

We agree that there have been a few cases in which legitimate concerns have been raised about whether specific submitted patents meet the statutory requirements for submission and listing. We believe that these concerns will be adequately and efficiently addressed by the clarification of the types of patents that must and must not be submitted and by improvements to the patent information required. We further believe that even if legally permissible, it is not necessary for us to develop a patent review mechanism. The final rule permits us to allocate our limited resources to public health activities, while leaving questions of patent law to the courts, which are better able to handle such questions. This division of responsibility is fully consistent with the process established in the Hatch-Waxman Amendments.

(Comment 9) One comment suggested that we create an administrative mechanism to ensure timely patent infringement litigation if no statutory notice is provided to the NDA holder.

(Response) We decline to amend the proposed rule as suggested by the comment. The act does not contemplate that we will play an active role in determining the timing of patent infringement litigation. In the absence of the 45-day timetable imposed when notice is given for a paragraph IV certification, a decision on whether and when to file suit for patent infringement may depend on multiple variables. For example, did the NDA holder or patent owner have sufficient information to decide whether to sue the ANDA or 505(b)(2) applicant for patent infringement? An ANDA applicant and the NDA holder may disagree on when the NDA holder had sufficient information to decide to file suit. The parties may also disagree as to what constitutes "timely" litigation. For example, an NDA holder who defers filing a lawsuit on a later-filed patent until a 30-month stay has elapsed may feel that the subsequent litigation is still "timely," given the information available to the NDA holder. The ANDA or 505(b)(2) applicant may view this latter lawsuit as an obstacle to marketing its drug product. Given the limits of our statutory authority as well as complex issues of patent litigation strategy that lie outside our expertise, we decline to create a mechanism to ensure "timely" patent litigation in situations where the NDA holder and patent owner did not receive notice of subsequent paragraph IV certifications.

ii. *Should There Be Time Limits on Patent Submissions or Certifications?* The proposed rule did not specify when patent information would need to be

submitted, or whether ANDA or 505(b)(2) applicants would need to provide certifications for patents listed after they had filed an ANDA or 505(b)(2) application.

(Comment 10) Several comments suggested revising the rule to create time limits relating to the submission of patent information or patent certifications. For example, one comment asserted that "abuse" occurs when NDA holders submit non-meritorious patent information to us shortly before an earlier-submitted patent is to expire. Another comment suggested that we limit the time during which NDA holders can submit patent information to a defined time period after we have approved their NDAs. Another comment said we should not require ANDA applicants to submit amended patent certifications if the patent was submitted after the first ANDA had been filed.

Similarly, one comment asserted that a patent submitted after NDA approval cannot claim the approved drug product because the later-submitted patent would be invalid. The comment explained that, under patent law, a person cannot obtain a patent if the subject of the patent is known and therefore "anticipated" under patent law.

(Response) We decline to amend the proposed rule as suggested by the comments. The act clearly contemplates the submission of additional patent information after an NDA has been filed. For example, section 505(b)(1) of the act instructs applicants to amend their NDAs to include information on a patent issued after the NDA has been filed, but before the NDA has been approved, which claims the drug or a method of using the drug that is the subject of the application. Section 505(c)(2) of the act directs NDA holders to submit patent information if the patent issued after we have approved the NDA. We do not interpret the act as permitting us to refuse to accept submissions of new patents either after an NDA has been filed or approved, or after an ANDA has been submitted.

Section 505(c)(2) of the act also instructs NDA holders to submit information on patents issued after NDA approval no later than 30 days after the date the patent issued. This deadline ensures prompt public notice that the NDA holder believes the patent claims the approved drug product and permits legal issues regarding these later-issued patents to be resolved as early as possible. Under § 314.94(a)(12)(vi), we do not require an ANDA or 505(b)(2) applicant with a pending application to certify to a patent issued after NDA

approval but not submitted to us within 30 days after issuance. However, the patent will be listed in the Orange Book upon submission of a complete declaration, and ANDA and 505(b)(2) applications filed after the patent is listed will be required to contain a certification to the patent. This longstanding interpretation is consistent with the statutory language describing patent submission deadlines, the notice concept inherent in patent publication, and early judicial resolution of patent disputes. We are not persuaded by the comments that we should change our interpretation.

We believe that removing the possibility of multiple 30-month stays per ANDA will diminish the incentive to obtain additional patents late in the patent life of the product described in the NDA. As described in the FTC Report, of the patents reviewed by FTC, many of the patents submitted well after NDA approval, and usually after an ANDA application was filed, were ultimately found to be invalid. Therefore, in the absence of the 30-month stay, these patents would have been unlikely to serve as a basis for a preliminary injunction precluding market entry of generic drugs.

We also decline to amend the proposed rule to exempt ANDA applicants from submitting patent certifications if the patent was listed after the ANDA was filed. Our pre-existing regulations do not require ANDA applicants to amend their patent certifications if:

- The NDA holder failed to provide the required patent information within 30 days after the issuance of the patent; and
- The ANDA had already been submitted and had contained an appropriate patent certification before the submission of new patent information (see § 314.94(a)(12)(vi)).

However, if the NDA holder has submitted patent information in a timely manner, consistent with section 505(c)(2) of the act, then section 505(j)(2)(A)(vii) of the act requires the ANDA applicant to certify to that patent. Section 505(j)(2)(A)(vii) of the act requires ANDA applicants to provide a certification with respect to "each patent which claims the listed drug," not only patents that are listed at the time the ANDA is submitted. The act contemplates the submission of patent certifications even if the patent was listed after the ANDA or 505(b)(2) application had been submitted.

We do not have the authority to declare any patent to be invalid. We leave questions regarding the issuance