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Lifecycle Management for FDA-Regulated Products: Navigating the Intersection of FDA's Regulatory Exclusivity Regimes and Patent Protection

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Lifecycle Management: FDA Regulatory Issues
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FDA's Regulatory Exclusivity Regimes: Balancing Competition and Innovation

- Introduction
- Listing Patents in the Orange Book
- FDA and PTO Collaboration
- Orphan Drug Developments
- Labeling Carve Outs/Skinny Labeling
- FDA Inflection Points
- Generic Drug Development

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Orange Book Patent Listing: Recent Cases and Controversies

FDA Patent Listing

- A key aspect of the Hatch-Waxman framework, which allows for pre-approval litigation between branded and generic manufacturers
  - Litigation of a patent that is listed with branded drug in Orange Book will typically result in 30-month regulatory stay, precluding FDA from approving the generic application
- Criticism of branded companies is that an improperly listed patent – particularly when it may be the last expiring protection – can impact the approval timing of a competitor

Quick Background on FDA Patent Listing

- The Hatch-Waxman Act codified three types of new drug applications:
  - **505(b)(1) NDA** – ***full showing of safety and effectiveness***; all data owned by applicant (or right of reference)
    - Must submit patent information to FDA on Form 3542 within 30 days of approval (or 30 days after patent issues)
  - **505(b)(2) NDA** – approval ***relies in part*** on findings of safety and effectiveness for previously approved NDA ("the listed drug") and/or studies reported in literature
    - Must submit patent information to FDA
    - Must submit patent certifications to any patents in Orange Book with listed drug
  - **505(j) ANDA** – approval ***relies in full*** on prior findings of safety and effectiveness for a single previously approved NDA; patent certification to "reference listed drug" (RLD)
    - ANDA approval based on bioequivalence and sameness of active ingredient(s), strength, dosage form and route of administration
- In exchange for the ability to rely on other products for approval, the ***timing of final approval of ANDAs and 505(b)(2) NDAs*** will depend on patent certifications, patent litigation and regulatory exclusivity

Which Patents Can (and Must) Be Submitted?

- Each patent "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
  - (I) ***claims the drug*** for which the applicant submitted the application and is a ***drug substance (active ingredient)*** patent or a ***drug product (formulation or composition)*** patent; or
  - (II) ***claims a method of using such drug*** for which approval is sought or has been granted in the application"
- Three categories of patents and patent claims that can be listed:
  - ***Drug Substance*** (DS), ***Drug Product*** (DP), and ***Method of Use*** (MOU) patents
  - NOT: Manufacturing or process patents, patents claiming packaging, metabolites or intermediates
- FDA takes a "ministerial" role; simply lists the provided information in the Orange Book

Implications of Patent Listing

- ***Patent certifications***: ANDAs or 505(b)(2) NDA that seeks to rely on an approved innovator drug as the "reference listed drug" (RLD) must certify to each listed patent or submit a "section viii statement"
- Four types of certifications; one must be submitted for each listed patent
  - Paragraph I – patent information has not been filed
  - Paragraph II – listed patent has expired
    - In both cases, FDA can approve the application "immediately," i.e., as soon as the agency completes its scientific review
  - Paragraph III – applicant will wait until patent has expired before receiving final approval
    - FDA cannot approve the application until the patent expires
  - ***Paragraph IV – applicant believes patent is invalid or will not be infringed; seeks approval during patent term***
    - Triggers a series of consequences for NDA holder, ANDA applicant and FDA
- ***Alternatively, an ANDA applicant can file a "section viii" statement*** indicating that the applicant does not seek approval for an indication or use claimed by the patent and approved in the NDA

