research.[11] Hatch-Waxman, which remedied this problem, was signed into law five months later.

Now, when a brand-name drug company files for FDA approval, the law requires that the company list all patents that "could reasonably be asserted" against a generic applicant.[12] These are then recorded in an FDA document commonly referred to as the "Orange Book" because of its orange cover in print form. The document is formally known as "Approved Drug Products with Therapeutic Equivalence Evaluations."[13] ("ADP-TEE" didn't quite roll off the tongue as well as "Orange Book.") In ways both good and definitely bad, the Orange Book resembles outdated print methods of information organization, such as a phone book. The book is intended to serve as a compendium of all currently approved drugs and the information their manufacturers provide about them. In the modern world of search and data storage, the printed Orange Book is an outdated method of assembling information.

The Orange Book has played a prominent role in some of the game playing that has unfolded across time, mainly because its contents are, unbelievably, not subject to FDA verification. Drug makers can list any patent numbers they wish for a drug and any description of what those patents protect, and the FDA does not make any judgment on the validity of the contents. These listing decisions then have enormous consequences for the legal steps a generic company needs to take to reach the market. It seems strange that so much of the generic pipeline relies on an unchecked document (available only in print until recently) that is readily subject to abuse, but that is the system as it currently exists.

When a generic drug maker arrives later on the scene and files an application for approval with the FDA, the generic must make one of four "certifications" to each of the patents the brand-name drug maker has listed for the drug in the Orange Book.[14] Most of these certifications result in limited fuss and bother because they either represent that all the patents have expired, that no relevant patents are listed in the Orange Book, or that the generic company will wait until all patents expire before taking the drug to market.[15]

All the action, however, is in what is known as a "Paragraph IV" certification. A Paragraph IV certification alleges that the listed patent either (1) is invalid or

[11] *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863–64 (Fed. Cir. 1984).

[12] 21 U.S.C. § 355(b)(1) (2012).

[13] Feldman, Rethinking Patent Law, *supra* note 2, at 60–61; *see Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. Food & Drug Admin. (May 17, 2013), www.accessdata .fda.gov/scripts/cder/ob/default.cfm.

[14] *See* 21 U.S.C. § 355(j)(2)(A)(vii) (2012); *see also* 21 U.S.C. § 355(j)(7)(A) (2012) (describing the workings of the Orange Book).

[15] *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III) (2012).