

condition of ANDA or 505(b)(2) NDA approval, the Hatch–Waxman Bolar provision effectively permits an ANDA or 505(b)(2) NDA sponsor to stockpile reasonable quantities of product for product launch in anticipation of final approval. However, it does not provide a safe harbor from infringement for any additional product manufactured before final approval. Likewise, there is no safe harbor from infringement of patents covering equipment or products that may be related to product development but that are not of themselves subject to the FDA approval process.* To the extent that an ANDA or 505(b)(2) NDA sponsor’s proposed product is developed or manufactured in a foreign country, differing patent laws will apply and there may be no safe harbor.

AUTHORIZED GENERICS

An authorized generic is a drug product approved under the innovator firm’s NDA but marketed through generic marketing channels in generic trade dress rather than under the innovator’s brand name. Authorized generics are sometimes marketed by a subsidiary of the innovator drug company; more often, they are marketed by an independent company pursuant to a contract between that company and the innovator company. In some cases, an authorized generic results from the settlement of Paragraph IV patent infringement litigation, whereby the generic company entitled to 180-day exclusivity rights for that drug product receives the right to market an authorized generic version of the product, typically starting 6 months or so before patent expiration. In other instances, the innovator company has entered into an agreement for marketing and distribution of an authorized generic version of its product to coincide with the commercial launch of a “true” (ANDA) generic.

Authorized generics are a definite source of controversy between different industry segments. The innovator industry and some segments of the generic industry generally contend that authorized generics give consumers more choice and save money, by leading to competition in the “generic” marketplace sooner. For example, the availability of an authorized generic at the time that a true generic is launched will typically result in lower prices, as it is well recognized that the price of generic products decreases as the number of marketplace competitors increases. Not surprisingly, many segments of the generic industry generally take a different view. These segments of the generic industry contend that the real underlying purpose of authorized generics is to reduce or destroy the value of the 180-day exclusivity incentive, thereby undermining and devaluing the entire incentive for challenging patents on innovator drug products. In several lawsuits against the FDA, generic companies have asserted that authorized generics are unlawful. However, these lawsuits have been rejected by two Courts of Appeals.†

Agreements between innovator drug companies and Paragraph IV ANDA sponsors that concern, among other matters, authorized generics have to be reported to

* *Proveris Scientific Corporation v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).

† *Teva Pharmaceutical Industries Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005) (involving gabapentin); *Mylan Pharmaceuticals, Inc. v. Food and Drug Administration*, 454 F.3d 270 (4th Cir. 2006) (involving nitrofurantoin).