Implications of Paragraph IV Certification

- For every ***Paragraph IV certification***, the ANDA applicant must provide notice to the NDA holder and patent owner within 20 days of the ANDA being "received" by FDA
- The Notice Letter must include "detailed statement of factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed"
  - If litigation is filed within 45 days of receipt of Notice Letter, a regulatory stay arises, which prevents FDA from granting final approval to the ANDA, ostensibly to allow patent litigation to run its course
    - Typically referred to as "30-month stay" but operates a bit differently when NDA product has 5-year "new chemical entity" (NCE) exclusivity → stay expires 7.5 years from date of NDA approval
- By contrast, a ***section viii statement*** does not trigger the same notice requirement, and no opportunity for pre-approval litigation or 30-month stay
  - As a practical matter, the ANDA will have a labeling "carve out," a/k/a "skinny labeling," because it must omit the indication or use (more on this later)
  - For example, the ANDA could be approved for Indication 1 of the innovator drug but not the patent-protected Indication 2

Key Cases: Device and REMS Patents

- In the absence of clear guidance from FDA, the federal courts have stepped in, in the context of Hatch-Waxman patent litigation and antitrust litigation
  - Device patents: *In re: Lantus Direct Purchaser Antitrust Litigation* (1st Cir. 2020)
  - REMS patents: *Jazz v. Avadel CNS* (Fed. Cir. 2023)

Background on Device Patents

- Historically uncertain whether device patents could be listed
  - A patent that claims use of the drug with a specific device
  - A patent that claims only the device
  - A patent that claims a component of the device
- Multiple sponsors sought advisory opinions between 2005 and 2011, but FDA declined to opine on whether device patents could be listed, and under what circumstances
- So, sponsors have typically listed device patents, based on regulatory language and preambles
  - Devices can be "integral" parts of the finished dosage form, and dosage forms are identified in the OB
  - "The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product." 68 FR 36675, 36680 (June 18, 2003)
- In 2020, FDA opened a docket seeking stakeholder input on these issues, Docket No. FDA-2020-N-1127

Listing Device Patents in the Orange Book – *In Re: Lantus*

- *In Re: Lantus Direct Purchaser Antitrust Litigation,* 950 F.3d 1 (1st Cir. 2020)
- Sanofi-Aventis listed a patent (the '864 patent) with its NDA for Lantus SoloSTAR (insulin glargine), a disposable injector pen product
  - US Patent No. 8,556,864 is entitled "Drive mechanisms suitable for use in drug delivery devices" and generally claims a component of the SoloSTAR pen used with the dosage selector
  - Ten claims concerning aspects of a "drive mechanism" that serves as a part of a pen injector
  - Does not expressly identify insulin glargine in claims
- Plaintiffs brought antitrust suit, alleging that patent was improperly listed, which led to H-W litigation and a 30-month stay, thereby delaying competition and resulting in higher prices for plaintiffs

Listing Device Patents in the Orange Book – *In Re: Lantus*

- Massachusetts District Court granted Sanofi's motion to dismiss, on the basis that FDA's patent listing requirements were ambiguous as to listing of device patents that do not claim a drug substance/active ingredient; thus, Sanofi's patent listing was reasonable
- On appeal, however, the First Circuit overruled the district court
  - The First Circuit concluded that "[t]he statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book[, and] [t]he '864 patent, which neither claims nor even mentions insulin glargine or the Lantus SoloSTAR, does not fit the bill."
  - Remanded to determine whether Sanofi can prove the defense that at the time it listed the '864 patent in the Orange Book it had a reasonable basis in regulatory policy to conclude, and in good faith concluded, that its actions were required by regulation
    - Litigation ongoing, but antitrust plaintiffs have cited this case in several other cases

Listing REMS Patents in the Orange Book – *Jazz v. Avadel CNS*

- This dispute relates to Jazz Pharma's Xyrem (sodium oxybate), a drug used to treat narcolepsy
  - Xyrem was approved with a Risk Evaluation and Mitigation Strategy (REMS) to address safety risks and concerns about abuse/misuse of the drug; among other things, the REMS employs a central pharmacy and computer database to track prescriptions, patients, and prescribers
- Jazz obtained a patent (the '963 patent) on a "computer implemented system" that keeps track of ***prescription drugs used to treat a narcoleptic patient*** that are at risk for misuse, abuse or diversion
  - That patent was listed in the Orange Book as a "method of use" patent
  - The '963 patent does not expressly claim the active ingredient or drug substance of Xyrem
- Seeking to launch its own sodium oxybate product, Avadel initially submitted a "(B)(2)(b) statement" (the equivalent of a "section viii statement" for a 505(b)(2) NDA)
  - FDA refused to approve the labeling carve out proposed by Avadel and required Avadel to submit a Paragraph IV certification to the REMS patent

