Marketing Exclusivity & Other Incentives to Innovate
Marketing Exclusivity

What is it?

- If marketing exclusivity granted, FDA will not approve a subsequent abbreviated application for same drug product until the expiration of exclusivity period.
- Exclusivity types are different and may overlap in some cases.
Exclusivity vs. Patent

- Marketing exclusivity vs. patent protection
  - Patent protection generally 20 years and covers broad claims to an invention, issued by PTO anytime during drug development;
  - Marketing exclusivity is marketing rights granted by FDA upon approval and can run concurrent with patent term or not.
  - These are completely different types of protections but can be combined to maximize value of the product development.

- Hatch-Waxman impact on Innovator Patent
  - 35 USC §156 added to extended term equal to $\frac{1}{2}$ IND period plus NDA review period (no more than 5 years);
  - Total patent life post-FDA approval must not exceed 14 years.
Marketing Exclusivity

- **Marketing Exclusivity for Drugs**
  - New Chemical Entity (NCE) – 5 years (21 CFR §314.108)
  - New Clinical Information Change or “Other” – 3 years
  - Pediatric (PED) – 6 months add-on exclusivity
  - Orphan Drug – 7 years (21 CFR §316.31)
  - Qualified Infectious Disease Product (QIDP) – 5 years add-on exclusivity (*NEW*)
  - Generic Drug Exclusivity (available for §505(j) applicant only) – 6 months

- **Marketing Exclusivity for Biologics**
  - New Biologic – 12 years
  - Interchangeable Biosimilar – 1 year

- **No Marketing Exclusivity for Devices**
Marketing Exclusivity

**Drug Exclusivity**

- **New Chemical Entity (NCE) – 5 years (21 CFR §314.108)**
  - BAR: 505(b)(2) or 505(j) applicant; **not** full 505(b)(1) NDA (see §505(c)(3)(E)(ii); §21 CFR 314.108(b)(2))
  - Request in NDA

- **New Clinical Information or “Other” – 3 years**
  - Available to 505(b)(2) [21 CFR 314.108(b)(4)] Applicant or as Supplement [21 CFR 314.108(b)(5)]
  - BAR: §505(b)(2) or §505(j) applicant; not full §505(b)(1) NDA

- **Pediatric (PED) – 6 months add-on exclusivity**
  - Awarded for conduct of pediatric clinical studies in response to written request
  - Only extends; does not create additional bars
Marketing Exclusivity

- **Drugs Exclusivity (cont.)**
  - **Orphan Drug** – 7 years (21 CFR §316.31)
    - First approval of drug or biologic approved
    - BARS: any application [included full-scale NDA or BLA] that includes the active ingredient for that indication
    - Request before filing of NDA/BLA, as early as possible.
  - **Generic Drug Exclusivity** – 6 months
    - BARS: subsequent §505(j) ANDA for 180 days / 6 months.
    - Rewards ANDA applicant that challenges a listed patent
    - Tentative approval of a generic permissible during exclusivity period.
Marketing Exclusivity

• **Drugs Exclusivity** (cont.)
  • Qualified Infectious Disease Product (QIDP) – 5 years add-on exclusivity
    • Title VIII of FDASIA entitled “Generating Antibiotic Incentives Now (GAIN)"
    • QIDP = "an antibacterial or antifungal drug (*) for human use intended to treat serious or life-threatening infections, including those caused by: (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens."
    • BARS: same as underlying exclusivity period; BUT applicable to drugs only (potentially even in instance where it’s a biologic obtaining orphan status); not applicable to 3 year New Clinical Information exclusivity; issue w/ interpreting re: supplements where original NDA was eligible, but came before GAIN.
  • Rulemaking required.
Marketing Exclusivity

- **Biologics Exclusivity**
  - **New Biologic – 12 years**
    - Biologics Price Competition and Innovation Act of 2009 (BPCI), Public Law 111-148, enacted as part of the Affordable Care Act on March 23, 2010, amended §351 of the Public Health Service Act (PHSA)
    - BAR: licensure of biosimilar or interchangeable version of a reference product. 42 USC §262(k)(7)(A); bars any abbreviated application for 4 years; does not bar submission of full-scale BLA
  - **Interchangeable with Reference Biologic – 1 year**
    - BAR: subsequent interchangeable product for that reference product (42 USC §262(k)(6)
    - Decouples from patent litigation, unlike Hatch-Waxman
    - Duration may extended up to 3.5 years if patent litigation is ongoing
Priority Review Vouchers (PRVs)

- Priority Review Vouchers
  - Applications for drugs for the treatment or prevention of certain tropical diseases under §524(a)(3) and (4) of the FD&C Act
    - FDAAA (2007)
    - Applicable to both §505(b)(1) NDAs or §351 BLAs
    - Enumerated “tropical disease”
    - Not applicable to any active ingredient approved under 505(b) (1) NDA or 351 (BLA).
  - Transferable option by contract;
  - 1 Year notice required before use
Priority Review Vouchers (PRVs)

- Applications for drugs to treat of rare pediatric diseases as defined under 529(a)(3) of the FD&C Act
  - FDASIA (2012)
  - Must be designated for “rare pediatric disease”
    - Primarily affects individuals birth to age 18
    - Within meaning of §536 of the FD&C Act
  - Can’t include active ingredient previously approved under §505(b)(1), §505(b)(2), or §505(j) of the FD&C Act, §351(a) or §351(k) of the PHSA.
  - Applicable to both NDAs and BLAs
  - No transfer limit
  - Requires only 90 days notice to use
Priority Review Vouchers (PRVs)

Examples of the value of PRVs:

- 7/20/14: Biomarin sold pediatric PRV (obtained at approved of rare disease drug Vimzim) to Sanofi and Regeneron for $67.5 million
- 11/19/14: Knight Pharmaceuticals sold its PRV to Gilead Sciences Inc. for $125 Million
- 7/5/15: Retrophin Inc. sold its pediatric PRV to Sanofi for $245 million
- 10/20/15: United Therapeutics Corp. sold its pediatric PRV (obtained when Unituxin approved for rare pediatric disease) to AbbVie, Inc. for $350 Million.

Notice the trend…