

commitment, for example, if the brand company does not market generics in the United States.² This type of provision appears in 1 agreement in FY 2021.

- A reduced or eliminated if the brand launches an authorized generic product or authorizes a third party to launch an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment and appears in 2 agreements in FY 2021

litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of these 101 first-filer settlements:

- 14 contain explicit compensation to the generic and a restriction on generic sales. All these agreements include compensation in the form of litigation fees.

1 of these 14 agreements contains compensation in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

2 of these 14 agreements also include possible compensation.

- 3 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation.
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manufacturer a license or covenant not to sue to begin selling the generic product prior to the expiration of the relevant patent(s).

- 166 of these 167 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events. The remaining agreement does not contain any acceleration provisions.
- Some of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient.

At-Risk Launch None of the final settlements occurred after the generic manufacturer had launched its product at risk.

PTAB Settlements 7 of the final settlements involve the resolution of an *inter partes* review or a post-grant review initiated by the generic manufacturer.

- 6 of these final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer.
- None of these settlements involve compensation to the generic manufacturer.

Additional Agreements Entered Within 30 Days For 22 final settlements, the FTC received one or more additional agreements that the parties entered into within 30 days of the primary agreement (but not on the same day as the primary agreement).

- For 3 of these final settlements, one or more of the additional agreements the FTC received contain explicit compensation in the form of litigation fees. For 1 of these final settlements, one or more of the additional agreements the FTC received also contain possible compensation.
- For 19 of these final settlements, none of the additional agreements the FTC received contain compensation.

EXHIBIT 1

	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245	194	205	199
w/ Restriction on Generic																		