Listing REMS Patents in the Orange Book – *Jazz v. Avadel CNS*

- Following the Paragraph IV certification, Jazz sued Avadel for infringement in the District Court of Delaware, and Avadel counterclaimed for delisting the REMS patent from the Orange Book
  - Litigation resulted in 30-month stay on FDA approval of Avadel's 505(b)(2) NDA
- **February 2023**: The Federal Circuit affirmed the District Court decision in favor of Avadel
  - The District Court held, and the Federal Circuit affirmed, that the REMS patent should be de-listed, because it did not claim an approved method of using the drug
    - "We therefore find that the claims of the '963 patent were properly construed by the district court as system claims, not method claims." 60 F.4th 1373, 1378
  - No holding that a REMS patent is *per se* ineligible for listing, however
    - "On its face, the delisting statute does not require inquiring as to whether the NDA holder was authorized to list the patent in the first instance." 60 F.4th 1373, 1382

Listing REMS Patents in the Orange Book – *Jazz v. Avadel CNS*

- **March 2023**: Jazz submits request to de-list the '963 patent from the Orange Book
  - Effectively eliminates the need for a patent certification and the litigation stay
- **May 2023**: FDA approves Avadel's Lumryz (sodium oxybate)
  - There were orphan drug issues that also needed resolution prior to approval of Lumryz (and these issues are also the subject of ongoing litigation between Jazz and FDA)

- Takeaways:
  - No clarity on whether REMS patents are eligible for listing
  - Antitrust claims are likely to follow
  - FTC filed an amicus brief asserting that the patent was improperly listed

FTC Policy Statement (September 2023)

- The Policy Statement was issued to put brand drug manufacturers on notice that the FTC "intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition" as a so-called "standalone" Section 5 violation.
- In addition, the FTC stated that it may consider enforcement action against brand drug manufacturers under a monopolization theory and scrutinize a brand drug manufacturer's patent listing history during merger review. Finally, the FTC announced that it may begin disputing allegedly improper patent listings under FDA's administrative patent listing dispute process.
- The FTC noted that its policy was not just forward-looking. "Failure to remove" patents that are allegedly improperly listed "could result in legal liability," according to the FTC's statement.

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The Biden Executive Order: Increased Collaboration between USPTO and FDA

Background

- Executive Order on “Promoting Competition in the American Economy”
- Letter Exchange between FDA and USPTO
  - FDA invited the USPTO to engage with FDA in “evaluating the impact of pharmaceutical patents in certain areas relevant to FDA regulation of drugs products, with a focus on facilitating timely access to drug products approved under [FDA’s] abbreviated pathways.”
  - USPTO proposed collaboration initiatives to strengthen our patent system “so that the system promotes research and development and protects key innovation while not incentivizing, protecting, or permitting activity that will improperly or unnecessarily delay access to low-cost medicines.”

FDA Letter to PTO Expresses Concerns

- Practice of filing "continuation" patent applications, which may allow the filer to obtain follow-on patents directed to inventions disclosed in earlier patents.
  - Can allow companies to create "patent thickets" by obtaining multiple patents on different aspects of the same product within a patent application.
  - Although the term of a continuation patent typically expires at the same time as the original patent expires, the existence of multiple patents increases litigation burdens and potentially delays the approval and launch
- Patent "evergreening" or patenting "post-approval" or "secondary" changes to previously approved products (i.e., new formulations of the same drug, new delivery systems, claiming additional methods of use)
- "Product-hopping" – brand sponsors submit a new application for modified drug product (e.g., changing the dosing regimen from twice a day to once a day) obtain a patent for the related modification that can forestall competition, and effectively switch the market to the new product right before generic or biosimilar competition on the previously approved product is set to commence.

