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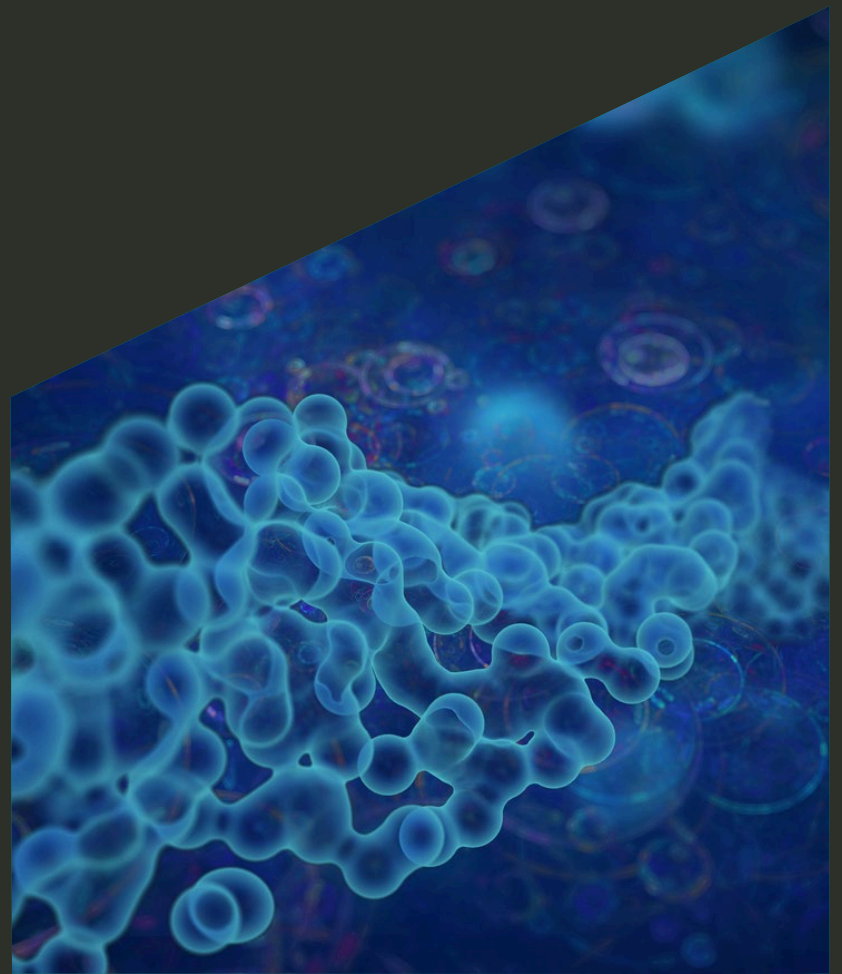
LIFE SCIENCES BOOTCAMP SERIES



