

# ANDA Litigation Basics Under the Hatch-Waxman Act and Medicare Prescription Drug, Improvement and Modernization Act of 2003





# Generic drugs

- Are safe, effective and less expensive than brand name prescriptions
- Used in approximately 50-60% of all prescriptions dispensed
- Have same active ingredient(s), route of administration, dosage form, strength, indications



# Food, Drug & Cosmetic Act

- Under the Food, Drug and Cosmetic Act (“the FDCA”), the Food and Drug Administration (“the FDA”) determines whether a generic drug product is safe and effective and should be approved for sale to the public under 21 U.S.C. § 355(a).



# Hatch Waxman Act of 1984

- Under the Hatch-Waxman Act, a generic pharmaceutical manufacturer seeking FDA approval to market a generic version of a patented drug may submit an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j), also known as Section 505(j) of the FDCA.



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# NDA and ANDA Requirements

Brand (NDA)

Generic (ANDA)

Chemistry  
Manufacturing  
Controls  
Labeling  
Testing

Animal Studies )

Clinical Studies) --

Bioavailability )

Bioequivalence



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# Hatch-Waxman Amendments– 1984

- Increased availability of generics.
- Legislation benefits both brand and generics.
- Generics can rely on findings of safety and efficacy of branded drug after expiration of patents and exclusivities (do not have to repeat expensive clinical and pre-clinical trials).
- Allowed patent extensions and exclusivities to brands.
- The Act attempts to strike a balance between the interests of the party seeking approval of an ANDA and the owner of a drug patent.



# Approved Drug Products With Therapeutic Equivalence Evaluation ("Orange Book")

- Lists all FDA approved drugs.
- Expiration dates of patents and exclusivity (marketing right).
- Brand drugs listed for generics to compare with their proposed products.
- Under 21 U.S.C. § 355(j)(6)(A)(i), the Secretary of Health and Human Services (HHS) shall publish and make available to the public a list in alphabetical order of each drug which has been approved for safety and effectiveness (known as the Approved Drug Products With Therapeutic Equivalence Evaluation, also known as the "Orange Book").



# Patent Submissions in Orange Book

## Patent Holder Submits Patents to be Listed in Orange Book

- Under 21 U.S.C. § 355(j)(6)(A)(iii), when patent information (e.g., patent number for each drug for which a reasonable claim of patent infringement could be made) is submitted concerning a drug on the list to be published by the Secretary, the Secretary shall include such information in the Orange Book.



# Patent Submissions in Orange Book

- When a brand name company receives a patent covering a pharmaceutical composition or method of use it is required to send that information to the Secretary of Health and Human Services so that the patent may be listed.
- A generic manufacturer studies the Orange Book for the listed patents to determine: which if any patents exist; when they expire; whether the proposed product would infringe the listed patents; or whether the listed patents may be invalid.



# Generic Patent Certifications

- An entity submitting an ANDA for a generic product must make a certification to the FDA only for patents listed in the Orange Book when the ANDA is actually filed.
- If a patent is subsequently listed in the Orange Book after the ANDA is filed, the generic manufacturer is not required to certify the listed patent.
- Under 21 U.S.C. § 355(j)(6)(A)(vii)(IV), found in 21 C.F.R. § 314.94(a)(12)(vi), as interpreted by the FDA.



# Types of Patents Listed in Orange Book

- A patent holder must list in the Orange Book, drug substance patents (ingredient), drug product patents (formulation and composition) and method of use patents.
- Processes of making the product may not be submitted to the FDA. 21 CFR § 314.53(b).
- The Secretary is required to update the list every thirty days under 21 U.S.C. § 355 (j)(6)(A)(ii).



# Four Types of Patent Certifications

When an applicant submits an ANDA to the FDA, the applicant must certify one of four things under 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (also known as Section 505(j)(2)(A) of the FDCA):

- (I) that such patent information has not been filed by the patentee (a "paragraph I Certification"); or
- (II) that such patent has expired (a "paragraph II Certification"); or
- (III) the date on which the patent will expire (a "paragraph III Certification"); or
- (IV) that such patent is invalid or that it will not be infringed by the manufacture, use or sale of the new drug for which the ANDA is submitted (a "paragraph IV Certification").

