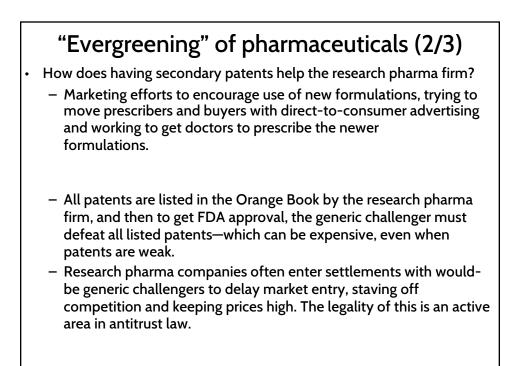


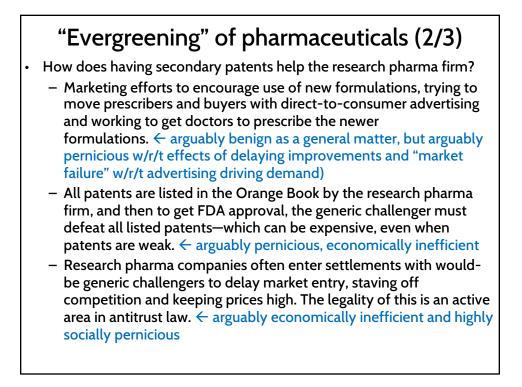
Hatch-Waxman 2/2

- encourages brand-name companies to identify patents covering their drugs—these are listed in the Orange Book
- when a generic drug company seeks FDA approval for an existing drug, they must account for Orange-Book listed patents, either by
 - 1. saying they will wait until the patent expires
 - 2. asserting the patents are invalid or don't cover the drug
 - if No. 2, then the generic firm can be sued for infringement
- created new "regulatory exclusivities" periods of exclusive marketing rights that operate alongside patent protection

"Evergreening" of pharmaceuticals (1/3)

- "[D]rug makers do all they can to soften the blow of losing market monopoly. Some strategies ... involve what is known as 'evergreening'. [In] its broadest connotation [the term means] trying to refresh one's monopoly protection on a drug." (Feldman 2018)
- Techniques include filing for new patents on new formulations (e.g., extended release), new methods of use, new dosage schedules, new combinations with other ingredients, etc. This often includes very weak patents unlikely to survive challenge, for instance for lacking nonobviousness.





"Evergreening" of pharmaceuticals (3/3)

- "Many ... evergreening strategies involve applying for new patents. Even if the patents are of questionable validity, the process of challenging them through Hatch-Waxman litigation is expensive and lengthy for a generic, again allowing years of additional profits for the brand-name company. If companies are able to ... justif[y] obtaining new patents or exclusivity protections, these companies [may avoid the drop-off in profits from patent expiration]. Our data suggest that this is occurring in a widespread manner throughout the industry." (Feldman 2018)
- "In short, despite the quaint theory that competitors will enter after a pharmaceutical patent expires, the reality is quite different. Numerous strategies and opportunities exist that allow companies to extend their protection and prolong the period of market monopoly for their drugs." (Feldman 2018)