nothing else. In this case, a generic may be able to get on the market by declaring the generic form of the drug will only be sold to treat allergies, since that use of the drug is not patent protected. The protected use is "carved out," as it is called in pharmaceutical parlance, and what remains is a "skinny label" specifying only use for allergy symptoms.

In fact, many patents on pharmaceuticals do not cover substances and chemical formulas, but particular uses of a drug. Hatch-Waxman, however, expressly allows a generic applicant to seek approval for a "skinny label" version that only covers uses of the drug not protected by patents or FDA exclusivities.[127] Applicants also can ask permission to omit some of the brand-name drug's other labeling language from the generic label if that language relates to uses that are protected.[128] Along with the "skinny label" term, these requests are often known as "Section viii carve-outs," referring to a section in Hatch-Waxman.

For example, the brand-name company's only patent on a drug could be a "method-of-use" patent, which protects only certain indications of the drug, with "indication" referring to a reason why the drug is administered (e.g. "for treatment of *Helicobacter* infections"). This scenario might occur when the drug's chemical formula had been patented or used in the past, and the company could receive only a more limited patent for a new indication of the medicine. Under these circumstances, the generic could request approval for uses of the medication that had already gone off patent.[129]

Request for a "skinny label" could also apply when the brand-name drug company has received special FDA exclusivities available for circumstances such as use of a drug for orphan categories or new pediatric indications. A generic could file a request indicating that it does not seek approval for the protected uses.[130]

Generally, these carve-out requests are approved unless they cause the generic to be less safe or effective than the brand-name drug for all remaining, nonprotected uses.[131] Such carve-outs can be an effective way for generics to bypass weak or limited

[127] 21 U.S.C. § 355(j)(2)(A)(viii) (2012).

[128] 21 C.F.R. § 314.127(a)(7) (2015).

[129] Remember how there are still active Nexium patents, some of which grant exclusivity that does not expire until 2020? One of those patents protects a specific use of the drug. While Nexium made its name on acid reflux treatment, the patent is associated with the example use of the drug named in the previous paragraph – "for treatment of *Helicobacter* infections" – referring to bacterial infections often associated with stomach ulcers and cancer. The patent was filed more than 10 years after Nexium first received FDA approval. *See* Patent and Exclusivity Search Results from *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. Food & Drug Admin., https://perma.cc/TJ9B-HUWL (last updated Mar. 2016) (patent no. 8,466,175 at the bottom of the list); U.S. Patent No. 8,466,175 (filed Nov. 17, 2011).

[130] 21 C.F.R. § 314.127(a)(7) (2015).

[131] *Ibid*.