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# TAKING ADVANTAGE OF THE NEW PURPLE BOOK PATENT REQUIREMENTS FOR BIOLOGICS

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New federal legislation will take effect this year that will require a reference product sponsor to submit to the FDA a list of any patents identified to a biosimilar applicant during the patent dance. The FDA is required to list these patents in the Purple Book. Small and medium-sized enterprises (SMEs)—and others in the industry—can take advantage of this new source of information by using it to identify (i) potential partnerships for licensing of existing IP; (ii) targets for IPRs; or (iii) design around opportunities for the development of new technology.

The Consolidated Appropriations Act was signed into law on December 27, 2020. While perhaps most newsworthy for its provisions related to COVID-19 relief and spending, the Consolidated Appropriations Act (the longest bill ever passed by Congress) included several provisions on biosimilars. One of these provisions, Section 325 of Division BB, is directed to "Biological Product Patent Transparency." This section requires a reference product sponsor to provide to the FDA a list of any patents identified to a biosimilar applicant as part of the patent dance (subsections (l)(3)(A) or (l)(7)), not later than 30 days after those patents were identified to the applicant. The FDA is then required to "include such information for such biological product" in a searchable, electronic format.

## BACKGROUND ON BIOLOGICS

Biological products, commonly referred to as biologics, can be used in the prevention, diagnosis, treatment, or cure of various diseases. Biologics are distinguished from traditional "small molecule" pharmaceuticals by their size and method of synthesis. While "small molecule" drugs are chemically synthesized, biologics are more complex—they are typically proteins that are derived and manufactured from living cells.

While small molecule drugs have "generic" versions of the brand name products, biologics have "biosimilars." Because biologics are more complex and are derived from living cells, biosimilars are unlikely to be identical replicas of the comparable biologic developed by the reference product sponsor.

Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA) to create an abbreviated approval pathway for biosimilars (42 USC § 262 subsection (k)) and to create a process for biosimilar applicant

and the sponsor of the reference product to resolve patent disputes (subsection (l)). The patent dispute procedure is commonly referred to as the "patent dance."

To start the patent dance, the biosimilar applicant provides the reference product sponsor with its Abbreviated Biologics License Application (aBLA) and additional information about its manufacturing process (subsection (l)(2)). Within 60 days of this initial exchange, the reference product sponsor must provide the biosimilar applicant with a list of unexpired patents for which a claim of infringement could reasonably be made (subsection (l)(3)(A)). The biosimilar applicant has 60 days to provide noninfringement and invalidity positions (subsection (l)(3)(B)(ii)), after which the reference product sponsor has 60 days to respond with its positions (subsection (l)(3)(C)). The reference product sponsor can update its list with any newly issued patents within 30 days after those patents issue (subsection (l)(7)). Following these initial rounds of disclosures, the parties engage in a series of responses and negotiations, culminating with the reference product sponsor bringing a lawsuit for patent infringement in US federal court.

## WHAT IS THE 'PURPLE BOOK?'

In connection with small molecule drugs, the FDA has published the "Approved Drug Products with Therapeutic Equivalence Evaluations" since 1980. This publication is generally known as the "Orange Book." Congress codified the publication of the Orange Book in 1984, and since then, the Orange Book has provided information on approved small molecule drugs, patent, and other exclusivity information related to those drugs and generic equivalents.

In 2014, with the development of biologics and biosimilars, the FDA began publishing a "List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," which is commonly known as the "Purple Book." Originally, the Purple Book consisted of two lists—one containing biologics regulated by the Center for Drug Evaluation and Research (CDER) and the other containing biologics regulated by the Center for Biologics Evaluation and Research (CBER). The lists included the biologic's name, BLA number, licensure date, exclusivity information, biosimilar information, and whether the biologic had been withdrawn—but did not include any information about patents covering biologics. Eventually, the FDA transitioned the Purple Book to an online searchable database with the same information. However, the publication of the Purple Book was not codified until the recent passage of the Consolidated Appropriations Act.

## THE NEW PURPLE BOOK REQUIREMENTS

With Section 325 of Division BB of the Consolidated Appropriations Act, Congress codified the Purple Book and established new requirements for information to be included. There are a number of key provisions which set out different aspects of the Purple Book requirements:

**Timing**: The FDA must begin publication of the new Purple Book information within 180 days of enactment—June 25, 2021.

**Revisions**: The FDA must update the publication at least every 30 days.

**General Information**: The Purple Book must include (i) the nonproprietary or proper name of the biologic, (ii) the date of licensure of the marketing application and the application number, (iii) and the licensure and marketing status.

