

the final rule does not allow submission of patents that claim intermediates for the reasons explained in the proposal.

f. *“Double” Patents—What Are They, and Must We Allow Them to Be Submitted?* The proposal did not discuss “double” patents.

(Comment 6) One comment suggested that we prohibit the listing of patents that contain a terminal disclaimer over a patent that had already been listed. The comment explained that patent law generally prevents an inventor from double patenting—that is, extending the term of the patent “by the subsequent patenting of variations that are not patentably distinct from the first-patented invention.” The comment stated that this “double patenting” can be cured if the patent holder files a “terminal disclaimer” which “acts to disclaim the term of the later patent that extends beyond the term of the original patent, so that both patents expire on the same day.” The comment expressed concern that NDA holders could list a later patent and have an opportunity to obtain a 30-month stay even if the later listed patent had a terminal disclaimer. In other words, the terminal disclaimer would prevent the inventor from enjoying a longer term of patent protection, but it would not prevent the imposition of another 30-month stay if the NDA holder or patent owner sued to enforce the later patent. The comment noted that, for the drugs PAXIL and FOSAMAX, the NDA holder had submitted earlier patents and a later-issued patent that had a terminal disclaimer. The patents were listed in the Orange Book, paragraph IV certifications were required for both patents and the NDA holder sued ANDA applicants on both patents, triggering 30-month stays.

(Response) We acknowledge that the “double patenting” described by the comment may, indeed, provide an NDA holder an opportunity to obtain an additional 30-month stay under the prior interpretation of the act. Under the final rule, there is no opportunity for multiple 30-month stays if patents with terminal disclaimers are submitted for listing. If such a patent is submitted after an ANDA applicant has filed a paragraph IV certification to a previously filed patent, and one full opportunity was provided for the 30-month stay, no notice need be given for a subsequent paragraph IV certification and no additional 30-month stay for that ANDA applicant can result under the final rule.

The act expressly contemplates listing of patents after NDA approval. It does not prevent an NDA holder or patent owner from submitting a patent with a

terminal disclaimer. As long as the patent meets the statutory requirements, the patent must be submitted, even if it contains a terminal disclaimer. Again, we note that the PTO is responsible for the issuance of such patents. We defer to the PTO on matters of patent issuance.

g. *Method-of-Use Patents—Must the “Use” Be Approved in the Approved Drug Product?* The preamble to the proposed rule mentioned that patents claiming a method of use would be able to be submitted, but did not address such patents except to confirm our position that patents may not be submitted for listing if they claim methods of use that are not approved for the listed drug or are not the subject of a pending application.

(Comment 7) Comments disagreed as to whether the method-of-use claim in a patent submitted for listing must be a use approved in the NDA. Several comments urged us to list only those patents claiming methods of use approved in the NDA or that required clinical trials. One comment argued that listing only patents for approved uses was the only way to stop NDA holders from claiming broad uses or indications not in the approved labeling. In contrast, other comments argued that the act did not prevent NDA applicants or holders or patent owners from submitting patents for listing that claimed uses not approved by FDA. Some comments stated that patent infringement is not limited to approved uses. Other comments stated that section 505(b)(1) of the act contemplates the listing of patents claiming unapproved uses if a claim of patent infringement could reasonably be asserted, citing *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) (*Purepac*).

(Response) If an NDA applicant or holder or patent owner intends to submit information on a patent that claims a method of use, the patent must claim a use that is described in the NDA. If we have already approved the NDA, the patent must claim a method of use that is in the labeling of the approved NDA. This has been our position since before we issued the final patent information rule in 1994 (see 59 FR 50338, 50363–50364 (Oct. 3, 1994)). The pre-existing requirement can be found at § 314.53(b) and (c)(2).

Sections 505(b) and (c) of the act support our position that only patents claiming approved methods of use be submitted for listing. Section 505(b)(1) of the act provides that the NDA applicant “shall file with the application the patent number and the expiration date of any patent which

claims the drug for which the applicant submitted the application or which claims a method of using such drug * * * .” The corresponding language in section 505(c)(2) of the act is nearly identical. Only method-of-use patents “which claim the drug for which the applicant submitted the application” must be listed. “Drug” is an ambiguous term, one which, for many years, we have consistently interpreted in the Hatch-Waxman Amendments to refer to the drug product. One court has said that:

The meaning of the word “drug” in 21 U.S.C. § 355(b)(1) cannot be determined apart from its context. Neither the FDA nor this court disputes that the definition of drug in § 321(g) covers both drug products and active ingredients. The relevant statutory section in this case, however, modifies the word “drug” by attaching the phrase “for which the applicant submitted the application.” In that context the FDA’s interpretation of drug as meaning drug product is consistent with and indeed required by the statute. (See *Pfizer, Inc. v. FDA*, 753 F. Supp. 171, 176 (D. Md. 1990).) All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product. Accordingly, only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted. Method-of-use patents for uses that the NDA holder “has not chosen to make available to the public” (*id.* at 177) must not be submitted for listing.

This construction of the statute is also supported by the more recent case law. Since we issued the proposed rule, there have been several judicial opinions discussing method-of-use patents. In *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), and in the related case *TorPharm, Inc. v. Thompson*, Civ. No. 03–0254 (D.D.C. April 25, 2003) (appeal pending for both *Purepac* and *TorPharm*), the district court held that, where a patent did not claim a use approved in the NDA, an ANDA applicant could not be required to certify to that patent, and the agency could properly find that no ANDA applicant was entitled to 180-day exclusivity on that patent. In *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), the Federal Circuit held that an ANDA applicant does not need to certify to a patent claiming a use not covered by the applicable NDA, and there is no cause of action against an ANDA applicant for patent infringement under 35 U.S.C. 271(e)(2)(A) for patents that claim an unapproved use. In *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed.