patents that were listed in the Orange Book before submission of the ANDA or 505(b)(2) NDA.* This provision applies to patents listed in the Orange Book on or after August 18, 2003.† The practical result is that there is, in most cases, a single 30-month stay per ANDA or 505(b)(2) NDA. A notable exception is where the ANDA or 505(b)(2) NDA sponsor initially submits a Paragraph III certification to a patent listed in the Orange Book at the time of original application submission but subsequently converts its Paragraph III certification to a Paragraph IV certification.‡

Hatch–Waxman Patent Infringement Litigation

Under the current interpretation of 180-day generic drug exclusivity, 180-day exclusivity is available whenever a Paragraph IV ANDA is filed. Although a discussion of patent infringement litigation is beyond the scope of this book, two brief points are worthy of note.

First, the sponsor of a Paragraph IV ANDA always stands a reasonably likelihood of being sued for patent infringement in the Hatch–Waxman 45-day window. Although ANDA sponsors may, as a matter of business tactics, want to be aggressive in filing Paragraph IV ANDAs and pursuing patent challenges, the merit—or lack of merit—of any particular challenge should be viewed objectively. Paragraph IV ANDA applicants have been found liable for the NDA sponsor's and patent holder's very substantial attorneys' fees for pursuing what the court characterized as baseless patent challenges.§ In such cases, attorneys' fees often amount to millions of dollars.

Second, in some cases, Paragraph IV ANDA applicants have been sued, within the Hatch–Waxman 45-day window, for infringement of patents not listed in the Orange Book. The Federal Circuit ruled that a patent holder could seek a declaratory judgment that its process patent (which is not eligible for Orange Book listing) will be infringed by the ANDA sponsor.¶ In other cases, Paragraph IV ANDA applicants were sued, again within the 45-day Hatch–Waxman window, for alleged infringement of, and inducement to infringe, Orange Book method-of-use patents claiming unapproved uses. The Federal Circuit has affirmed district court decisions granting summary judgments of noninfringement in such cases.**

Declaratory Judgment Actions

Since the enactment of the Hatch–Waxman Amendments in 1984, ANDA and 505(b)(2) NDA sponsors have been able to bring a declaratory judgment action seeking

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

† MMA § 1101(c)(3).

‡ *Draft Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch–Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Questions and Answers*, October 2004. Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072887.pdf. Accessed June 13, 2013.

§ E.g., *Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc.*, 549 F.3d 1381 (Fed. Cir. 2008) (upholding award of $16.8 million in attorneys' fees in connection with pioglitazone).

¶ *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997) (involving ranitidine).

** E.g., *Warner-Lambert Company v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003) (involving gabapentin).