Takeda reportedly bestowed upon the generics the ability to tell Teva about the acceleration clauses.[45]

Of particular note among the contract clauses are we what we call "boy scout clauses." These are clauses in which the brand-name company promises good behavior but does so in a way that has anticompetitive effects. To explain boy scout clauses, we need to introduce a concept known as "authorized generics."

Brand-name companies often introduce generic, unbranded versions of their own drugs, at a lower price, to compete against the incoming first generic. Given that the brand-name company already has FDA approval, it is not subject to generic approval processes, and, therefore, its own "generic version" is not restricted from entering the market during the first filer's six-month exclusivity period. In 2005, the D.C. Circuit ruled that the six-month exclusivity does not block authorized generics because brand-name approval has already taken place. The exclusivity provision only bars *future* approvals.[46]

(As an aside, the existence of authorized generics is an example of both how cheap the marginal cost of production can be once research and development are completed, and of how extensive the markup can be on branded pharmaceuticals. It demonstrates that a brand-name company can instantly reduce the price on its drug if it so wishes toward the end of its exclusivity life span.)

Authorized generics allow a brand-name company to hold on to a portion of the profits that would otherwise go to the first generic filer, and it reduces the incentive for entering generics. This changes the Hatch-Waxman calculus for a perspective generic: if you win your patent challenge, you will now be entering a market with another generic on the shelves, not just the expensive brand-name drug. Licenses to manufacture authorized generics also tend to appear in "side deals" in Generation 2.0 agreements.[47]

Early on, commentators expressed concern about the potential anticompetitive effects of the authorized generics and whether the practice undermines the Hatch-Waxman incentive structure. After all, does it not seem to be a bit of a bait and switch? We have spent the first part of this book talking about first filers and the six-month exclusivity, only to find out that it is not so exclusive after all. If the goal of Hatch-Waxman is to incentivize generic challenges, it certainly feels as if authorized generics might hamper this goal by cutting into the monetary reward of the exclusivity period. At the same time, authorized generics pose an interesting problem. While

[45] *Ibid*. at paras. 216.

[46] *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

[47] For example, the authorized generic version of Lipitor (atorvastatin) was not made by Pfizer, but was instead manufactured by Watson. *See* Jing Luo *et al.*, *Effect of Generic Competition on Atorvastatin Prescribing and Patients' Out-of-Pocket Spending*, J. Am. Med. Ass'n. Intern. Med. (Jun. 27, 2016), http://archinte.jamanetwork.com/article.aspx?articleid=2530416#ioi160055r28.