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FDA's Hatch-Waxman Regulations Get a Long Overdue Update

On December 5, 2016, twenty-two (22) pages of new Hatch-Waxman regulations will be codified in the Code of Federal Register. These new regulations bring several significant changes to the Hatch-Waxman landscape, which has been largely unchanged for over a decade.

The Final Rule,[1] titled "Abbreviated New Drug Applications and 505(b)(2) Applications" (Final Rule) was published in the Federal Register twenty (20) months after the Food and Drug Administration (FDA or Agency) published the Proposed Rule, which outlined Agency's plan for implementing portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[2]

Specifically, the Final Rule implements portions of the MMA that pertain to:

- *Notices provided to the patent owners and the new drug application (NDA) holder for certain patent certifications made in 505(b)(2) applications or ANDAs;*
- *The availability of 30-month stay of approval for 505(b)(2) applications or ANDAs that are otherwise ready to be approved;*
- *Submission of amendments and supplements to 505(b)(2) applications and ANDAs; and*
- *The types of bioequivalence and bioavailability data that may be used to support 505(b)(2) applications or ANDAs.*

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With the aim of reducing litigation and delays in the approval and marketing of generic drugs, the Final Rule revises and clarifies its regulations on a number of different parts of the Hatch-Waxman process.

Notable changes, which will be discussed in-more depth below, including a new patent listing dispute mechanism for method-of-use patents, timing requirements for Paragraph IV certification notices, and patent certification requirements for amendments and supplements to follow-on applications. FDA has provided a summary description of these and other changes here (see section I.B.).

Method-Of-Use Patent Listing Disputes

To the relief of many, FDA declined to finalize new regulations on the submission of method-of-use patent information as described in the Proposed Rules. The Proposed Rules described a process for resolving disputes between NDA holders and others regarding the listed use codes for method-of-use patents. The Proposed Rule required any person disputing a use code published in the Orange Book to contact FDA with an explanation of the dispute and grounds for disagreement. FDA would then permit the NDA holder to confirm and explain the appropriateness of the identified code. FDA would then make a final determination about the appropriate code.

This proposed process was criticized as being overly reliant on follow-on applicants to interpret the scope of the method claims in situations where the same follow-on applicant may be seeking to carve out the protected conditions of use from the product label in order to avoid certifying to the patent.

The Final Rule explains that FDA did not adopt this process because it "intend[ed] to take a stepwise approach to evaluat[ing] whether FDA's revisions to the regulations on submission of method-of-use patent information . . . and patent listing dispute procedures adequately address the problem of overbroad and ambiguous use codes before [it] establish[es] a process to review a proposed labeling carve-out with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent." [3]

The Final Rule does permit third party challenges to use code listings by submission of a written request to FDA. The NDA holder will have thirty (30) days to respond to the written request and submit a signed verification under penalty of perjury that the information is accurate and complete. FDA will amend information in the Orange Book based on the NDA holder's response, if necessary. An amendment of patent information under this procedure will not be considered untimely filed patent information.[4]

Timing for Paragraph IV Certification Notices

The new Final Rules establish the date before which follow-on applicants may not mail or otherwise provide notice of a Paragraph IV certification for a listed patent to the NDA holder or patent holder, as "the first working day after the day the patent is published on the Orange Book."[5] This amendment was implemented to address what FDA labeled as a system of "serial submissions," in that ANDA applicants submit multiple Paragraph IV notices between the time of patent grant and listing on the Orange Book. Serial submissions are used in order to secure ANDA first-filer status by having a submission filed on the same day as the listing in the Orange Book. This practice of filing multiple notices, however, creates a heavy burden on FDA and industry.

Patent Certification Requirements for Amendments and Supplements to Follow-On Applications

Under the current regulations, a 505(b)(2) applicant or ANDA applicant that submits an amendment to a pending submission is required to amend its patent certification if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement, as amended.[6] The Proposed Rule would have required a follow-on applicant to submit a patent certification or recertification for an amendment: "(1) [t]o add a new indication or other condition of use; (2) to add a new strength; (3) to make other than minor changes in product formulation; or (4) to change the physical form or crystalline structure of the active ingredient."[7] In contrast, if filing a supplement, the Proposed Rule would have required the submission of a patent certification or recertification for only the first two categories of changes.[8]

In the Final Rule, FDA adopted the provision concerning amendments to unapproved follow-on applications;[9] however, the Final Rule does not finalize the provision concerning supplements to approved follow-on applications.[10]

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The 505(b)(2) and ANDA approval pathways were enacted by Congress to balance the need and desire to make low-cost generic drugs available by establishing an abbreviated approval process that also provided incentives for drug development, namely in the form of marketing exclusivity and patent terms extensions.[11] After publication of the Proposed Rule in early 2015, FDA received many comments expressing concerns that the Proposed Rules did not strike the appropriate balance of protecting patent rights without unnecessarily delaying entry of generics to the market. For example, comments suggested that the patent certification process for amendments and supplements to the follow-on applications were either under-inclusive or over-inclusive.[12] As FDA continues to evaluate comments and concerns that the Final Rules do not strike the appropriate balance, it is possible that we may see additional amendments to these regulations.

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[1]Federal Register, Vol. 81, No. 194, Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule (October 6, 2016), available at, https://www.gpo.gov/fdsys/pkg/FR-2016-10-06/pdf/2016-22690.pdf.

[2] Federal Register, Vol. 80, No. 25, Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Rule (February 6, 2015), available at, https://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-01666.pdf.

[3]Final Rule at 69,604.

[4]Id. at 69,604-69,605.

[5]Id. at 69,611.

[6]21 C.F.R. §§ 314.50(i)(6)(iii), 314.94(a)(12)(viii)(V).

[7]Proposed Rule at 6847.

[8] Id.

[9] Final Rule at 69,615-16.

[10]Id. at 69,617.

[11]Id. at 69,615.

[12]Id.

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