AstraZeneca believes the authority for its argument stems from the unique interplay between laws governing all pharmaceutical labeling and those that specifically apply to pediatric treatment, which the company says prevents any of the pediatric labeling from being omitted from a generic label.

This was not the first time such pediatric labeling problems had arisen during the generic application process. In December 2014, with exclusivity expiring in just a few months, the brand-name company Otsuka received a pediatric Orphan Drug Designation for Abilify, a blockbuster antipsychotic drug used for treatment of depression, bipolar disorder, and schizophrenia, among other illnesses.[170] The approved supplementary new drug application allowed Otsuka to market Abilify for the pediatric treatment of Tourette's disorder.[171]

Just as AstraZeneca did more than a year later, Otsuka argued that the pediatric Tourette's indication could not be carved out of the label. The legal argument is from 21 U.S.C. § 355A(o), added in 2002's "Best Pharmaceuticals for Children Act," which states that generics are not barred from approval if "the labeling of the drug omits a *pediatric indication* or any other aspect of labeling pertaining to *pediatric use* when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of Section 355(j)(5)(F) of this title" (emphasis added).[172] Clauses (iii) and (iv) of Section 355(j)(5)(F) refer to new drug and new study exclusivities that are provided for under Hatch-Waxman – notably, it does not expressly mention orphan drug exclusivity, which is contained in a different section of the Food, Drug, and Cosmetic Act.[173] (That would be Sections 360aa to 360ff, by the way.)[174] Thus, Otsuka argued that the absence of the Orphan Drug Act from the statutes precludes the FDA from allowing a carve-out of a pediatric indication – a novel argument, to say the least.[175]

Otsuka also argued that the FDA went to unprecedented lengths to stop it from blocking generics with the pediatric indication, adding a complicated twist to an already labyrinthine story. In a complaint, it argues that, a few months after

[170] Ed Silverman, *FDA is Sued by Otsuka for 'Unlawfully' Widening the Market for Abilify*, Wall. St. J. (Mar. 26, 2015), http://blogs.wsj.com/pharmalot/2015/03/26/fda-is-sued-by-otsuka-for-unlawfully-widening-the-market-for-ability/.

[171] Federal Defendants' Opposition to Plaintiffs' Motion for a Temporary Restraining Order and/or Preliminary Injunction, *Otsuka Pharmaceutical Co., Ltd., et al. v. Burwell et al.*, No. 8:15-cv-00852, at 7–8 (D. Md. Apr. 20, 2015), www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2015/April/Otsuka%20v%20Burwell%20FDA%20opposition%20to%20TRO%20PI%20042015.pdf.

[172] 21 U.S.C. § 355A(o).

[173] 21 U.S.C. § 355(j)(5)(F)(iii)–(iv).

[174] 21 U.S.C. § 360aa–ff.

[175] Amended Complaint, *Otsuka Pharm Co., Ltd., et al. v. Burwell et al.*, No. 8:15-cv-00852, at 11 (D. Md. Apr. 15, 2015), http://assets.fiercemarkets.net/public/lifesciences/complaint76-1.pdf.