May 25, 2021

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INTRODUCTION

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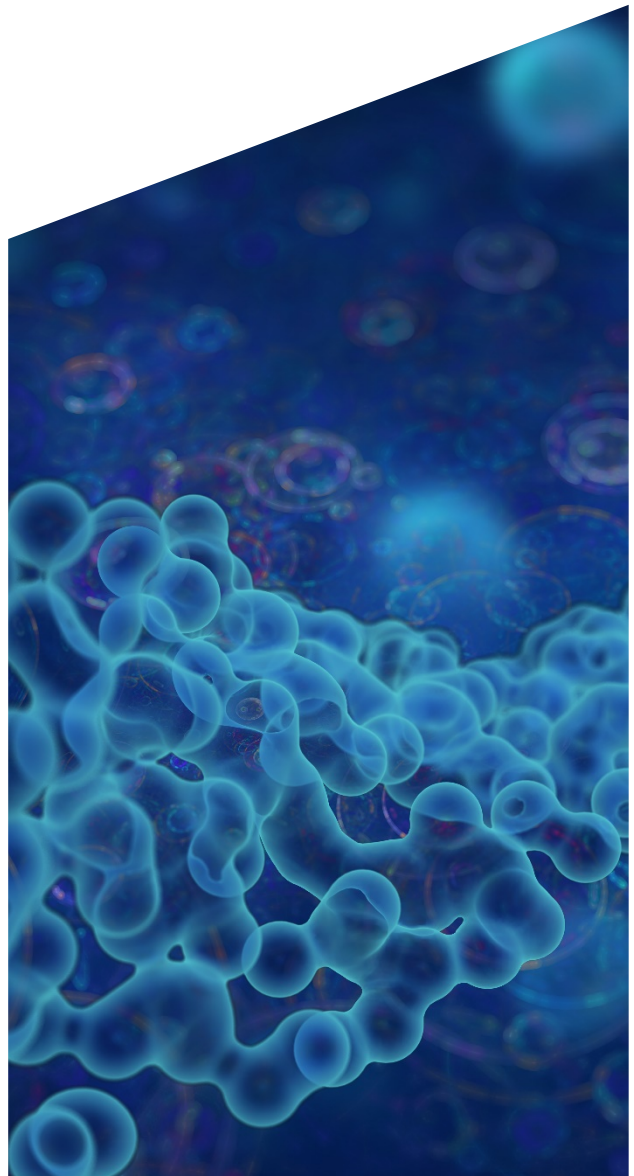
AGENDA

- Achieving Drug Protection
- Where to Sue?
- Product Exclusivity Considerations
- Patent Term Extensions
- Product Labels



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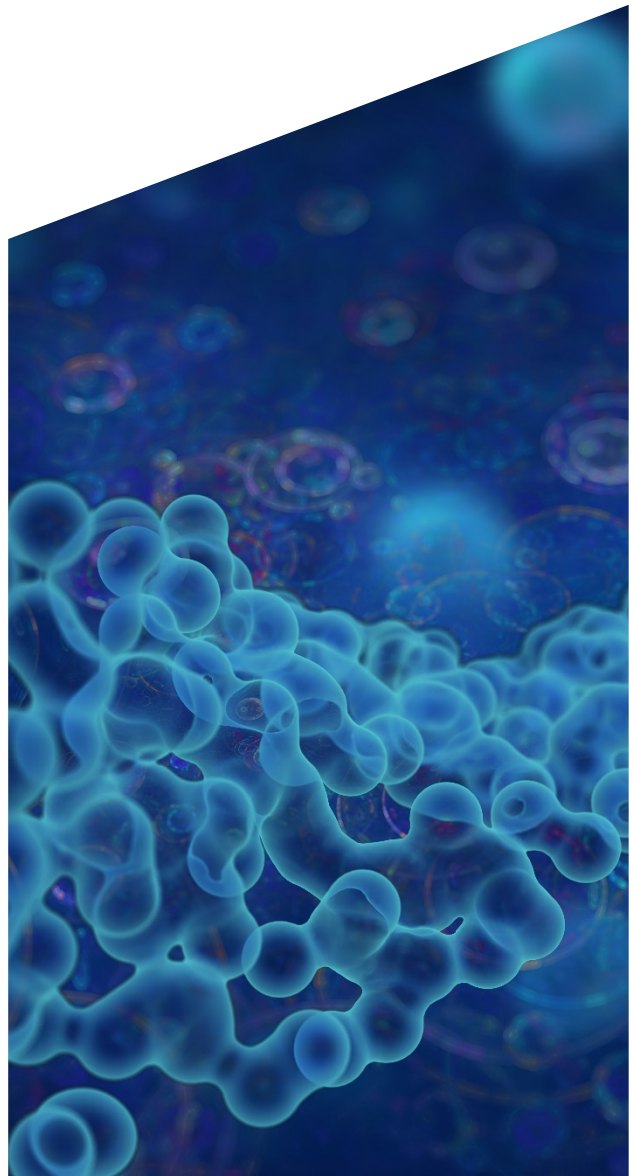
- “When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed”

