the *Alice* line of cases, the Supreme Court rejected both ordinary business method patents and those implemented through software. In fact, the Supreme Court has emphasized repeatedly that patentability requires an inventive concept beyond combining a series of well-known conventional steps, such as testing, tracking, and informing.

Armed with that suspect patent on its REMS safety plan, Celgene then set about blocking generic entry. When a generic company applied for approval, the original drug maker, Celgene, filed a petition asking the FDA to deny the application, including on the grounds that no generic could use Celgene's patented REMS safety plan and that any other plan would compromise patient safety by compounding burdens and confusion.[26] In other words, no generic could ever exist.

The FDA denied Celgene's petition a full seven years later.[27] But the damage was done – a decade later, no generic for Thalomid exists, and after all the trouble the one beleaguered generic went through to try to reach the market, it withdrew its application in 2010.[28]

The attempt to patent a REMS program is a particularly suspect approach, but setting this aside, REMS manipulation, in theory, could be particularly dangerous for generic competition. REMS are not linked to patents on a drug's active ingredient or mechanism of action. As a result, they can continue indefinitely, even after the expiration of all patents – they are safety programs, after all. Thus, if a company, hiding behind a restrictive REMS, refuses to allow samples to generic hopefuls, the brand-name company could continue its monopoly past the end of the patent term. And even if the company is eventually forced to share samples, every month of delay is valuable.

Furthermore, a restricted distribution scheme does not even need a REMS, or even an active patent, to be effective in blocking generic competition. For example, the case of Turing Pharmaceuticals, Martin Shkreli (yes, he is back), and Daraprim involved a restricted distribution system not imposed by the FDA, as did schemes

of Age for the Federal Circuit, 18 Green Bag 2D 27 (2014); Robin Feldman, *A Conversation on Judicial Decision-Making*, 5 Hastings Sci & Tech. L.J. 2 (2013).

[26] *See* Sarpatwari, Avorn, & Kesselheim, *Using a Drug-Safety Tool*, *supra* note 24, at 1477 (discussing Citizen Petition from Celgene Corporation to the FDA at 17–18 (September 20, 2007), www.regulations.gov/document?D=FDA-2007-P-0113-0002).

[27] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, FDA, to Gary L. Vernon, Sidney Austin LLP, Re: Docket No. FDA-2007-P-0113 (Sept. 30, 2014), www.regulations.gov/document?D=FDA-2007-P-0113-0028 (denying the Celgene citizen petition).

[28] Press Release, Celgene Corp., Celgene Announces Dismissal of Suit against Barr Laboratories Following Withdrawal of Thalidomide ANDA (May 27, 2010), http://ir.celgene.com/releasedetail.cfm?releaseid=799456 (press release confirming withdrawal of the application).