

situation in which an ANDA or 505(b)(2) applicant has filed an initial paragraph IV certification and the NDA holder or patent owner has filed a lawsuit to protect the patent and obtain a 30-month stay. There is little reason to doubt that an NDA holder or patent owner who had submitted a second patent to us for listing would bring another lawsuit to protect the second patent if an ANDA or 505(b)(2) applicant were to manufacture the drug, even if no notice of a subsequent paragraph IV certification was provided. In other words, the NDA holder or patent owner should have an incentive to protect the patented invention regardless of whether the ANDA or 505(b)(2) applicant provided notice.

We acknowledge that the court in *Jervis B. Webb Co. v. Southern Systems, Inc.*, 742 F.2d 1388 (Fed. Cir. 1984), found that a case or controversy did not exist when the plaintiff had not produced a product (a device) at the time of the declaratory judgment counterclaim. However, an ANDA or 505(b)(2) applicant is engaged in “producing” a product at the time the ANDA or 505(b)(2) application is filed. Although 35 U.S.C. 271(e)(1) makes it an act of non-infringement to use a patented invention for uses related to submitting an ANDA or 505(b)(2) application (such as testing and producing sample batches of drug product), 35 U.S.C. 271(e)(2) expressly makes it an act of infringement to submit an ANDA or 505(b)(2) application seeking approval of the drug product before a patent expires. This statutory provision does not require that the NDA holder or patent owner receive formal notice of a paragraph IV certification for the submission of the application to be an act of infringement. Thus, unlike the plaintiff in *Jervis B. Webb Co. v. Southern Systems, Inc.*, the second element of the case or controversy test would be satisfied.

In another case cited in the comments, *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999), the court explained that a case or controversy did not exist in the underlying declaratory judgment action. There was no reasonable apprehension of suit—the first element of the case or controversy test—because the patent owner had disavowed an intent to sue. A disavowal of the intent to sue is an unusual circumstance that we do not expect to occur in many cases. In any event, the availability of a declaratory judgment action is less important when the innovator or patent owner disavows an intent to sue because the ANDA applicant will face less risk in marketing its competing product. We are not aware

of any other Hatch-Waxman patent infringement case in which a court has found no reasonable apprehension of suit.

In response to the comments arguing that a single 30-month stay would create uncertainty regarding litigation and later-submitted patents, we note that a firm’s inability to predict whether it will or will not be sued for patent infringement is a matter outside the scope of this final rule. A decision by the NDA holder or patent owner on whether to file suit for patent infringement may depend on many factors. For example, litigation decisions could be affected by the strength of the underlying patent, the party’s resources, licensing agreements if the patented invention is made under a license, or other factors. We also note that some patent infringement suits may be initiated after the 45 day period available to obtain a 30-month stay has expired. The act only requires the initiation of a patent infringement suit within a specific time if the NDA holder or patent owner wishes to get the benefit of a 30-month stay in the approval of an ANDA or 505(b)(2) application; the NDA holder or patent owner can bring suit at a later time, but loses the opportunity to obtain a 30-month stay of approval.

In addition, there are various types of patents which must not be submitted for listing in the Orange Book. These patents are not subject to the certification, notice, and 30-month stay provisions. The fact that such patents must not be listed does not prevent the NDA holder or patent owner from defending those patents in litigation as it deems appropriate.

*e. Is the Correct Legal Interpretation Applied to Provide Only One 30-Month Stay?*

(Comment 19) Numerous comments challenged our proposed interpretation of the act to permit only one 30-month stay per ANDA or 505(b)(2) application. Some comments advanced a legal analysis different than the one we described in the preamble to the proposal to support a single 30-month stay. The comments asserted that their legal theories were either better than ours or were the only appropriate legal arguments possible.

In contrast, other comments maintained that section 505(j)(2)(B)(iii) of the act requires that notice be provided to the NDA holder and patent owner each time a new paragraph IV certification is added to an ANDA. These comments maintained that multiple 30-month stays are clearly required if the notices result in patent litigation. Several comments contended

that the plain meaning of “include” or “amended to include” is to “contain” or “comprise as part of a whole,” and that our interpretation of section 505(j)(2)(B)(iii) of the act is not reasonable. The comments also argued that our interpretation of “include” in this provision differs from its use elsewhere in section 505 of the act. One comment stated that the meaning of “include” in sections 505(j)(7)(A)(ii) and (iii) of the act cannot be reconciled with our interpretation of that term in section 505(j)(2)(B)(iii) of the act. Section 505(j)(2)(B)(iii) of the act states that “If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.” The comment noted that section 505(j)(7)(A)(ii) of the act provides that the Secretary “shall revise the list [Orange Book] to include each drug which has been approved . . . during the [intervening] thirty-day period” and, when that updated drug information is recorded “in revisions made under clause (ii), [shall] include such [patent] information for such drug.”

Several comments questioned whether the legislative history of the Hatch-Waxman Amendments supported our proposed interpretation of section 505(j)(2)(B)(iii) of the act. One comment contended that House Report language (see 67 FR 65448 at 65456) we had cited should be read as supporting multiple 30-month stays. The comments also argued that our interpretation failed to consider the importance of the final compromise that led to a 30-month, rather than 18-month, stay to ensure that patent litigation was resolved before a generic drug was approved. Finally, other comments criticized our failure to consider other language from a House Report that allegedly shows that Congress intended the availability of multiple 30-month stays. This language, found at H. Rept. 98–857, Part 1, 98th Cong., 2d Sess. at 28, states: “In the case where the patent certification is amended in an ANDA to allege invalidity or non-infringement of a patent, the FDA may not make the approval effective within the 45 day period that an action for patent infringement may be brought.”

(Response) We agree that section 505(j)(2)(B)(iii) of the act can be read to permit multiple 30-month stays. Indeed, this has been our position since the enactment of the Hatch-Waxman Amendments. The proposal put forth a different interpretation, one that we believe is equally reasonable and more in line with the intent of the Hatch-