of generic-related citizen petitions each year has not decreased. In 2003, 12 generic delay-related petitions were filed; in 2010, that number had more than doubled to 31. In that same time frame, delay-related petitions had also doubled as a proportion of *all* citizen petitions, with delay-related petitions filed by pharmaceutical companies constituting 20 percent of *all* citizen petitions by 2010, including those related to food, cosmetics, and medical devices. We will return to the rest of our empirical research on citizen petitions in Chapter 5.

The 505(q) amendment's most biting provision also has proven difficult to apply. Recall that the statute allows the FDA to deny petitions summarily, but only when they are both 1) submitted for the main purpose of delay and 2) raise no valid scientific or regulatory issues on their face. Proving both of these requirements concurrently has turned out to be quite difficult, with the FDA calling it a standard that is "extremely difficult to meet."[109] In fact, since the amendments took effect in fiscal year 2008, the FDA has *never* applied the summary denial provision.[110]

In theory, the wounded would-be generic could file a lawsuit asserting that the brand-name company engaged in anticompetitive behavior by submitting a sham citizen's petition. Such a lawsuit is unlikely to succeed, however.[111] The difficulty flows back to *Noerr-Pennington*, a line of Supreme Court cases from the 1960s that establishes a general right to petition the government without fear of antitrust liability.[112] *Noerr-Pennington* does carve out an exception that allows antitrust liability when petitioning the government constitutes a sham filing that is meant merely to interfere with a competitor.[113] The Supreme Court, however, has set an extremely high standard for demonstrating that a legal petition is a sham. Specifically, the petition must be objectively baseless – which means that no reasonable petitioner can realistically expect success on the merits – as well as subjectively baseless – which means that the petition tries to conceal an attempt to interfere directly with

[109] U.S. Food & Drug Admin., Seventh Annual Report to Congress on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2014, at 9 (2015) [hereinafter FDA Seventh Annual Report for FY 2014].

[110] FDA Sixth Annual Report for FY 2013, *supra* note 106, at 7. *See generally* Seth C. Silber, Jonathan Lutinski & Rachel Taylor, *Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?* 25 Antitrust Health Care Chron. 26 (2012).

[111] *See* Silber, Lutinski & Taylor, *Abuse of the FDA Citizen Petition Process*, *supra* note 110, at 30.

[112] For a detailed description of the development of *Noerr-Pennington*, see generally Robin Feldman, *Federalism, First Amendment, and Patents: The Fraud Fallacy*, 17 Colum. Sci. & Tech. L. Rev. 30 (2015).

[113] *United Mine Workers v. Pennington*, 381 U.S. 657, 669–72 (1965); *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *see also* Silber, Lutinski & Taylon, *supra* note 110, at 30; Robin Feldman, Rethinking Patent Law 166 (2012); Robin Feldman, *Intellectual Property Wrongs*, 18 Stan. J.L. Bus. & Fin. 250, 301–05 (2013) (suggesting that there may be a pathway for proving sham litigation, at least with actions that demonstrate multiplicity).