

having multiple ANDA applicants qualify for 180-day exclusivity was extremely low, as evidenced by the number of times that 180-day exclusivity was granted.³ By contrast, after the *Mova* decision, it is now relatively easy to qualify for 180-day exclusivity. As a result, FDA has had to address a number of new issues, including eligibility for exclusivity when multiple paragraph IV certifications are submitted on the same day.

Congress did not address the possibility that multiple applicants would submit patent challenges to FDA on the same day in the 180-day exclusivity provisions of the act. Similarly, FDA regulations now in effect do not address this specific situation. However, in an August 1999 proposed rule addressing 180-day exclusivity issues, FDA proposed an approach whereby all applicants submitting a paragraph IV certification to a patent on the first day such a certification is submitted are "first applicants" for 180-day exclusivity purposes (64 FR 42873, August 6, 1999). FDA received comments both for and against this approach (see Docket No. 85N-0214). The August 1999 proposed rule was withdrawn in November 2002 for reasons unrelated to the merits of the multiple first applicant approach (67 FR 66593, November 1, 2002). When the proposed rule was withdrawn, the agency noted it would continue to regulate directly from the statute and any applicable regulations, and make decisions on an issue-by-issue basis. The agency continues to believe that the approach to multiple first day patent challenges described in the proposed rule is a reasonable and appropriate interpretation of the statute. Two citizen petitions have specifically asked the agency to follow the approach described in the proposed rule when addressing 180-day exclusivity in cases where there are multiple ANDAs containing challenges to the same patent(s) submitted on the same day (see Docket Nos. 00P-1445 and 03P-0217).

Same day patent challenges generally occur when the expiration of 4 years of a 5-year exclusivity period under section 505(j)(5)(D)(ii) of the act permits submission of ANDAs containing a paragraph IV certification as of a specific date, and multiple applicants vie to be first to make such a submission. Multiple submissions on the same day may also occur when a

new patent is issued by the Patent and Trademark Office and submitted to FDA by the NDA sponsor after ANDAs have been submitted. Because new patents must be submitted to FDA within 30 days of issuance, ANDA applicants position themselves to be the first to submit a paragraph IV certification as soon as the patent is submitted to FDA, often exactly 30 days after patent issuance.

Implementation of a rule that determined eligibility for 180-day exclusivity by the minute or second of submission would be problematic for several reasons. First, applications arrive at CDER by different means and at different locations. They are delivered by U.S. mail, delivery service, courier, and in person by the applicant or its agent.⁴ They may be delivered to mailrooms at FDA's Parklawn Bldg. or at its Metro Park North Bldg., which have different zip codes and are miles apart (§ 314.440). Second, when multiple ANDAs are delivered to the mailrooms on the same day, there is no effective way to determine in what order the documents were submitted. Also, when more than one application is present in a given delivery, the order in which the applications are date-stamped by the document room is random and reflects only the application's arbitrary place in the pile of mail. Moreover, a submission delivered to the agency early in the day may, in fact, be date-stamped after a submission delivered later in the day because the former submission was underneath the latter in the mail pile. Third, some ANDA applicants have assumed that hand delivery would be the best way to secure the "first" application slot. Applicants have arrived outside of an FDA-occupied building on or before the date on which ANDAs may be submitted. Recently, there have been a number of cases in which multiple ANDA applicants or their representatives have camped out adjacent to an FDA-occupied building for periods ranging from 1 day to more than 3 weeks to await the first date on which applications could be submitted to the agency. FDA does not have a system for determining which of those multiple applicants who are present either before the date of submission, or at 12:01 a.m. on the date of submission, or when FDA opens its doors to receive submissions, should be considered "first." The order of applicants in a line that has formed before applications may be submitted is as random as the

location of an application in a pile of mail in the mailroom.

Where multiple applicants are simultaneously present to submit patent certifications on the first day that such submissions are made, rewarding only the first applicant in line does not further any of the goals of the Hatch-Waxman amendments. Even if it were reasonable to argue that someone who is willing to stand in line for days or months should benefit by being considered the first to submit a patent challenge, security and other concerns have foreclosed that option.

The agency can no longer permit applicants to line up outside FDA-occupied buildings in advance of the date ANDA submissions are permitted. For example, when an applicant arrived outside of the FDA-occupied building in mid-May 2003 to establish first place for a number of ANDA submissions, one of which could not be submitted until mid-December 2003, the owner of the government-leased building informed FDA in a June 4, 2003, letter that the 24-hour presence of the pharmaceutical company representatives violated the policy described in the rules and regulations governing the use of the property. In addition, the owner noted its serious liability concerns regarding safety and security. Because of the owner's concerns, FDA directed the waiting ANDA applicant representative to leave the premises.

Furthermore, measuring submissions by the minute or second would be inconsistent with CDER's general administrative practices. CDER conducts its business by calendar day, not by the hour, minute, or second. For example, NDA review times under the Prescription Drug User Fee Act are based upon the date an application was submitted, and approvals are effective as of the date of the issuance of the approval letter (§ 314.105). In addition, 180-day exclusivity runs for 180 calendar days from the date of a commercial marketing or court decision triggering event, without regard to the precise time of day the exclusivity was triggered (§ 314.107(c)(1)). CDER considers most documents, including NDAs, ANDAs, and application amendments and supplements, to have been submitted to FDA as of the date-stamped on the document by the appropriate CDER document room.

In considering how to apply the 180-day exclusivity provisions to multiple patent challenges, FDA reviewed a number of possible approaches. First, the agency examined whether there was a safe and practical way to determine whose patent challenge is actually submitted to the agency first. The only

³ In the years from 1984 to 1998, only three ANDA applicants qualified for 180-day exclusivity. Since the *Mova* decision in 1999, more than 60 ANDAs have received 180 days of exclusivity.

⁴ FDA does not consider submission by facsimile or e-mail official for purposes of determining the date of submission.