ACHIEVING DRUG PROTECTION

Christopher M. Bruno

OVERVIEW

- **Achieving Drug IP Protection**
  - Good Practice Tips
  - Claiming Biologics
  - Formulations
  - Dosing Regimens
  - Polymorphs
- Product Exclusivity Considerations
- Patent Term Extensions
- Where to Sue
- Product Labels



GOOD PRACTICE TIPS

- Screen publications
- Get counsel team involved early, alongside the science
- Track your license dates
- Align IP with regulatory
- Build the timeline, adjust frequently, and scenario-planning based on different exclusivity/ patent coverage options

ACHIEVING DRUG IP PROTECTION – BIOLOGICS

- Functional claiming may be in jeopardy. *Amgen v. Sanofi*, *Aventisub LLC*, 994 F.3d 1080 (Fed. Cir. 2021), *opinion withdrawn*
- Shift thinking towards more traditional methods of patent portfolio building.
  - Methods of manufacture
  - Capture the genus initially, then assert specific formulations or functions with supporting data in later applications.
  - Drug/device combination patents

ACHIEVING DRUG PROTECTION – FORMULATIONS

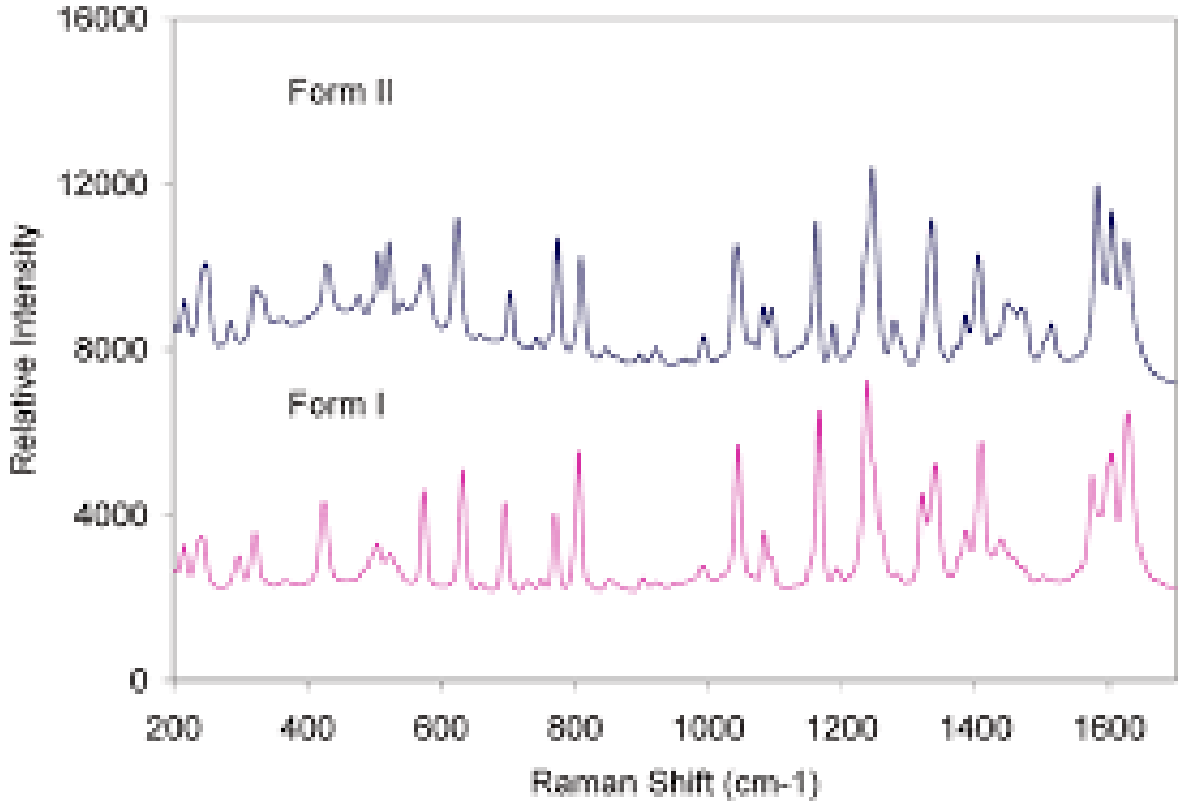
- If the underlying API isn't obvious to use, neither is a formulation including it. *Onyx Therapeutics, Inc. v. Cipla Ltd.*, 2020 U.S. Dist. LEXIS 80164 (D.Del. May 4, 2020) (Kyprolis)
- Switching formulation types, and using ingredients already known for their known purposes, is unlikely to provide firm protection. *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 2020 U.S. Dist. LEXIS 109257 (D.N.J. June 5, 2020) (NARCAN Nasal Spray).
- Claiming results of use of formulations has protected against anticipation/obviousness, but that could change. *Galderma Labs., L.P. v. Teva Pharms. USA, Inc.*, 799 Fed. Appx. 838, 842–45 (Fed. Cir. 2020)
- Mere prior existence of excipients is not enough to result in obviousness; emphasize decision points. *AstraZeneca AB v. Mylan Pharma. Inc.*, 2021 WL 798856 (N.D. W. Va. March 2, 2021) (Symbicort)
- Secondary considerations can be crucial in formulation protection.

