use of the drug.[136] In a response to a recent citizen petition, the FDA said requiring this type of "foreseeable use" analysis is "inconsistent with our long-standing policy of not interfering with the practice of medicine" and noted that a circuit court already rejected this argument as a bar to generic approval.[137]

Nevertheless, there are clear instances of brand-name companies making small labeling changes or securing weak method-of-use patents and then filing citizen petitions to block the carve-out requests that follow.[138] Admittedly, these tend to be some of the more complex examples in this book. Everything we have discussed so far builds up to this point, so let us dive in.

The history of Skelaxin, while complicated, is one of the most illustrative in this area, showing how adding one or two method-of-use patents along with clever labeling can lead to years of delay. Skelaxin, the brand name for the well-known muscle relaxant metaxalone, was first approved back in 1962.[139] The drug did not face the threat of generic competition for more than 30 years, even though the initial patent on the active ingredient expired in 1979.[140] The competitive landscape changed, however, in 2001, when a company filed for approval to market generic Skelaxin.[141]

With generic competition on the horizon, King, the brand, went to work on extending the monopoly market for the drug. In 2001, King conducted a study measuring bioavailability – how much of the drug actually reaches the desired destination over

[136] *See* Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Church & David Fox, Hogan Lovells US LLP, No. FDA-2014-P-1649, at 13–14 (Feb. 24, 2015), www.regulations.gov/#!documentDetail;D=FDA-2014-P-1649-0005.

[137] *See ibid.* at 14 n.27 (citing *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002)).

[138] Brand-name companies also have sought to block carve-outs by modifying the "use codes" associated with a given patent in the Orange Book. Use codes provide a brief description of what use of the drug is covered by the listed patent, and brand-name companies have been accused of trying to broaden the scope of use codes to prevent a Section viii carve-out. Like the patents listed in the Orange Book, use code information is not verified by the FDA. In *Caraco v. Novo Nordisk*, 132 S. Ct. 1670 (2012), however, the Supreme Court found that generic manufacturers can file a statutory counterclaim seeking correction of an inaccurate use code.

[139] *FDA Approved Drug Products*, U.S. Food & Drug Admin., www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (Enter drug name [Skelaxin] in search bar and click "submit.").

[140] Consolidated Class Action Complaint and Jury Demand at 10, *United Food & Commercial Workers Union & Midwest Health Benefits Fund v. King Pharm., Inc.*, No. 12-cv-00085 (E.D. Tenn. Mar. 8, 2012), ECF No. 1, *consolidated into* Skelaxin (Metaxalone) Antitrust Litig., No. 12-md-02343 (E.D. Tenn. June 14, 2012), *class certification denied* 299 F.R.D. 555 (2014).

[141] Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Application No. ANDA 40–445, Approval Package for Abbreviated New Drug Application Approval 211 (Mar. 31, 2010) [hereinafter ANDA 40–455 Approval Package], www.accessdata.fda.gov/drugsatfda_docs/anda/2010/040445Orig1s000.pdf (indicating, in the "Factual Background" of a 2010 Memorandum from Martin Shimer to the Dep't of Health & Human Servs., that ANDA 040445 was submitted on September 5, 2001). Although all relevant patents had expired at the time of filing, the generic did not receive immediate approval because of chemistry and bioequivalence problems that caused at least two years of delay before the relevant saga begins. *Ibid.*