a declaration of patent invalidity, noninfringement, or unenforceability once the 45-day window for a patent infringement lawsuit has run and no suit was brought.* A successful declaratory judgment action can help bring patent certainty, as a patent owner can bring a patent infringement lawsuit after a generic sponsor receives final approval and begins marketing even if the patent owner had elected not to bring a patent infringement lawsuit pursuant to notice of a Paragraph IV certification. For a "subsequent" Paragraph IV ANDA sponsor that is blocked by the first-filer's 180-day exclusivity, a successful declaratory judgment lawsuit can trigger (or help trigger) the first filer's 180-day exclusivity.

The MMA added a condition precedent to the bringing of a declaratory judgment lawsuit seeking a declaration of patent noninfringement. Before an ANDA or 505(b)(2) NDA sponsor can bring such a declaratory judgment action, it must make an offer of confidential access to its pending application. The offer of confidential access is to be part of the notice of a Paragraph IV certification given to the NDA sponsor and the patent owner.†

The MMA also amended patent law to provide that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over declaratory judgment actions regarding patents.‡

The existence (or lack thereof) of subject matter jurisdiction over declaratory judgment lawsuits involving Orange Book patents has been a source of substantial controversy. The Federal Circuit has held that the courts may have jurisdiction over a declaratory judgment lawsuit based on an Orange Book patent that was not the subject of a Paragraph IV patent infringement lawsuit.§ However, there is no jurisdiction if the declaratory judgment plaintiff has stipulated to the validity and noninfringement of an Orange Book patent that blocks generic competition.¶ A covenant not to sue granted to the declaratory judgment plaintiff by the patent owner does not automatically defeat declaratory judgment jurisdiction.** In the author's view, there is room for interpretation as district courts continue to apply these Federal Circuit decisions to specific factual scenarios.

Bolar-Type Considerations

The Hatch–Waxman Amendments permit an ANDA or 505(b)(2) NDA sponsor or prospective sponsor to engage in activities reasonably related to seeking government approval for its generic drug, without infringing any patents covering the innovator drug.†† This provision is commonly known as the Bolar provision. Because the FDA requires validation data from three commercial-size manufacturing batches as a

* 21 USC § 355(c)(3)(D)(i) and (j)(5)(C)(i) (as amended by MMA).
† 21 USC § 355(c)(3)(D)(i)(III) and (j)(5)(C)(i)(III) (as added by MMA).
‡ 35 USC § 271(e)(5) (as added by MMA).
§ *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corporation*, 482 F. 3d 1330 (Fed. Cir. 2007) (involving famciclovir).
¶ *Janssen Pharmaceutical, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008) (involving risperidone).
** *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008) (involving escitalopram).
†† 35 USC § 271(e)(1).