ACHIEVING DRUG PROTECTION – DOSING

- Not much movement here.
- Dose ranging studies, and the results thereof, are often themselves found to be obvious. *Boehringer Ingelheim Pharma. Inc. v. Mylan Pharm. Inc.*, 803 Fed. Appx. 397 (Fed. Cir. 2020)
- Dose criticality remains an important safety net where doses are otherwise previously disclosed in broad ranges.
- Unexpected trajectory is the basis for valid dosing claims.
  - Lower amounts of API with similar or better efficacy.
  - Less frequent dosing is more efficacious than More frequent dosing.
  - Combinations of these

ACHIEVING DRUG PROTECTION – POLYMORPHS

- The Federal Circuit has upheld polymorph patents, although it has rejected a *per se* rule against finding them obvious. *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1336 (Fed. Cir. 2019).
  - The problem for invalidators has been that there is no expectation of success in achieving a particular polymorph, even when running a routine screen.
- One recent decision has invalidated a patent touching upon API polymorph issues. *UCB, Inc. v. Actavis Labs. UT, Inc.*, 2021 WL 1880993 (D. Del. Mar. 26, 2021).
- Issues affecting obviousness/anticipation
  - Prior on-the-market degradation products
  - Known polymorphism
  - Known variables resulting in polymorphism
- Is this enantiomerism v. 2.0?

