Previous reforms of pharmaceutical patents

Source: Pharmaceutical Patent Regulation

1. Hatch-Waxman Act fueled exponential growth in the generic drug market.
   - 1.1 The bill introduced an abbreviated FDA approval process for generic drugs called ANDA
2. Generic applicants using the ANDA need to certify one of four categories of patent coverage
   - 2.1 The generic drug does not overlap with any patents ever approved
   - 2.2 The generic drug overlaps with patents that have expired
   - 2.3 The generic manufacturer will not market until overlapping patents expire
   - 2.4 The generic manufacturer believes overlapping patents are not relevant or invalid
3. Hatch-Waxman Act litigation can be only for patents that are reported in the Orange Book
4. AIA enacted another route toward challenging a patent, the IPR procedure
5. IPR, unlike ANDA, may challenge any patent, including patents that were not required to be reported in the Orange Book or the Purple Book.

Discuss the economic justification of patents

Source: Pharmaceutical Patent Regulation

1. Patents allow the entity that generated the new product to exclude competitors for a period
2. Patents are public documents that document the invention
3. A patent system fuels innovation, distributes research without attaching financial penalties
4. Drug products cannot be protected as trade secrets. Their composition can be readily determined.
5. Biologic products are not easily analyzed and the processes that led to creation are not clear.
6. Patents can be “rented” through payment of royalties, and can also be sold or acquired.

What factors add to the high cost of bringing a drug to market

Source: Pharmaceutical Patent Regulation

1. Drug discovery can take a team of scientists between 3 and 20 years
2. FDA's three-phase clinical trial testing process can cost millions per phase
3. only a fraction of products tested succeed

Discuss intellectual property protection in the pharmaceutical industry

Source: Pharmaceutical Patent Regulation

1. Two types of intellectual property protection
   - 1.1 patent exclusivity and regulatory exclusivity
2. A successful patent grant requires demonstration of (3)
   - 2.1 Usefulness, novelty, non-obviousness
3. Pharmaceutical patents can include a variety of claims
4. Secondary patents
5. Regulatory exclusivity
   - 5.1 granted to new drugs. prevents FDA from approving competitor drugs
   - 5.2 Unlike patents, regulatory exclusivity varies in term
   - 5.3 Patents and regulatory exclusivity operate separately
   - 5.4 Patent exclusivity term is longer and secondary patents
6. FDA Orange Book – info about drug products
   - 6.1 Patent and regulatory exclusivity data
   - 6.2 Name, active ingredients, dosage, equivalence to other drugs
   - 6.3 Drug products have well-defined chemical structures
7. FDA Purple Book – info about biologic products
   - 7.1 Complex molecules that are difficult to characterize analytically
   - 7.2 The process of producing a biologic is subject of the patent

Briefly describe the potential abuses within pharmaceutical patent regulation

Source: Potential Abuses Pharmaceutical Patent Regulation

1. Evergreening
   1.1 Occurs when a patent holder files secondary patents to renew the 20-year patent exclusivity period
2. Product hopping
   2.1 Uses reformulations of a drug to extend exclusivity and prevent ANDA applicants from referencing the primary patent
3. A brand manufacturer withholding samples
   3.1 Inhibits generic distributors from performing bioequivalence assessment
4. Patent thicket
   4.1 uses multiple patents on a drug to deter potential litigants
5. Pay-for-delay
   5.1 a brand producer pays a generic producer to delay entry of the generic

Legislative proposals to prevent abuses of pharmaceutical patents

Source: Potential Abuses Pharmaceutical Patent Regulation

1. The CREATES Act makes samples more accessible for generic manufacturers
2. The Preserve Access to Affordable Generics and Biosimilars Act restricts settlement agreements
3. The Prescription Drug Price Relief Act would void patent rights and regulatory exclusivity for excessive prices
4. The FLAT Prices Act would shorten regulatory exclusivity periods
5. The Biologic Patent Transparency Act would require purple book to include patent information
6. The Affordable Prescriptions for Patients Act codifies definitions of patent thicketing and product hopping