

Orange Book Listings and Delistings

In order to list a patent in the Orange Book, the NDA holder must certify that the patent either claims the approved drug or an approved method of using the drug. In June of 2003, FDA issued a Final Rule (68 Federal Register 36676) that attempts to clarify which patents should and should not be listed in the Orange Book.

In general, the NDA sponsor is the only party that can request, on his own accord or by an order from a federal district/circuit court, that a listed patent be removed (delisted) from the Orange Book.

I. At FDA:

According to 21 CFR 314.53(f), patent listings in the Orange Book can be corrected.

The regulations states:

(f) Correction of patent information errors. If any person disputes the accuracy or relevance of patent information submitted to the agency under this section and published by FDA in the list, or believes that an applicant has failed to submit required patent information, that person must first notify the agency in writing stating the grounds for disagreement. Such notification should be directed to the Drug Information Services Branch (HFD-84), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The agency will then request of the applicable new drug application holder that the correctness of the patent information or omission of patent information be confirmed. Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list. If the new drug application holder does not change the patent information submitted to FDA, a 505(b)(2) application or an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

The FDA procedure involves:

- (1) a request to remove a patent from the Orange Book, can be from the NDA holder/patent owner or from a third party;
- (2) Orange Book staff will request listing clarification from NDA holder about the listing;
- (3) NDA applicant ultimately determines changes necessary to Orange Book listing. If NDA holder confirms that patent is properly listed, the patent remains listed in the Orange Book.

II. Before the courts:

In general, according to the provisions in 21 USC § 355(j)(5)(C)(ii), a party subject to suit in an infringement action may assert a counterclaim seeking an order which requires the NDA holder to correct or delete specified patent information submitted and currently listed in the Orange Book.

The language of 21 USC 355(j)(5)(C)(ii) states:

(ii) Counterclaim to infringement action.--

(I) In general.--If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action.--Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

In order to bring a counterclaim for delisting a patent pursuant to the provisions provided for in the Medical Modernization Act of 2003, the patent owner must have brought suit against a party accused of infringing a listed patent. As a counterclaim to the infringement suit, the accused infringer can seek an order to remove the patent from the Orange Book listing.