement to remove invalidated patents from the Orange Book may be useful for the Orange Book's accuracy, but it does little to assist generic manufacturers who can already quickly determine through other means whether listed patents have been invalidated.

Perhaps the provision with the most uncertain effect is publication of 180-day exclusivity in the Orange Book. Until now, companies have long sought to read tealeaves to determine which ANDA filers had the potential for exclusivity. So making that information known should promote a market dynamic of early settlement with generic filers without exclusivity, and perhaps decreased cooperation amongst potential first filers who will have a clearer picture of the competitive landscape. That said, it is unclear—especially for cases with several potential first-filers—how both brand and generic manufacturers will react to the more transparent environment.

Biologics Products: Adding One More Step to the Patent Dance

For biologics products, different rules apply—especially after March 2020, when biologics drugs previously listed in the Orange Book were removed. Currently, biologics drugs (and their biosimilar analogues) are listed in the *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, known as the Purple Book. Given the sometimes hundreds of patents that can cover aspects of a biologic drug and its manufacture, biologics manufacturers are currently not required to list any patent information in the Purple Book. That, however, may change in a limited way should the "Purple Book Continuity Act of 2020," H.R. 1520, become law.

Though most of the law already codifies existing practice, the major difference would be the requirement imposed on biologics license holders in submitting patent information. Under the Biologics Price Competition and Innovation Act, biologics license holders and companies seeking to market a biosimilar product engage in a statutorily proscribed exchange of information about patents that could be asserted in subsequent litigation. That exchange, except as revealed in subsequent court filings, has been private. The Purple Book Act seeks to change that by making the list of patents provided by the reference product sponsor during the dance available to the public at large through required submission to the FDA. That said, the Purple Book Act does not require, in the absence of a "patent dance," the submission of any patent information.

Similar to the changes to the Orange Book, the proposed changes to the Purple Book are likely to have only a minimal impact. While the bill puts a new burden on brand manufacturers to list their patent information for public availability, the disclosure only includes patents that have already been

identified and exchanged between parties in a BPCIA pre-litigation exchange. In light of the timing of this exchange process, it may not be all that helpful. First, the dissemination of the patent list does not help the first Section 262(k) applicants, or any applicants seeking to design around before any pre-litigation activity has taken place. Thus, the patent information disclosures in the Purple Book take place many years after most biosimilar companies will be on the path to development. And of course, given the significant patent portfolios covering biologics drugs and their many, complex steps of manufacture, there always remains the likelihood of additional patents to be asserted in later litigations that did not exist at the time of the prior BPCIA pre-litigation exchanges. Thus, it is unclear how, if at all, the new listings can be used practically to benefit manufacturers seeking to market a biosimilar approval.

What Comes Next?

It is hardly certain that either bill passes; after all, similar bills failed in prior Congresses, and the Senate amended the bills under consideration here. Thus, the bills must return to the House for another round of approval, and the House has only until January 3, 2021 to pass them. Given the current legislative environment and the impending recess, this may not be high on the list of legislative priorities. And so, as Congress works to finalize coronavirus relief, it is hard to tell whether the Orange Book Act and Purple Book Act will make it signed and off President Trump's desk before the new Congress convenes.

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