patents (or exclusivities) that brand-name companies may add near the end of a drug's patent term in the hopes of holding on to its exclusive market position for a drug.

For every action, however, there is an equal and opposite reaction, and that is certainly the case for carve-outs. Under Hatch-Waxman, when a generic application requests only Section viii carve-outs and contains no Paragraph IV certifications, that application does not trigger the artificial act of patent infringement that allows for litigation and a 30-month stay of approval. Thus, the generic application should theoretically be eligible for immediate approval.[132] Undaunted, brand-name companies file citizen petitions, arguing that the carve-out should be disallowed. These petitions generally argue that the requested carve-out contains information related to the safety or efficacy of the drug, and that such information cannot be removed from the label.[133]

A generic could, indeed, be attempting disingenuously to get around the Hatch-Waxman litigation process by removing certain uses from the label knowing that physicians may prescribe the drug for all uses, nonetheless. The off-label use of medication is a widespread phenomenon that affects many aspects of pharmaceutical law, and one of the authors has expressed serious concerns about the practice.[134] In the case of carve-outs, brand-name drug companies have expressed concern that carve-outs only remove uses and indications in name only – once on the market, the generics could be prescribed and used "off-label" for all uses approved for the brand-name version.[135] The FDA, however, has refused to accept this as a rationale for not approving a carve-out, even when the reference listed drug holder says off-label use could implicate safe and effective

[132] Lisa Barons Pensabene & Dennis Gregory (on behalf of Fitzpatrick, Cella, Harper, and Scinto), *Hatch-Waxman Act: Overview*, Practical L. Co. 4 (2013), www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20lpensabene_dgregory.pdf. There are also scenarios where an ANDA filer uses a Paragraph III or IV certification for some patents and carves out other patents via a section viii statement.

[133] *See*, *e.g.*, Citizen Petition from Ernest Lengle, Exec. Dir. Regulatory Affairs, Watson Labs., Inc., to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2008-P-0069-0001, at 2 (Jan. 29, 2008), www.regulations.gov/#!documentDetail;D=FDA-2008-P-0069-0001 (requesting that the FDA refrain from allowing a carve-out for irinotecan hydrochloride on grounds that it would render the generic less safe or effective than the listed drug).

[134] *See* Robin Feldman, *Regulatory Property: The New IP*, 40 Columbia J.L. & Arts 53 (2016). For example, pharmaceutical companies have enjoyed considerable success in recent years in convincing courts that FDA restrictions on truthful statements about off-label uses of drugs may violate free speech. *See generally United States v. Caronia*, 703 F.3d. 149 (2d Cir. 2012); *Amarin Pharm., Inc. v. U.S. Food & Drug Admin*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). For a discussion of the widespread off-label uses of drugs, see *Amarin*, 119 F. Supp. 3d at 200–01.

[135] *See* Citizen Petition from Robert Church & David Fox, Hogan Lovells US LLP on behalf of Spectrum Pharmaceuticals, Inc., to Div. of Dockets Mgmt., U.S. Food & Drug Admin., No. FDA-2014-P-1649, at 12 (Sept. 30, 2014), www.regulations.gov/#!documentDetail;D=FDA-2014-P-1649-0001.