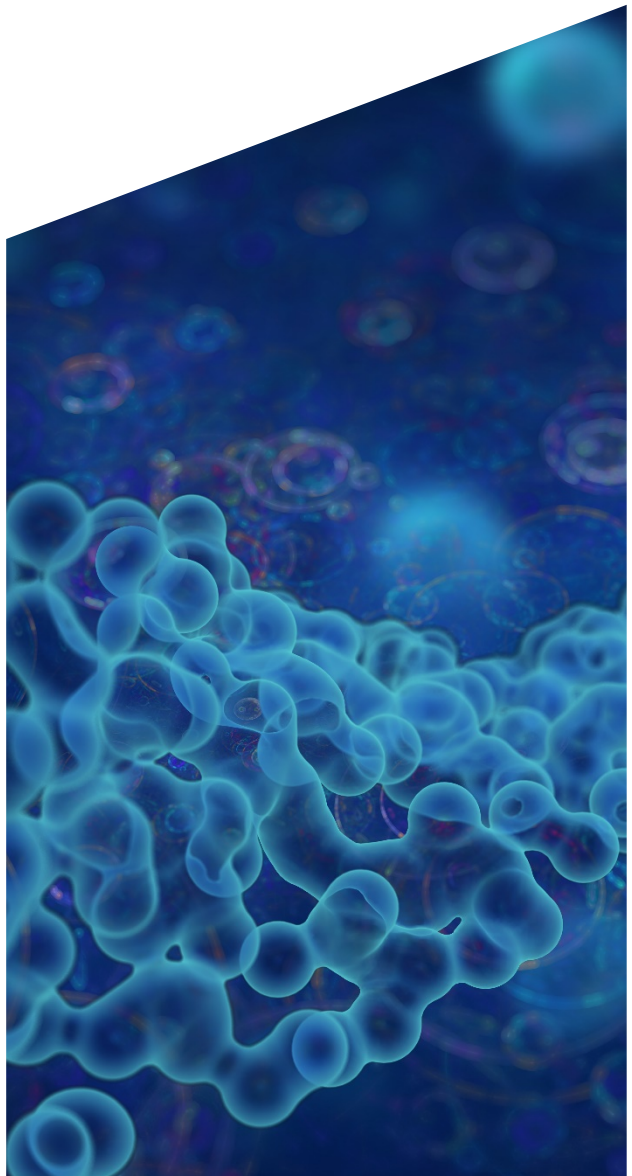


FDA EXCLUSIVITIES

Brian Malkin

OVERVIEW

- **Product Exclusivity Considerations**
- Patent Term Extensions
- Where to Sue
- Product Labels



BRIEF BACKGROUND

Types of FDA Exclusivities

- Non-Patent Exclusivity
  - NCE exclusivity – 5 years
  - New clinical study – 3 years
- Patent Exclusivity
  - 30-month stay for patent litigation
  - Delayed approval until patent expiration including extensions
- Generic Drug Exclusivity – 180 days (ANDA only)
- Competitive Generics Therapy – 180 days (ANDA only)
- Innovator Biologics / Interchangeable Biosimilars Exclusivity
- Orphan Drug Exclusivity – 7 years (drugs and biologics)
- Pediatric Exclusivity – 6 months (add-on only)

HATCH-WAXMAN COMPROMISE

- Created modern-day generic drug industry
- Benefits for generic industry
  - Abbreviated approval mechanism for all drugs (ANDA)
  - Reversal of *Roche v. Bolar* to allow testing prior to patent expiration
  - 180-day ANDA exclusivity as a reward for patent challenges
- Benefits for innovator industry
  - 505(b)(2) NDA approval / patent/exclusivity listings in Orange Book
  - Patent Term Restoration (PTR) (extension)
  - 30-month stay and process for resolving patent disputes prior to generic approval
  - Protection for innovative drugs even in absence of patents

HATCH-WAXMAN BACKGROUND

Overview of Drug Applications

- "Full" New Drug Application (NDA) – 505(b)(1)
  - Includes "full reports" of studies to prove safety and effectiveness
- 505(b)(2) Application – 505(b)(2)
  - NDA where applicant does not have rights to some of the "full reports" necessary for approval
  - Potential for "generic"-type rating (rare) or physician substitution
- Abbreviated New Drug Application (ANDA) – 505(j)
  - No requirement for "full reports"
  - Approval based on showing of similarity to previously approved drug product, including bioequivalence

HATCH-WAXMAN EXCLUSIVITY INCENTIVES

- Exclusivity Protections for Full NDAs and for 505(b)(2)s
  - Non-Patent Exclusivity (5 and 3 years)
  - Patent Listing and Certification (30-month stay)
  - Orphan Drug Exclusivity (7 years)
  - Pediatric Exclusivity (6 months)
- Full NDAs are not blocked by any exclusivity period other than Orphan Drug Exclusivity
- 505(b)(2) applications are blocked by all types of exclusivity protecting the listed drug, including patent certification
- 505(b)(2) applications are not eligible for, or subject to, 180-day ANDA exclusivity

HATCH-WAXMAN EXCLUSIVITY INCENTIVES (CONT'D)