**Patent Information**: As part of Section 325, any reference product sponsor engaged in a patent dance must provide to the FDA a list of patents identified to a biosimilar applicant as part of subsection (l)(3)(A) or (l)(7). The information must be provided within 30 days of the disclosure to the biosimilar applicant and must

patent expiry information. The FDA is then required to include the patent and expiry information in the Purple Book in connection with the biologic.

**Exclusivity Information**: If the biologic or biosimilar is still entitled to exclusivity, the Purple Book must identify the exclusivity period.

The key difference between the new Purple Book requirements and the information in the existing Purple Book published by the FDA is the inclusion of patent information. Previously, information exchanged between a reference product sponsor and a biosimilar applicant during the patent dance was treated as confidential.

Historically, third parties have had few strategies to identify potential biologic patent coverage other than traditional patent searching and competitive patent landscaping exercises. Companies can always find information by perusing relevant publications (e.g., Morgan Lewis's Blockbuster Biologics Review). Of course, parties can also conduct patent searches to identify potential patents, but given the various types of patents involved, such searches are expensive and not guaranteed to be comprehensive. Alternatively, later biosimilar applicants can identify some of the patents related to a biologic after a patent infringement lawsuit was filed—but that information would only include the patents that were eventually asserted, not all patents identified by the reference product sponsor as being reasonably infringed. The publication of patent information in the Purple Book changes the accuracy, scope, and access to available patent information.

This additional information will not affect the first biosimilar to file an application. They will still be in the dark as to patents likely to be identified by a reference product sponsor during the patent dance. But publication of the patent information in the Purple Book will allow subsequent applicants to more easily prepare noninfringement and invalidity positions before the patent dance even starts. This advance notice could be critical to a biosimilar applicant's legal and business strategies when pursuing a biosimilar filing. The publication of this information will also open opportunities for others in the biologics arena—including SMEs.

## SMES' INVOLVEMENT IN BIOLOGICS

Why are these new Purple Book requirements relevant to SMEs? Well, a large portion of SMEs in medical development research are working on biologics rather than traditional small molecule drugs. A report from the UK found that over 50% of UK SME companies involved in medicine discovery are focused on non-small molecule work. This includes over 150 companies working to develop antibody therapies, therapeutic proteins, vaccines, and cell and gene therapies.

SMEs are also very active in the development of intellectual property related to their technology. According to a report by the European Patent Office, SMEs account for over one-fifth of new patent applications. The same report notes that SMEs often prefer to use their intellectual property resources to collaborate with others in the industry. However, a lack of specific experience with intellectual property protection can impact the ability of SMEs to find potential partners. As a result, almost 60% of collaborations result in SMEs partnering with already known clients or customers.

## HOW SMES CAN USE THE PURPLE BOOK'S PATENT INFORMATION

The availability of patent information in the Purple Book will allow SMEs in the biologics space to identify new business opportunities in a variety of different ways.

First, SMEs should review the Purple Book's patent information with their own existing technology in mind. SMEs can use the information to identify potential licensing or collaboration opportunities with the reference product

sponsor or with a biosimilar applicant. For example, if there is a clear gap in a reference product sponsor's patent coverage, and an SME has relevant patent coverage in that area, there may be an opportunity for the SME to license its intellectual property to the sponsor to improve patent protection. Alternatively, if a reference product sponsor has patent coverage in a specific area, and the SME has technology that would allow a biosimilar applicant to design around that coverage, the applicant may be interested in collaborating with the SME related to that technology.

An SME can also use the Purple Book's patent information to commercialize intellectual property that is similar to or overlaps with the reference product sponsor's patents. For example, a reference product sponsor may be interested in licensing intellectual property from an SME even if the sponsor already has patent coverage in the same area. Or, a biosimilar applicant may be interested in collaborating with an SME in filing an IPR, especially if the SME's intellectual property could invalidate a reference sponsor's patent.

Finally, when reviewing the Purple Book's patent information, SMEs should consider areas for future technological development. If an SME has expertise in a specific area, it may be able to utilize that expertise to collaborate with a biosimilar applicant in developing technology to design around the reference product sponsor's existing patents.

## CONCLUSION

The new Purple Book requirements on the disclosure of patent information open up opportunities for SMEs (and others) to identify specific targets for collaboration regarding the SMEs' existing technology or for the development of new technology.

## CONTACTS

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