Proposed USPTO Initiatives

- Enhance interagency collaboration
- Improve robustness and reliability of patent rights
- Improve processes for challenging issued patents
- Improve public participation in the patent system

Activities

- Enhancing Interagency Collaboration
  - Cross-training
  - Joint listening session and request for comments
- Improving Robustness and Reliability of Patent Rights
  - Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights
  - Federal Register Notice on Duty of Disclosure and Duty of Reasonable Inquiry
- Improving Process for Challenging Issued Patents
  - Patent Trial and Appeal Board ANPRM
- Improving Public Participation
  - New webpage to enhance accessibility to patent term extension information

Activities

- FDA Report to Congress, The Listing of Patent Information in the Orange Book (January 2022)
- Joint USPTO-FDA Listening Session (January 2023)

Joint USPTO-FDA Listening Session (January 2023)

- What publicly available FDA resources should be included when training USPTO patent examiners on tools they can use to assess the patentability of claimed inventions?
- What mechanisms could assist patent examiners in determining whether patent applicants or patent owners have submitted inconsistent statements to the USPTO and the FDA? Please explain whether such mechanisms present confidentiality concerns and, if so, how those concerns could be addressed?
- What are the opportunities and challenges related to the use of AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, including with respect to how such proceedings may intersect with Hatch-Waxman paragraph IV disputes and the Biologics Price Competition and Innovation Act "patent dance" framework that biosimilar applicants and reference product sponsors use to address any patent infringement concerns?

Joint USPTO-FDA Listening Session (January 2023)

- How can the USPTO and the FDA reinforce their collaboration and information exchange in relation to determining whether a patent qualifies for a patent term extension (PTE) and the length of any extension under 35 U.S.C. 156, as described in the Manual of Patent Examining Procedure § 2756? Identify any specific areas for improvement in the effectiveness of the current USPTO-FDA process for adjudicating applications for PTE and in the opportunity for public comment on such applications.

- The FDA already publishes PTE applications on www.regulations.gov, and the USPTO publishes PTE applications on its Patent Center portal (https://patentcenter.uspto.gov/), which replaced the Public Patent Application Information Retrieval (PAIR) system. The USPTO also recently provided centralized access to a listing of PTE applications filed during the last five years at www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156. This list includes the patent application number, patent number, link to the electronic file wrapper in Patent Center, PTE application filing date, and trade name identified in the PTE application. The status of each PTE application, including disposition, may be determined by reviewing the electronic file wrapper in Patent Center. What additional information would be useful to include on this web page?

Joint USPTO-FDA Listening Session (January 2023)

- What policy considerations or concerns should the USPTO and the FDA explore as they relate to method of use patents and, as applicable, associated FDA use codes, including with respect to generic drug, 505(b)(2), and biosimilar applicants who do not seek approval for (i.e., who seek to carve out from their labeling) information related to a patent-protected method of use (sometimes described as “skinny labeling”)?
- What policy considerations or concerns should the USPTO and the FDA explore in relation to the patenting of risk evaluation and mitigation strategies associated with certain FDA-approved products? What other types of patent claims associated with FDA-regulated products raise policy considerations or concerns for the USPTO and the FDA to evaluate?
- Apart from, or in conjunction with, the initiatives set forth in the USPTO Letter, what other steps could the USPTO and the FDA take collaboratively to address concerns about the potential misuse of patents to improperly delay competition or to promote greater availability of generic versions of scarce drugs that are no longer covered by patents?
- What additional input on any of the initiatives listed in the USPTO Letter (1(a)–1(h)), or any other related suggestions for USPTO–FDA collaboration, should the agencies consider?

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The Orphan Drug Act: Key Issues

The Orphan Drug Act

- Goals: encourage the development of drugs for rare diseases where the market alone may not provide sufficient incentive
- Incentives:
  - Marketing exclusivity
  - Tax credits on certain clinical testing expenses
  - Exemption from required pediatric studies under Pediatric Research Equity Act (PREA)
  - Exemption from PDUFA application fees and Prescription Drug Fees in ACA
  - Inflation Reduction Act exemption (limited)
- Key issues
  - Catalyst case and any ongoing impact
  - IRA exemption for orphan drugs is very narrow
  - *Jazz v. FDA* case

