

### III. Description of the Final Rule

#### A. Section 314.53(b)—What Patents Must Be Submitted?

##### 1. Which Patents Would the Final Rule Require To Be Submitted?

Section 314.53(b) describes the patents for which information must be submitted. The final rule states, in relevant part, that information must be submitted on the required declaration forms for each patent that claims the drug or a method of using the drug that is the subject of the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. The patents include patents that claim:

- The drug substance (active ingredient),
- The drug product (formulation and composition), and
- A method of use.

Those patents that claim a different polymorphic form of the drug substance that is the active ingredient described in the NDA must be submitted if the applicant has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. The drug product (formulation and composition) patents submitted must claim the specific drug product described in the pending or approved NDA. For patents that claim a method of use, the NDA applicant or holder must submit only those patents that claim indications or other conditions of use that are the subject of a pending or approved application. Each pending or approved method of use and related patent claim must be described.

##### 2. What Patents Must Not Be Submitted?

Section 314.53(b), as finalized, states that information on patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must not be submitted. Process patents also must not be submitted. The final rule clarifies that the prohibition on submission of packaging patents does not apply to patents that claim the drug product as defined in § 314.3. If a patent claims the finished dosage form of the drug product, it must be submitted for listing.

#### B. Section 314.53(c)—What Does the Patent Declaration Say?

Section 314.53(c)(1) describes the general requirements for submission of patent information and the conditions for acceptance of the patent information.

Section 314.53(c)(2)(i) requires a person submitting an NDA, an amendment, or a supplement, to submit an original signed declaration form as part of its submission of patent information. The appropriate declaration form must be used for submitting patent information. The information required to be submitted is described. Each form seeks specific patent information and requires a signed attestation from the NDA applicant or holder or patent owner that the information is accurate and complies with the requirements of the regulations.

Section 314.53(c)(2)(ii) requires that the NDA holder submit a declaration form with information relating to the approved NDA and additional information on use codes within 30 days of NDA approval. The information required to be submitted is described. Each form includes specific patent information and requires a signed attestation from the NDA holder or patent owner that the information is accurate and complies with the requirements of the regulations. This section also requires submission of information on patents submitted for listing after NDA approval. This declaration form is the only declaration form that we will rely on to determine whether a patent is eligible for listing based on the patent information submitted.

#### C. Section 314.53(c)(3)—What Is Required to Be Filed If There Are No Relevant Patents?

The final rule modifies the statement used to describe the fact that the NDA applicant or holder believes there are no relevant patents to be submitted. The language is changed to conform to the descriptions used for drug substance (active ingredient), drug product (formulation and composition) and method of use to those used in the other regulatory provisions.

#### D. Sections 314.95(a) and 314.52(a)—When Are Notice and Certification Required?

The final rule modifies §§ 314.95(a) and 314.52(a) to state that, if an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation,

such paragraph IV certification and related notice are not considered to have satisfied the requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

### IV. Implementation

The final rule will be effective on August 18, 2003.

- Patent information submitted to us (FDA) before the effective date will be subject to our pre-existing regulations governing patent submission, declarations, certifications, notice and availability of 30-month stays;

- Patent information submitted to us on or after the effective date will be subject to the final rule's provisions governing patent submission, accompanying declarations, certifications, notice and availability of 30-month stays;

- Patent information submitted to us on a newly applicable claim, even if the patent was previously submitted to us, will be subject to the final rule's provisions.

The final rule will have a compliance date of December 18, 2003, for patent information submitted to us on patents claiming a polymorph of the same active ingredient of the product described in the NDA.

As a result, within a single same approved or pending NDA, some patents may be subject to our pre-existing regulations while other patents may be subject to the final rule. The date on which the patent information was submitted to us will determine which set of regulations applies.

We believe that the effective dates will provide adequate time for the NDA applicants, NDA holders, and patent owners to adjust their business practices. The patent information required for submission is information readily available to the NDA applicants and holders and patent owners.

We have delayed the implementation date for patent information to be submitted to us on patents claiming a polymorph that is the active ingredient of the drug product described in the approved NDA. NDA applicants and holders and patent owners with patents pending at the PTO will have additional time (i.e., until 6 months after the date of publication in the **Federal Register**) to conduct the tests needed to produce the data required for the declaration statement in time to submit any newly issued patent within 30 days of issuance.

### V. Legal Authority

Our principal legal authority for the final rule is section 505 of the act, in