

for the generic and the FDA. As the FDA admitted, “Carving out patent-protected language from the Precautions section of a label that pertains to a labeled use would generally not be permitted.”¹⁵⁸

The FDA, at an impasse, essentially chose to punt on the issue, making no decision on the brand-name company’s citizen petitions. Instead, a resolution eventually arrived through the courts five years later, when a Brooklyn-based district court judge invalidated the two bioavailability patents.¹⁵⁹ The judge held that, given what was already known about the drug, it was obvious that Skelaxin would be better absorbed if taken with food.¹⁶⁰ The supposed innovation named in the patents was nothing new at all. Thus, the generic won its Paragraph IV challenge, and the FDA approved the generic application in 2010, making the carve-out discussion entirely moot.¹⁶¹

The delay earned by King, however, was not a moot point. From the date that the FDA accepted the first generic application to the date of approval, King’s tactics delayed the entry of generic Skelaxin for almost a decade, despite the fact that the company eventually found its new patents invalidated. The delay may have been worth as much as \$3 billion in sales¹⁶² – all over one sentence on a label and two patents claiming the supposedly novel finding that Skelaxin is better absorbed when taken with food.

A more recent carve-out conundrum shows how exclusivities can create confusion in the carve-out process. In 2014, AstraZeneca received an Orphan Drug Designation for Crestor, a popular cholesterol-lowering statin.¹⁶³ The designation was granted because studies found that Crestor could be used for the treatment

Drug Admin., to Douglas Dewar, Senior Dir., Regulatory Affairs, King Pharm., Inc. (Nov. 4, 2006), www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/013217s046ltr.pdf (noting that the only label change was to the pharmacokinetics information).

¹⁵⁸ ANDA 40–455 APPROVAL PACKAGE, *supra* note 141, at 217.

¹⁵⁹ *King Pharm., Inc. et al. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501 (E.D.N.Y. 2009).

¹⁶⁰ See *ibid.*

¹⁶¹ ANDA 40–455 APPROVAL PACKAGE, *supra* note 141, at 227.

¹⁶² The figure of \$3 billion was calculated as follows: First, 2002 sales figures of \$238 million and 2009 sales of \$476 million for Skelaxin were averaged to produce an estimate of average yearly Skelaxin sales of \$357 million. The first full year in which Skelaxin faced a pending generic application was 2002, while 2009 was the last full year before generic approval. Then, \$357 million was multiplied by 9, representing approximately nine years of delay, to reach a total value of \$3.2 billion. Press Release, King Pharm., King Pharmaceuticals Acquires Primary Care Business Unit from Elan (Jan. 30, 2003), www.sec.gov/Archives/edgar/data/1047699/000095014403000944/g80411exv99w1.txt (noting 2002 sales of \$238 million); Press Release, Sandoz, Sandoz Announces Launch of First Generic Version of Leading Muscle Relaxant Skelaxin (May 20, 2010), www.fiercepharma.com/press-releases/sandoz-announces-launch-first-generic-version-leading-muscle-relaxant-skelaxin-and-a (noting 2009 sales of \$476 million).

¹⁶³ Citizen Petition from AstraZeneca Pharm. LP to Div. of Dockets Mgmt., U.S. Food and Drug Admin., No. FDA-2016-P-1485, at 1 (May 31, 2016) [hereinafter “AstraZeneca Petition”], www.regulations.gov/document?D=FDA-2016-P-1485-0001.