The *Catalyst* Case: The Scope of Orphan Exclusivity

- **January 2022**: The Eleventh Circuit struck down FDA's "indication-specific" view of the scope of orphan drug exclusivity in *Catalyst Pharms., Inc. v. Becerra* (11th Cir. 2021)
- For several years, both Catalyst and Jacobus had been developing amifampridine for the treatment of Lambert-Eaton myasthenic syndrome (LEMS), a rare autoimmune disorder; both had orphan designation
  - **November 2018**: Catalyst's Firdapse (amifampridine phosphate) approved for treatment of LEMS "in adults"
    - Two pivotal trials that enrolled a total of 64 adults (aged 21 to 88 years)
  - **May 2019**: Jacobus's Ruzurgi (amifampridine) was approved for treatment of LEMS in pediatric patients 6 to less than 17 years of age
    - Tentative approval in adults, due to Catalyst's orphan exclusivity; no pediatric efficacy data
- **2019-2021**: Catalyst sues FDA; Jacobus intervenes
  - S.D. Fla.: Held that FDA's regulatory interpretation was permissible construction of the statute
  - 11th Circuit: Overturned and remanded back to FDA; statute unambiguous

The *Catalyst* Case (cont'd)

- Compare the statute to the regulation:
  - **Statute**: If FDA approves an application "for a drug designated under [section 360bb of this title] for ***a rare disease or condition***, the Secretary may not approve another application [...] ***for the same drug for the same disease or condition*** ... until the expiration of seven years from the date of the approval of the approved application ...." 21 USC 360cc(a) (emphasis added).
  - **Regulation**: "FDA may approve a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which the drug was designated, or for ***select indication(s) or use(s) within the rare disease or condition for which the drug was designated***. Unless FDA previously approved the same drug for the same use or indication, FDA will not approve another sponsor's marketing application ***for the same drug for the same use or indication*** before the expiration of 7 years...." 21 CFR 316.31(a) (emphasis added).
- The Eleventh Circuit held that the statutory language was unambiguous
  - On remand, FDA acquiesced and converted Rizurgi final approval to tentative approval in pediatric patients

Catalyst Aftermath

- **January 2021**: FDA begins deferring orphan exclusivity determinations and certain product approvals
- **July 2022**: Catalyst settles patent litigation with Jacobus and acquires rights to Rizurgi in the US
  - **September 2022**: FDA approves sNDA for Firdapse for treatment of LEMS in pediatric patients
- **July 2022**: User fee reauthorization bills include legislative fix with retroactive application
- **September 2022**: "Clean" reauthorization passes without legislative fix
  - **December 2022**: FDORA passes without legislative fix
- **January 2023**: FDA Federal Register Notice: "at this time, while complying with the court's order in Catalyst, FDA intends to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order" 88 FR 4086 (Jan. 24, 2023)

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Labeling Carve-outs/Skinny Labeling

Labeling Carve Outs / Skinny Labeling

- As discussed above, an ANDA applicant can submit a "section viii statement," rather than a patent certification, if the ANDA applicant does not seek approval for a method of use claimed by a listed patent
  - Only applicable for Method of Use patents, which are listed in the Orange Book with a Use Code
- The ANDA applicant must then omit that protected use from its proposed labeling
  - This is an exception to the rule that an ANDA must generally have the "same labeling" as the innovator
- FDA may approve the ANDA with different labeling than the innovator product, so long as "such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, non-protected conditions of use" 21 CFR 314.127(a)(7)
  - Remember, FDA takes a "ministerial" approach to patent issues, including description of Use Codes
    - (1) Based on the Use Code, FDA determines what labeling must be omitted in order not to disclose the protected use, and
    - (2) The agency also decides whether an ANDA that omits the protected information from the labeling will be rendered less safe or effective for its remaining non-protected conditions of use

Can a "Skinny Label" Induce Infringement?

