specific outlets, and the generic company, naturally, is not one of those outlets. As described later, some brand-name companies refuse, even as the FDA insists that the company is free to sell to the generic hopeful.

Actelion was one of the first cases on this subject when the suit was filed in 2012.[12] In *Actelion*, the brand-name company refused to provide samples of two drugs to potential generic companies, preventing the generic hopefuls from filing their applications.[13] The brand-name company's position is difficult to fathom. Congress anticipated this type of tactic, and the legislation establishing REMS includes a provision specifically stating that an ETASU cannot be used to block or delay approval of a generic.[14] Further, the FDA has repeatedly said that brands may sell samples to firms for bioequivalence testing without violating their REMS program, and the Agency has even issued letters to branded manufacturers specifically permitting them to give samples to prospective generics.[15]

The legal arguments in the *Actelion* case focused on whether refusal to sell samples to a generic competitor constitutes an antitrust violation.[16] Actelion asserted that it has a right to refuse to sell even in the absence of the REMS and the company has no legal duty to provide samples to a potential generic competitor.[17] The FTC filed

[12] *Actelion Pharm. LTD v. Apotex Inc.*, No. 12–5743, 2013 WL 5524078 (D.N.J. Sept. 6, 2013); *see also* Kat Greene, *Actelion Settles Row over Giving Drugs to Generic Makers*, Law360 (Feb. 28, 2014, 7:07 PM), www.law360.com/articles/514434/actelion-settles-row-over-giving-drugs-to-generics-makers. In one other previous case filed in 2008, Lannett accused Celgene of refusing to provide it samples of Thalomid. The case ended in a settlement. Verified Complaint for Mandatory Injunctive Relief, Declaratory Relief and Money Damages, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912 (E.D. Pa. Aug. 15, 2008).

[13] *Actelion Pharm.*, 2013 WL 5524078, at *1.

[14] 21 U.S.C. § 355–1(f)(8) (2012).

[15] *See* Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) Public Meeting 270–72 (July 28, 2010) (statement by Jane Axelrad, Associate Director of Policy, Ctr. for Drug Evaluation and Res.), www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf (asserting that REMS should not be a barrier to acquiring generic samples). In part, these letters came about after a citizen petition filed in 2009 by Dr. Reddy's asking the FDA to issue guidance regarding the use of REMS to block or delay generic entry. It also asked the FDA to establish a procedure by which the FDA would provide letters on behalf of generic applicants to explain that the generic will meet the REMS safe use requirements that might be implicated in bioequivalence testing. *See* Citizen Petition from Kumar Sekar, Senior Dir., to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2009-P-0266-0001, at 10 (June 10, 2009), www.fdalawyersblog.com/Dr_Reddys_Laboratories,_Inc_-_Citizen_Petition.pdf. Dr. Reddy's was attempting to obtain samples of Celgene's Revlimid and Thalomid, which are also the subject of another ongoing REMS-based lawsuit described later in the chapter.

[16] *See generally* Darren S. Tucker, Gregory F. Wells & Margaret Sheer, *REMS: The Next Pharmaceutical Enforcement Priority?* 28 Antitrust 74 (2014).

[17] *See* Memorandum of Law in Support of Plaintiffs' Motion for Judgment on the Pleadings and to Dismiss Counterclaims at 8, *Actelion Pharm. Ltd. v. Apotex Inc.*, Case 1:12-cv-05743-NLH-AMD (D. N.J. Mar. 18, 2013).