approval, the FDA said it made an error and changed its orphan drug approval to cover Tourette's disorder in *all patients* instead of just pediatric patients.[176] This likely would have hurt Otsuka's generic-blocking argument under § 355A(o), since the orphan use would have no longer been a specific pediatric use, but rather a general-population indication.[177] It is also amusing, because Otsuka was essentially suing the FDA for approving the use of Abilify for *too wide* a population, a move that also points to the pediatric indication as a targeted addition by Otsuka to block generics. The FDA denies this change ever took place, and says any communication to the contrary was an error and not an official change.[178] Nevertheless, Otsuka filed a motion to stop generic approval, and by April 2015, it was clear that the indication was only for pediatric Tourette's despite any action the FDA may or may have not taken.[179]

Matters did not work out so well for Otsuka. The FDA approved generic versions of Abilify, and a federal judge denied Otsuka's motion for a preliminary injunction.[180] He found that § 355A(o) does not preclude the FDA from allowing Orphan Drug Act pediatric carve-outs, but instead seems to clarify that the FDA *can* in fact allow carve-outs related to Hatch-Waxman exclusivities. And the judge had a point. The language of the statute does say that applications "shall not be considered ineligible for approval," an extremely confusing double negative that supports the judge's finding, by broadening what is eligible for a carve-out rather than restricting it. The FDA made a similar determination in its denial of Otsuka's argument, finding that Otsuka's arguments regarding § 355A(o) turn the section "on its head."[181] Statutory interpretation has not been this interesting since the Supreme Court tackled the definition of an Affordable Care Act "Exchange" in *King v. Burwell*![182]

Moving back to Crestor, AstraZeneca tried to argue that this time was different, making a very similar assertion regarding pediatric labeling and the Orphan Drug Act. Along with arguing that the decisions made by the FDA and the federal court were incorrect, the company tried to differentiate itself from Otsuka's Abilify debacle. Another deep breath – okay, ready? Abilify was only approved for

[176] *Ibid*. at 13–14.

[177] Silverman, *FDA Is Sued by Otsuka for 'Unlawfully' Widening the Market for Abilify*, *supra* note 170.

[178] Federal Defendants' Opposition to Plaintiffs' Motion, *supra* note 171, at 8–10.

[179] *Ibid*. at 9; Amended Complaint, *supra* note 175, at 14 (both referring to April 2015 letter).

[180] *Otsuka Pharm Co., Ltd., et al. v. Burwell et al.*, No. 8:15-cv-00852, at 13–14 (D. Md. Apr. 29, 2015) (memorandum opinion) (denying Otsuka's motion for temporary restaining order or preliminary injunction).

[181] Letter from John R. Peters, Acting Dir., Off. of Generic Drugs, U.S. Food & Drug Admin., to Ralph S. Tyler, Venable LLP, at 9–12, 15 (Apr. 28, 2015), www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM444858.pdf (discussing Otsuka's arguments regarding Abilify generics).

[182] *King v. Burwell*, 135 S. Ct. 2480 (2015).