

a brief stating that the company's action may amount to exclusionary conduct.¹⁸ The case ended in a settlement in early 2014.¹⁹

In a similar case filed against the brand-name drug manufacturer Celgene, a generic hopeful alleged that it spent five years trying unsuccessfully to get a sample of Celgene's Thalomid (thalidomide) and another five years trying unsuccessfully to obtain a sample of Celgene's Revlimid (lenalidomide), two drugs with clear safety concerns.²⁰ The complaint alleged that Celgene repeatedly asked for more information and FDA assurances until the generic "recognized that further engagement with Celgene would be fruitless."²¹ Although the judge dismissed some claims in the generic's complaint, she allowed important antitrust claims to survive a motion to dismiss, finding that the generic pleaded with enough detail that Celgene had no "legitimate business reasons" for denying samples.²² Celgene's actions also led to the initiation of an FTC investigation into the company's practices.²³

Celgene went even further, however, by obtaining a patent on its method of protecting patient safety. The patent on the thalidomide REMS safety plan specifies that the company has exclusive rights in the supposedly novel invention of "delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated."²⁴

This is what is known as a "business method patent," a notoriously suspect category of patents that the Supreme Court has repeatedly attacked in recent years.²⁵ In

¹⁸ For a detailed analysis of the potential antitrust issues in restricted distribution cases, see Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. (forthcoming 2016), <http://ssrn.com/abstract=2724604>.

¹⁹ Greene, *Actelion Settles Row*, *supra* note 12; Lance Duroi, *Actelion Denied Judgment in Tracleer Antitrust Suit*, LAW360 (Oct. 21, 2013, 8:00 PM), www.law360.com/articles/481879. Although a settlement may represent a party's rational calculation of the strength of its case and the costs of continuing to litigate, it may also represent the strategic choice to abandon a case or pay off the other side if damaging information might emerge or dangerous precedents might be set.

²⁰ *Mylan Pharmaceuticals v. Celgene Corp.*, No. 14-cv-2094, Transcript of Oral Opinion at *4-9 (D.N.J. Dec. 22, 2014) (denying in part and granting in part Celgene's motion to dismiss by oral opinion). The case later ended in a settlement.

²¹ *Mylan Pharmaceuticals v. Celgene Corp.*, No. 14-cv-2094, Transcript of Oral Opinion at *7 (D.N.J. Dec. 22, 2014) (denying in part and granting in part Celgene's motion to dismiss by oral opinion).

²² *Ibid.* at *17-18; see also Carrier, Levidow & Kesselheim, *Using Antitrust Law*, *supra* note 18, at *13-14 (discussing this case).

²³ Laura S. Shores, *Pharmaceutical Patent Life Extension Strategies: Are REMS Programs Next?* ANTITRUST HEALTH CARE CHRON. 19, 27 (March 2012) (citing Form 10-Q Quarterly Report for Celgene Corp. (filed Nov. 2, 2011)).

²⁴ See Ameet Sarpatwari, Jerry Avorn, & Aaron Kesselheim, *Using a Drug-Safety Tool to Prevent Competition*, 370(16) NEW ENGLAND J. OF MED. 1476, 1477 (April 17, 2014) (describing US Patent US 7,141,018 B2 and discussing the thalidomide REMS in the context of problems within the REMS system).

²⁵ See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); see also *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). For a description of these cases, see Robin Feldman, *Coming*