Summary: Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Information

Notice of Availability Publication Date: June 1, 2020

Comments Due: August 31, 2020

On June 1, 2020, the Food and Drug Administration (FDA) published "Listing of Patent Information in the Orange Book; Establishment of a Public Docket," soliciting comments on the listing of patent information in the Orange Book, including on the types of patent currently listed and how changes to current patent listing practices may impact drug product development. The request for comments includes several questions aimed at examining whether the agency should further evaluate or provide additional clarity regarding the types of patent information listed in the Orange Book.

Comments on this public must be submitted to the FDA by August 31, 2020. You may provide feedback via email to advocacy@amcp.org on any provisions included in the request for comments by **August 14, 2020**. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the request for comments that may be of interest to AMCP members:

A. Background on the listing of patent information in the Orange Book

a. The Food, Drug and Cosmetic (FD&C) Act requires new drug application (NDA) applicants to file the patent number and expiration date of any patent related to the drug or the method of using the drug with their application. Once a drug is approved by the FDA, NDA holders must also provide updated information on any patents related to the drug or its method of use that are issued post-approval.

b. The FDA is required to regularly revise the Orange Book to include this information.

c. Abbreviated new drug applications (ANDAs) must include an appropriate patent certification or statement for each patent that claims the listed drug(s) relied upon or the reference listed drug, or a method of using such drug.

   i. ANDAs must include at least one certification or statement including: that such patent information has not been filed; that such patent is expired; the date on which the patent will expire; that such patent is invalid, unenforceable, or will not be infringed upon by the manufacture, use, or sale of the drug for which the ANDA is submitted; that there are no patents that claim the listed drug; or that a method-of-use patent does not claim a use for which the ANDA applicant is seeking approval.

B. General Questions

a. Do 505(b)(2)[1] and ANDA applicants currently encounter any challenges because certain types or categories of patents are not listed in the Orange Book?
b. Given the general increasing complexity of products approved in an NDA (e.g. drug-device combination products, complex delivery systems, associated digital applications), are there any aspects of the FDA's interpretation of the statutory requirement for NDA holders to submit information on a patent that claims the drug or a method od using such drugs that are not sufficiently clear? If there is a lack of clarity, how could this be resolved?
c. How would NDA holders and prospective 505(b)(2) and ANDA applicants weigh any advantages that may result from listing of additional types or categories of patent in the Orange Book against the potential need to submit additional patent certifications that could result in a delay of a 505(b)(2) application or ANDA?
d. If you think FDA should clarify the type of patents that must be listed in the Orange Book, what factors should FDA consider in implementing this clarification?
e. Are there other issues related to the listing of patent information that we should consider?

C. Drug Product Patents

a. Are there elements of FDA's regulatory definition of 'drug product or dosage form' in § 314.3(b)[2] that may be helpful to clarify to assist NDA holders in determining whether a patent claims the finished dosage form of an approved drug product?
b. What factors should FDA consider in providing any clarifications related to whether device-related patents need to be submitted for listing as a patent that claims the drug?

D. Method of Use Patents

a. What information should FDA consider regarding when a patent that claims a method of using a device constituent part, or only a component of a device constituent part, might or might not meet the statutory standard for submission by the NDA holder for listing in the Orange Book as a method-of-use patent? Should FDA consider whether:
    i. The patent claims and/or discloses the active ingredient or formulation of the approved drug product (or the drug product class)?;
    ii. The device constituent part is described in certain sections of the listed drug labeling; or
    iii. Use of the device is described in labeling for the listed drug, but the device is not a constituent part of the drug product?

[1] See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2
[2] See: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.3

iv. Should FDA consider whether the drug product labeling state that the drug is only for use with the specific device? Should the FDA also consider device labeling, for example whether the device labeling indicates the device is for use with the specific drug?

b. What information should FDA consider regarding whether there are circumstances in which a patent claiming the way and approved drug product is administered would meet the statutory standard for submission by the NDA holder for listing in the Orange Book as a drug product patent, rather than a method-of-use patent?
c. What information should FDA consider regarding whether there are circumstances in which a method-of-use patent claiming the way an approved drug product is administered that is not described in FDA-approved product labeling would meet the statutory standard for listing in the Orange Book?

E. REMS-Related Patents

a. What information should FDA consider regarding whether patents that claim how the sponsor has implemented a particular REMS requirement meet the statutory requirement for the type of patent information that is required to be submitted to FDA for listing in the Orange Book? What factors should be considered in making this determination?
b. Are there other issues related to patents that claim how the sponsor has implemented a particular REMS requirement that FDA should consider with regard to listing patent information in the Orange Book, including any potential impact listing such patents could have on development of REMS for generic versions of products? For example, does listing patent information in the Orange Book for such patents pose difficulties for ANDA applicants in developing a single, shared system REMS for that product?

F. Patents for Digital Applications

a. If an approved drug product has an associated digital application (e.g. a mobile application that accepts and records information from an ingestible sensor in a drug product), what factors should be considered in determining whether a patent that claims an aspect of that digital application meets the standards for listing in the Orange Book?
b. Are there other issues related to patents for digital applications associated with approved drugs that should be considered with regard to listing patent information in the Orange Book?