Industry & Invention
Patent

Utility Patents and Regulatory Exclusivities in Pharmaceuticals, *Part Two*

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Hatch-Waxman 1/2

a/k/a The Drug Price Competition and Patent Term Restoration Act of 1984

- amended both patent law and food-and-drug law
- provided for patent term extensions to compensate for FDA regulatory approval delays (35 U.S.C. § 156)
- established expedited path for approval of generic drugs that are bioequivalent
  - complaints by generic firms that brand-name firms won't sell them samples for use in needed bioequivalence testing
- created a safe harbor from patent infringement for generic drug companies until the time they request FDA approval

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 (2/3)

- How does having secondary patents help the research pharma firm?
  - Marketing efforts to encourage use of new formulations, trying to move prescribers and buyers with direct-to-consumer advertising and working to get doctors to prescribe the newer formulations.
  - All patents are listed in the Orange Book by the research pharma firm, and then to get FDA approval, the generic challenger must defeat all listed patents—which can be expensive, even when patents are weak.
  - Research pharma companies often enter settlements with would-be generic challengers to delay market entry, staving off competition and keeping prices high. The legality of this is an active area in antitrust law.

"Evergreening" of pharmaceuticals (2/3)

- How does having secondary patents help the research pharma firm?
  - Marketing efforts to encourage use of new formulations, trying to move prescribers and buyers with direct-to-consumer advertising and working to get doctors to prescribe the newer formulations. ← arguably benign as a general matter, but arguably pernicious w/r/t effects of delaying improvements and "market failure" w/r/t advertising driving demand)
  - All patents are listed in the Orange Book by the research pharma firm, and then to get FDA approval, the generic challenger must defeat all listed patents—which can be expensive, even when patents are weak. ← arguably pernicious, economically inefficient
  - Research pharma companies often enter settlements with would-be generic challengers to delay market entry, staving off competition and keeping prices high. The legality of this is an active area in antitrust law. ← arguably economically inefficient and highly socially pernicious

“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)