Book publication. The submission to the FDA of an allegedly incorrect patent use code is within the scope of the delisting counterclaim provision discussed above.*

It appears that FDA's 2003 revision of its patent listing regulation has addressed many prior problems with regard to the scope of patents submitted to the FDA for Orange Book listing. However, there remain a considerable number of patents submitted to the FDA for listing under FDA's prior regulation, some of which apparently would not qualify for listing under FDA's current criteria. NDA sponsors have in recent years asked the FDA to "delist" a number of Orange Book patents. These actions may have been founded, at least in part, on concerns about possible antitrust liability stemming from improperly listed patents.

30-Month Delay of ANDA and 505(b)(2) NDA Final Approval

The Hatch–Waxman Amendments provide that ANDA or 505(b)(2) NDA final approval is automatically delayed by 30 months following a Paragraph IV certification to an Orange Book patent, notice of the certification to the NDA sponsor and patent holder, and the timely filing of a Hatch–Waxman patent infringement lawsuit within 45 days of receipt of the notice. The 30-month delay period terminates if the ANDA or 505(b)(2) NDA sponsor obtains a court decision (including a district court decision) that the patent is invalid or not infringed, or there is a settlement order or consent decree signed by the court stating that the patent is invalid or not infringed.† Only a favorable court decision involving an ANDA or 505(b)(2) NDA sponsor will terminate that sponsor's 30-month delay period. A decision in litigation involving a different applicant that the patent is invalid or not infringed does not automatically terminate a sponsor's 30-month delay period.

In a situation where a Paragraph IV ANDA or 505(b)(2) NDA is filed on or after the NCE-1 date (4 years into the innovator product's 5-year NCE exclusivity period, discussed in Five-Year New Chemical Entity Exclusivity), the delay of final approval lasts until 7.5 years after approval of the innovator product.‡ Thus, in practice, the period during which final approval of the ANDA or 505(b)(2) NDA is delayed could be as long as 42 months.

The 30-month period can the lengthened or shortened by the court hearing the patent case "because either party to the action failed to reasonably cooperate in expediting the action."§ One district court's decision to shorten the 30 months, based on what it viewed as the NDA sponsor's improper conduct before the FDA in connection with the listing of the patent, was rejected on appeal by the Federal Circuit. The Federal Circuit concluded that the 30-month period could be shortened based only on delay related to the particular infringement lawsuit.¶

In 2003, the FDC Act was amended to provide that, in most cases, the 30-month stay of final ANDA or 505(b)(2) NDA approval is available only with regard to

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* *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012) (involving repaglinide).

† 21 USC § 355(c)(3)(C) and (j)(5)(B)(iii) (as amended by MMA).

‡ 21 USC § 355(c)(3)(E)(ii) and (j)(5)(F)(ii) (as amended by MMA).

§ 21 USC § 355(c)(3)(C) and (j)(5)(B)(iii).

¶ *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (involving diltiazem).