# Patent and Non-Patent Exclusivities

**Kim Dettelbach**
**U.S. Food and Drug Administration**

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# Patent Listings for NDAs

Section 505(b)(1)(G) and 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) Regulations at 21 C.F.R. 314.53

NDA sponsors file with FDA and FDA publishes (lists) patents that claim approved drug substances (active ingredients), drug products (compositions or formulations), or methods of use.

# Patent Certifications

Sections 505(b)(2) and 505(j)(2)(A)(vii) of FFDCA

Regulations at 21 C.F.R. 315.50(i) and 314.94(a)(12)

ANDAs and 505(b)(2) applications referencing approved drugs must include certifications to listed patents for the drugs referenced.

Listed patents may delay subsequent ANDA and 505(b)(2) approvals.

# Statutory Exclusivity vs. De Facto Exclusivity

- “De facto market exclusivity” referred to in Compliance Policy Guide (CPG) is different from statutory exclusivities
- De facto exclusivity in CPG refers to actual time on market without approved or unapproved competitors
- statutory exclusivities are bars on subsequent approvals and/or acceptance of future applications

# Four Types of Statutory Exclusivity

Five Year New Chemical Entity Exclusivity

Three Year New Clinical Studies Exclusivity

Seven Year Orphan Drug Exclusivity

Six Month Pediatric Exclusivity

# New Chemical Entity Exclusivity

Sections 505(c)(3)(D)(ii) and (j)(5)(D)(ii) of the FFDCA
Regulations at 21 CFR § 314.108

Granted to a drug that contains no active moiety that has been approved by FDA under section 505(b).

Active moiety is the molecule or ion … responsible for the physiological or pharmacological action of the drug substance.

NCE exclusivity runs from time of NDA approval and bars FDA from accepting for review any ANDA or 505(b)(2) application for a drug containing the same active moiety for

- five years if ANDA or 505(b)(2) does not contain a paragraph IV certification to a listed patent

- four years if ANDA or 505(b)(2) is submitted containing a paragraph IV certification to a listed patent

# Three Year New Clinical Study Exclusivity

Sections 505(c)(3)(D)(iii) & (iv) and (j)(5)(D)(iii) & (iv) of the FFDCA
Regulations at 21 CFR § 314.108

Granted to drug when application or supplement contains reports of
new clinical investigations (not BA studies) conducted or sponsored by applicant and essential for approval

New clinical study exclusivity runs from time of NDA approval and bars FDA from approving, for a three year period, any ANDA or 505(b)(2) application that relies on the information supporting the approval of the drug or the change to the drug for which the information was submitted and the exclusivity granted.

# Orphan Drug Exclusivity

Sections 526-527 of FFDCA
Regulations at 21 CFR §316

Orphan exclusivity granted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S. (or more than 200,000 and no hope of recovering costs).

Runs from time of approval of NDA or BLA.

Orphan exclusivity bars FDA from approving any other application (ANDA, 505(b)(2) or "full" NDA or BLA) for the same drug for the same orphan disease or condition for seven years.

Whether a subsequent application is for the "same" drug depends upon the chemical and clinical characteristics of the drugs.

FDA may approve applications for the "same" drug for indications not protected by orphan exclusivity.

# Pediatric Exclusivity

Section 505A of FFDCA (FDAMA and BPCA)
No regulations
Guidance dated September 1999

Grants an additional 6 months of market protection
at the end of listed patents and/or exclusivity
for sponsor's drug products containing the active moiety,
when the sponsor has conducted and submitted
pediatric studies on the active moiety in response
to a Written Request from FDA.

Pediatric exclusivity takes on characteristics of five year, three year or orphan exclusivity when it attaches to those protections.

It is not a patent extension when it attaches to a patent.