competition through the administrative process.[114] This burden on plaintiffs is crushing.

Still other pathways exist for abusing the citizen petition process, despite the limitations imposed by the amendments. As the FDA itself has noted, the 150-day clock applies only when a citizen petition has the power to delay generic approval.[115] If a citizen petition is filed before any generic application is submitted or before any generic application is "ready" for approval under the Hatch-Waxman rules, the 150-day deadline does not apply, a scenario that the FDA says is the case in "many instances."[116] Thus, citizen petitions filed before a generic application is ready can serve as yet another obstacle, perhaps combined with strategies already in play.

Finally, the 150-day limit applies to consideration of each petition, rather than providing a 150-day maximum for how long generic approval can be put on hold. That leaves the door open for what the FDA has called "serial" petitions, in which multiple petitions are filed about the same drug, frequently from the same petitioner.[117] In the FDA's 2011 report on citizen petitions, for example, it noted the following:

> For example, the agency received its fourth [delay-related] petition relating to the approval of ANDAs for topical ophthalmic products and a third [delay-related] petition related to Doryx (doxycycline). The various submissions raised different scientific issues, requiring serial review of different arguments, rather than one comprehensive review of all pertinent arguments.[118]

By filing separate petitions at staggered times on disparate issues, a brand-name company can force the FDA to spend time responding to each petition, thereby potentially lengthening the total delay by citizen petition far beyond 150 days.[119]

In our own review of citizen petitions, we came across a number of these petitions related to Doryx, an antibiotic and antimalarial drug, revealing how staggered petitions can tax FDA resources and lead to substantial delay. One petition, filed in 2004, suggests that a generic would need to file a suitability petition if its capsules

[114] *Professional Real Estate Inv'rs. v. Columbia Pictures Indus.*, 508 U.S. 49, 60–61 (1993); *see also* Silber, Lutinski & Taylon, *Abuse of the FDA Citizen Petition Process*, *supra* note 110, at 30–31; Feldman, Rethinking Patent Law, *supra* note 113, at 166–67.

[115] FDA Sixth Annual Report for FY 2013, *supra* note 106, at 6.

[116] Wilson Sonsini Goodrich & Rosati, Citizen Petitions Aimed at Delaying Generic Competition Remain a Concern 1 (2015), www.wsgr.com/publications/PDFSearch/wsgralert-citizen-petitions.pdf; *see also* FDA Sixth Annual Report for FY 2013, *supra* note 106, at 6–7.

[117] FDA Sixth Annual Report for FY 2013, *supra* note 106, at 7.

[118] U.S. Food & Drug Admin., Fourth Annual Report to Congress on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011, at 6 (2012), www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM369782.pdf.

[119] *Ibid.*; Wilson Sonsini Goodrich & Rosati, Citizen Petitions Aimed at Delaying Generic Competition Remain a Concern, *supra* note 116, at 2.