

Cir. 2003), the Federal Circuit issued a per curiam opinion that held that a method-of-use patent holder does not have an infringement action against an ANDA applicant when the use claimed in the patent is not FDA approved and the ANDA applicant is not seeking approval of that use. These decisions are consistent with our position that sponsors must not submit method-of-use patents that do not claim an approved use for listing in the Orange Book. They also highlight the need for an improved declaration that will clarify the claimed scope of the method-of-use patents being submitted.

We have modified the required declaration relating to method-of-use patents submitted. Although we agree, as discussed in the response to comment 11 of section II.A of this document, that each individual claim of a patent does not need to be listed on the declaration forms for drug substance and drug product patents, we do require identification of individual claims for method-of-use patents. The declarant must describe each individual method of use for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use. This information will expedite our review of ANDA and 505(b)(2) applications that do not seek approval for all the approved uses. In determining whether an ANDA applicant can “carve out” the method of use, rather than certify to the listed patent, we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book.

The need for accurate and detailed information related to the approved methods of use claimed in the patent being submitted for listing is underscored by the decision in *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002). In that case, the NDA holder submitted information on a patent claiming what was later determined to be an unapproved use of the approved drug product. This submission was accompanied by the required signed declaration from the NDA holder that the patent covered the method of use for the approved product. Accordingly, we listed the patent and the use code information submitted with the patent. Years later, well after litigation over this patent was underway, the NDA holder clarified to FDA that the patent did not, in fact, claim the use for which the NDA was approved.

This submission of inappropriate patent information led to confusion and

then to litigation over an ANDA applicant's obligation to submit either a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the act or a “section viii” statement under section 505(j)(2)(A)(viii) of the act. The section viii statement, which is also applicable to 505(b)(2) applications, permits the ANDA or 505(b)(2) applicant to avoid certifying to a patent by stating that it is not seeking approval for the use claimed in the listed patent. A section viii statement does not carry the requirement for notice to the NDA holder and patent owner, and the related opportunity for a 30-month stay.

We have implemented the section viii provisions of the act by deferring to the NDA holder's or patent owner's assertion that the method-of-use patent claims an approved use of the drug product. When the NDA holder or patent owner submits a method-of-use patent for an approved NDA, we rely upon the requirements in the regulations and the required declaration as the evidence that the patent claims an approved use. Therefore, when an ANDA applicant has sought to duplicate the labeling for which the innovator has submitted the patent, and not to specifically omit, or “carve out” labeling, we require the ANDA applicant to submit a certification to that patent. A section viii statement would not be appropriate because the ANDA applicant is seeking approval for exactly the same labeling as that in the NDA for which the patent was submitted.

Our position has been that, for an ANDA applicant to file a section viii statement, it must “carve out” from the proposed ANDA labeling, the labeling protected by the listed patent. Unless the ANDA applicant can show that it is carving out certain method-of-use labeling, a section viii statement is not a correct submission for the listed patent. In *Purepac*, the court rejected our reliance on the regulations and the general declaration as a reasonable basis for this approach to implementation. The court specifically pointed to the patent submissions in the case, and noted that the NDA holder had not complied with the requirement that NDA holders submit only those patents claiming an approved use for the drug. Although the court noted that the facts in *Purepac* were unique (the NDA holder later admitted that it made its submission “without regard” to FDA's regulations), there may be other cases in which NDA holders have submitted patents claiming unapproved uses of approved drug products.

Following the *Purepac* decision, we have two options for implementing the

section viii statement provisions under sections 505(b)(2)(B) and 505(j)(2)(A)(viii) of the act that intersect with the patent submission considerations described in the proposed rule. One approach would be to permit each ANDA and 505(b)(2) applicant to make its own independent decision on whether a listed method-of-use patent claims the use for which the ANDA applicant seeks approval, and then to submit a paragraph IV certification or section viii statement as the applicant sees fit. The second approach would be to require the NDA applicant or holder to identify specifically the approved uses claimed by the method-of-use patent, with reference to the approved labeling, and declare under penalty of perjury that the patent claims an approved use. This would permit ANDA and 505(b)(2) applicants, and us, to assess whether the ANDA or 505(b)(2) applicant is seeking approval for a use the sponsor states is claimed in the listed patent, and thus determine whether the applicant must submit a patent certification or may submit a section viii statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the act.

In the absence of explicit statutory language, we believe an approach that requires the NDA applicant or holder or patent owner to identify the approved methods of use protected by the patent is most consistent with the general balance adopted in Hatch-Waxman. This approach permits the NDA applicant or holder to determine which patents claim its approved drug product and then, when appropriate, to resolve disputes over infringement of those patents through patent litigation. If ANDA and 505(b)(2) applicants could always avoid the possibility of a 30-month stay by asserting in a section viii statement that certain labeling for which the applicant is seeking approval is not protected by a listed method-of-use patent—despite the NDA holder's assertion to the contrary—there would be little reason for any applicant to submit a paragraph IV certification for a method-of-use patent. This approach would essentially eliminate the certification, notice, and litigation process as to any listed method-of-use patent, producing an outcome that is inconsistent with the act.

To effectively implement the certification and section viii statement provisions set out in the statute, we must have adequate information concerning method-of-use patents. Since 1994, we have requested, but not required, that NDA applicants submit to FDA information on the approved use claimed by the patent. Since the