

## B IN RE LIPITOR: EVERYTHING BUT THE KITCHEN SINK

While the Court of Appeals for the Third Circuit appeared to easily see through the intent of the two parties' side deal in *K-Dur*, getting to the bottom of a settlement is not always so easy. Clarity is particularly difficult to achieve when companies settle multiple Hatch-Waxman cases at once, distributing the payoffs in a way that quickly becomes quite complex.

Consider the case of *In re Lipitor*, which involved one of the most tangled sets of agreements in all of generic delay.<sup>17</sup> Lipitor, a statin used to lower cholesterol, is widely known as the best-selling drug in history, with more than \$125 billion in sales between 1996 and eventual generic entry in late 2011.<sup>18</sup> It is no surprise that Lipitor's manufacturer, Pfizer, went to unprecedented lengths to protect the monopoly on its ultrablockbuster. A protracted six-year battle between Pfizer and the first generic filer, Ranbaxy, led to a settlement including delayed entry for generic Lipitor.<sup>19</sup> Scrutiny of this settlement then led to multiple class action lawsuits.<sup>20</sup>

Together, the resulting litigation implicated issues allegedly including, but not limited to, sham litigation, sham patent obtainment through data falsification,<sup>21</sup> Orange Book listings (and patents not listed in the Orange Book), petitions filed with the FDA, multiple and staggered lawsuits, multiple settlements, and even purposeful generic application approval delay on the part of Ranbaxy through delays in moving generic manufacture to an FDA-approved facility.<sup>22</sup> For the sake of providing

<sup>17</sup> See *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. 2014) (dismissing direct purchasers' class actions); see also ROBIN FELDMAN, *RETHINKING PATENT LAW* 162 (2012); Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 638–39, 683.

<sup>18</sup> See *Lipitor Becomes World's Top-Selling Drug*, CRAIN'S N.Y. BUS. (Dec. 28, 2011), [www.craigslist.com/article/20111228/HEALTH\\_CARE/111229902](http://www.craigslist.com/article/20111228/HEALTH_CARE/111229902).

<sup>19</sup> See Direct Purchasers' Amended Complaint and Demand for July Trial at para. 87, *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. Sept. 12, 2014) (Nos. 3:12-cv-2389 & 3:12-cv-4115), 2013 WL 5669146 (dismissing direct purchasers' class actions).

<sup>20</sup> See *ibid.* See generally End-Payor Plaintiffs' Amended Consolidated Class Action Complaint and Jury Demand, *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. Oct. 15, 2013) (No. 3:12-cv-2389), 2013 WL 7117787 (breaking down all the alleged methods of delay in the case).

<sup>21</sup> *AFI-AGC Building Trades Welfare Plan v. Pfizer, Inc.*, No. 12-0939 (S.D.N.Y. filed Feb. 6, 2012) (arguing that Pfizer filed fraudulent and duplicate patent applications for Lipitor), cited in Laura S. Shores, *Pharmaceutical Patent Life Extension Strategies: Are REMS Next?* ANTITRUST HEALTH CARE CHRON. 20, 22 (2012).

<sup>22</sup> See End-Payor Amended Complaint, *supra* note 20, (breaking down all the alleged methods of delay in the case); see also *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, 2013 WL 4780496, at \*12 (D.N.J. Sept. 5, 2013) (granting in part and denying in part motion to dismiss class action claims and referencing the claims regarding Ranbaxy's purposeful negligence of data integrity and manufacturing practices); see also Complaint and Jury Demand, *Meijer, Inc. v. Ranbaxy, Inc.*, No. 1:15-cv-11828, 2015 WL 2219184 (D. Mass. May 12, 2015) (arguing manufacturing problems have been widespread for Ranbaxy and the result of their haste to put in ANDAs and lock in 180-day exclusivity).