- Exclusivities and patents listed in FDA publication Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book
  - Therapeutic Equivalence evaluations (i.e., which products are substitutable also listed in OB)
  - Listable patents include:
    - Drug substance (including isoforms if could be ANDA)
    - Drug product (formulation and composition)
    - Method-of-use patents
    - Devices only if using approved drug substance
  - Non-listable patents include:
    - Intermediates / Metabolites
    - Process patents
    - Packaging patents

NCE EXCLUSIVITY

Basics

- Granted to drug products containing an active drug molecule that has never been approved before, i.e., a “new chemical entity” (NCE) (now defined as “active moiety”) (re: Ensuring Innovation Act)
  - “[T]he molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.”
- Blocks submission of 505(b)(2) applications and ANDAs for five years
  - 4 years if subsequent application contains a “paragraph IV” certification
  - Effectively provides 6-7 years of exclusive marketing
- Umbrella Policy: exclusivity protects all versions of the drug containing the same active moiety

NEW CLINICAL STUDY EXCLUSIVITY

Basics

- Granted for changes to previously approved drugs requiring the submission of new clinical studies
- Blocks approval of 505(b)(2) applications and ANDAs for three years
- Protects only the change supported by the new studies, e.g., extended release dosage form
  - Carve outs may be possible

NEW CLINICAL STUDY EXCLUSIVITY

Requirements

- Studies must be conducted or sponsored by the applicant
- Studies must be “new”
  - “New” does not mean newly conducted
  - It means that the results have not been relied on by FDA to demonstrate effectiveness of a previously approved drug
- Studies must be “essential to approval”
  - No other data could support approval
  - FDA will not make this determination prior to approval
  - Bioequivalence or bioavailability studies not eligible

180-DAY ANDA EXCLUSIVITY

- As an incentive for generic companies to further the statutory purpose of helping the public gain access to lower-cost drug products more expeditiously, the Hatch-Waxman Amendments grants a 180-day period of generic drug market exclusivity to the first ANDA applicant that submits and maintains a substantially complete application containing a Paragraph IV patent certification.
- 180-day exclusivity prevents the FDA from approving subsequently submitted ANDAs containing a Paragraph IV certification until exclusivity expires or is forfeited

180-DAY ANDA EXCLUSIVITY

- Under amendments made to the FDC Act by the Medicare Modernization Act of 2003, Pub. L. No. 108-173,117 Stat. 2066 (2003), the first ANDA applicant that submits a substantially complete application containing a Paragraph IV patent certification can forfeit 180-day exclusivity eligibility for various reasons.
- 180-day ANDA exclusivity begins on the date of commercial marketing.
- But 180-day ANDA exclusivity can still be parked …

180-DAY EXCLUSIVITY FORFEITURE EVENT

- 180-day exclusivity may be forfeited:
  - Failure to market
  - Withdrawal of application
  - Amendment of certification
  - Failure to obtain tentative approval
  - Entry into agreement with another applicant, the listed drug application holder, or a patent owner
  - Expiration of all patents
    - 21 U.S.C. § 355(j)(5)(D)
- But a first applicant that has forfeited exclusivity remains a first applicant, and approval of its ANDA does not need to wait until another first applicant's 180-day exclusivity has expired
- If all first applicants forfeit eligibility for exclusivity, then there will be no exclusivity, and FDA may approve subsequent ANDAs

CGT EXCLUSIVITY

- FDA may not approve another ANDA for the same product until the date that is 180 days after first commercial marketing of the competitive generic therapy
  - But nothing stops FDA from approving other ANDAs before the first commercial marketing
- For the "first approved applicant" of an ANDA for a "competitive generic therapy"
- "Competitive generic therapy": two definitions
  - A drug designated as a "competitive generic therapy" pursuant to FDC Act § 506H
  - A drug for which there are no unexpired patents or exclusivities listed in the Orange Book at the time of ANDA submission
- Like 180-day ANDA exclusivity, CGT exclusivity can be relinquished or waived
- See 21 U.S.C § 355(j)(5)(B)(v), as amended by FDARA § 808; FDA Guidance for Industry: *Competitive Generic Therapies*, March 2020

