lines allowing the tablet to be broken into three 50-mg pieces.[124] This petition is particularly suspicious: Warner received approval to change the 150-mg tablets from a single-scored version to a dual-scored version just 10 days before it submitted the petition and promised to withdraw the single-scored version from the market after receiving approval. About five months later, the FDA responded with what can only be called a governmental agency smackdown, denying every aspect of the brand-name petition. The language tiptoes close to directly alleging that the brand made the dual-scored change to delay a generic:

> Looking at the facts and circumstances of this case (including the fact that the RLD made scoring changes on the eve of expected generic approval and marketed the scored and unscored tablets concurrently without any added warnings, and the fact that the risk of medication error due to substitution of a single-scored tablet for a dual-scored tablet is low), we deny your request[.][125]

This denial also provides at least one confirmation of what is often thought to be true – that a last-minute citizen petition is often the final roadblock to generic approval. On the date of denial, the FDA approved a 150-mg *single-scored* tablet version of generic Doryx. In the end, Warner filed four unique petitions related to Doryx over seven years, and not a single one received a truly favorable decision from the FDA.

Thus, as with REMS delay, codified congressional condemnations of a practice[126] are just a new rule for which manufacturers must find a work-around – impose a deadline for responding to a petition, for example, and manufacturers will just file more petitions. Often, new rules are about as effective as admonishing schoolchildren to play nicely with each other on the playground.

C PREVENTING THE "SKINNY LABEL": BLOCKING CARVE-OUTS

As Generation 3.0 games advance, an additional tactic relates to "the skinny label." Before getting into the nitty-gritty of the different patents that may cover a drug, here is a general example of a "skinny label": say a hypothetical, panaceaic drug can be used for both the treatment of allergy symptoms and back pain. The brand-name drug company, however, has a patent only on the use of the drug for back pain and

[124] Citizen Petition from Warner Chilcott & Mayne Pharma Int'l Pty Ltd to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2011-P-0702 (Sept. 23, 2011), www.regulations.gov/document?D=FDA-2011-P-0702-0001.

[125] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Izumi Hara, Sen. Vice President & Gen. Counsel, Warner Chilcott, Re: No. FDA-2011-P-0702, at 8 (Feb. 8, 2012), www.regulations.gov/document?D=FDA-2011-P-0702-0003 (denying Warner & Mylan's petition).

[126] Referring to the REMS statute passed by Congress clarifying that a REMS cannot be used to block an ANDA and Section 505(q) for citizen petitions.