- "Whoever ***actively induces*** infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b).
  - Doctors prescribe/treat; generic companies may induce that conduct *via* the labeling, as well as press releases and other marketing communications
    - Do these materials "encourage, recommend or promote infringement"? *Takeda Pharms. v. West-Ward Pharm.*, 785 F.3d 625, 631 (Fed. Cir. 2015)
- How does the labeled indication(s) compare to the carved-out indication(s)?
  - No overlap?
  - Partial overlap?
  - Subset?
  - Does patented use apply to all indications, *e.g.*, a dosing regimen?

GSK v. Teva

- This dispute relates to GSK's blood pressure drug Coreg (carvedilol), which is approved to treat three indications: congestive heart failure (CHF), hypertension, and Left Ventricular Dysfunction Following Myocardial Infarction ("post-MI LVD")
- GSK listed a method of use patent (the '000 patent), after approval of Teva's product in 2007
  - Use Code: U-233 DECREASING MORTALITY CAUSED BY CONGESTIVE HEART FAILURE
  - Teva's 2007 labeling carved out the CHF use ("skinny label"), but in 2011, FDA required Teva to add that indication to its labeling ("full label"), after GSK delisted the '000 patent
  - Among other things, Teva's promotional materials stated that its product was "AB-rated" to Coreg, "generic version of…Coreg" and "indicated for treatment of heart failure and hypertension"
- GSK sued Teva in Delaware District Court in 2014 for induced infringement of its CHF patent during both the "skinny label" and "full label" periods
  - Jury verdict for GSK, then JMOL granted for Teva

GSK v. Teva

- In 2021, on rehearing following a complicated procedural history, a Federal Circuit panel found for GSK, holding that ***substantial circumstantial evidence supported a finding of induced infringement during the skinny label period***. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021).
  - The Supreme Court denied Teva's petition for certiorari, against Solicitor General's recommendation

- Generic industry fears that the decision could be broadly read as imposing liability on manufacturers of "A-rated" generic drugs for inducing infringement of patents covering "carved-out" indications
  - These concerns are likely overblown
  - The decision is very fact-specific, including a jury finding of induced infringement based on the skinny label
  - The procedural posture of the case was unusual, too
  - This is not the first time the Federal Circuit has held that an ANDA applicant induced infringement based on a labeling carve out and circumstantial evidence. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010)).

Amarin v. Hikma

- Only months after the 2021 *GSK* decision, a district court reached the opposite conclusion in *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F.Supp.3d 642 (D. Del. 2022)
- The product at issue was Amarin's Vascepa (icosapent ethyl), which has two approved indications: the treatment of severe hypertriglyceridemia (the "SH indication") and cardiovascular risk reduction (the "CV indication")
  - 3 method of use patents covering CV indication
  - U-2756: USE OF VASCEPA AS AN ADJUNCT TO STATIN THERAPY TO REDUCE THE RISK OF CARDIOVASCULAR DEATH IN AN ADULT PATIENT WITH ESTABLISHED CARDIOVASCULAR DISEASE
- Hikma's ANDA product was launched with a label that carved out the CV indication
  - Hikma's promotional materials stated that its product was "AB Rated" and "equivalent" to Vascepa® in the "Therapeutic Category: Hypertriglyceridemia"
- The Court in *Amarin* interpreted *GSK v. Teva* narrowly, and granted Hikma's motion to dismiss
  - Currently on appeal

Inflection points for interacting with FDA

- Citizen petitions
- Bioequivalence guidances and commenting process

Biologics and Biosimilars

- Labeling and interchangeability; different prescribing practices than for drugs
- No patent linkage
- Need for clinical studies to support approval as a biosimilar and switching studies to support interchangeability

Generic Drug Development

- Complex drug products and ongoing challenges for FDA and generic drug industry
- GDUFA proposals; faster bioequivalence guidance(s)
- The Bringing Low-cost Options and Competition While Keeping Incentives for New Generics Act (BLOCKING Act)
  - Designed to prevent "parking" of 180-day exclusivity. Would permit FDA to approve a later-filed Paragraph IV ANDA if 1) it is ready for final approval but for the outstanding Paragraph IV exclusivity of a first-filer, 2) at least 30 months have passed since the first-filer submitted its ANDA, 3) the 30-month patent litigation stay does not preclude approval of the first-filer, and 4) the first-filer is not yet approved.

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