Inclusion of a paragraph IV certification in an ANDA, however, is deemed a “highly artificial” act of infringement. 35 U.S.C.A. § 271(e)(2)(A).



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# 45-Day Window For Patentee To Sue ANDA Applicant

Under 21 U.S.C. § 355(j)(4)(B)(iii), if the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA “shall be made effective immediately” unless the patent owner brings an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five (45) days of receiving the Notice Letter required by 21 U.S.C. § 355(j)(2)(B).



# Automatic 30 Month Stay Against ANDA Approval by FDA

- The Hatch-Waxman Act provides that, when a patent owner brings a § 271(e)(2)(A) infringement action, the FDA suspends approval of the ANDA for a maximum of thirty (30) months, or until the court rules, whichever is earlier.



# Exempt Acts of Patent Infringement for FDA Approval

- The manufacture, use, or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. 35 U.S.C. § 271(e)(1).
- The Hatch-Waxman Act provides under 35 U.S.C. § 271(e)(1), generally that:

“[i]t shall not be an act of infringement to make, use, or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”



# Medicare Prescription Drug, Improvement, and Modernization Act of 2003

- On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act which implements significant changes to the Hatch Waxman Act, the 1984 law that governs the approval process for generic drugs.



# 30-Month Stay of ANDA Approval and 180-Day Marketing Exclusivity

- If the NDA holder or patent owners challenge the Paragraph IV certification by bringing a patent infringement action within 45 days, they are entitled to an automatic 30-month stay of FDA approval of the generic ANDA product.
- As an incentive to encourage generics to file Paragraph IV certifications, the Act provided a 180-day period of marketing exclusivity to the first to file an ANDA with a Paragraph IV certification.



# 30-Month Stay of ANDA Approval

- Under the new law, only one 30-month stay per ANDA is allowed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, §§ 1101, 1102 (codified as amended at 21 U.S.C. 355(j)(2) and (5)).
- Previously, if an additional patent were listed in the Orange Book after an applicant filed an ANDA, a new Paragraph IV certification had to be made and a second patent infringement action could be filed automatically resulting in a new 30-month stay.
- The amendments eliminate this by providing that ANDA applicants need only certify patents listed in the Orange Book when the ANDA was filed.



# ANDA Applicant Must Notify NDA Holder Within 20 Days of FDA Acceptance of Filing

- An ANDA applicant with a Paragraph IV certification must notify the NDA holder and the patent owners within 20 days of receiving notice from the FDA that its application has been filed.
- The law was previously silent on when the ANDA applicant had to give such notice.



# Declaratory Judgment Actions by ANDA Applicant

- An ANDA applicant may now bring a declaratory judgment action against an NDA holder if the NDA holder does not institute a patent infringement lawsuit within the required 45-day time period.



# Delisting of Orange Book Patents

- An ANDA applicant may now counterclaim seeking an order requiring the NDA holder or patent owners to delete a patent from the Orange Book because the patent does not claim the approved drug or an approved method of using the drug.



# Clarifications to the 180-day Exclusivity Period

- The 180-day exclusivity period does not begin until the date of first commercial marketing.
- This allows an ANDA applicant to stockpile product before a launch after obtaining a favorable ruling.



# Forfeiture of Exclusivity

- The exclusivity period may be forfeited if the first ANDA applicant fails to market its drug in a timely fashion.



# Tentative (Scientific) FDA Approval

- Exclusivity period is available only if tentative (scientific) FDA approval is granted within 30 months of filing the ANDA.



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# Some Forfeitures of Exclusivity

- Exclusivity is forfeited if the first ANDA is withdrawn for substantive reasons, the first applicant amends/withdraws its Paragraph IV certification, the listed patents expire or the applicant entered into an agreement violating the antitrust laws.



# First to File Obtaining 180-Day Marketing Exclusivity

- The first to file an ANDA with a Paragraph IV certification obtains the exclusivity, and does not share it with a later applicant that is first to file a Paragraph IV certification on a later-listed patent.



# “Shared” Exclusivity

- If more than one applicant is “first” and files a “substantially complete” ANDA on the same day, they share the 180-day exclusivity, but there is only one period, and begins the first day of marketing by either.