CGT EXCLUSIVITY (CONT'D)

- FDA to designate a drug as a "competitive generic therapy" upon request by the applicant when there is "inadequate generic competition" (i.e., there is no more than one approved ANDA for its corresponding reference product listed in the Orange Book)
  - Request prior to or concurrent with ANDA submission
  - FDA may act on the request within 60 days after receiving the request
- Other benefits for applicant include enhanced communications with FDA officials and advice from the Agency
- Eligibility for competitive generic therapy exclusivity may be forfeited if the ANDA applicant "fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective"
- Not available for ANDAs that are or were eligible for 180-day ANDA exclusivity
- See 21 U.S.C. § 356h, as amended by FDARA § 803(a); § 355(j)(5), as amended by FDARA § 808

BIOLOGICS PRICE COMPETITION AND INNOVATION ACT (BPCIA) EXCLUSIVITIES

- Provides for filing Abbreviated Biologics License Applications (aBLA or 351(k))
- Defines Biosimilar and Interchangeable biologic products
- Sets out the required information for an aBLA
- Provides for exclusivity for first interchangeable aBLA product relying on the same reference biologic
- Provides for 12-year exclusivity for the reference product
- Sets out the “patent dance”

BPCIA (CONT'D)

"Biosimilars" are

- Highly similar" to the reference product notwithstanding "minor differences" in clinically inactive components; and
- No clinically meaningful differences between the biological product and the reference product in terms of
  - Safety
  - Purity
  - Potency
    - 42 USC § 262(i)(2)

BPCIA (CONT'D)

"Interchangeable" means

- Biosimilar; and
- Can be expected to produce same clinical result as the RP in "any given patient"; and
- For a biological product that is administered more than once, the risk in terms of safety or diminished efficacy of alternating or switching between the biological product and the RP is no greater than using the RP without alternating or switching
- Biological product may be substituted for the RP without the intervention of the health provider who prescribed the RP
  - 42 USC § § 262(k)(4), (i)(2)

BPCIA EXCLUSIVITY - RP

- “Data exclusivity”: the period when FDA cannot rely on its prior finding of safety, purity, and potency of the reference product based on BLA holder’s clinical data to support approval of a biosimilar
- Under BPCIA, biosimilar applicant may not submit application for 4 years after date when reference product first licensed
- Also, FDA may not approve application until 12 years after date when reference product first licensed **including structural changes** (e.g., amino acid sequence, post-translational events, infidelity of translation or transcription, glycosylation patters or tertiary structure, or differences in biological activity) **that result in changes in safety, purity, or potency**

BPCIA EXCLUSIVITY – RP (CONT'D)

Data Exclusivity Period: Evergreening

BPCIA – RP may have orphan drug & pediatric exclusivity

But BPCIA specifies no new 12-year exclusivity period for:

- Supplemental BLA
- Subsequent application with change that results in:
  - New indication
  - New route of administration
  - New dosing schedule
  - New dosing form delivery system
  - New delivery device or strength
  - Structural modification to molecule that does not change safety, purity, or potency

BPCIA EXCLUSIVITY – ABLA

- Interchangeable aBLA Exclusivity
  - First 351(k) application to obtain FDA determination of interchangeability is entitled to exclusivity (not first to file)
  - Exclusivity attaches based on determination of interchangeability for any condition of use
  - Exclusivity prevents a determination that another product is interchangeable but does not prevent approval of additional biosimilar products
  - But Interchangeable aBLA exclusivity period is subject to forfeiture
    - 42 USC § 262(k)(6)

BPCIA EXCLUSIVITY – ABLA (CONT'D)

- Interchangeable aBLA Exclusivity (cont'd)
  A. 1 year after first commercial marketing;
  B. 18 months after
     - A final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
     - The dismissal with or without prejudice of an action instituted under subsection (l)(6) against the application that submitted the application for the first approved IP; or

  C.
     - 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing; or
     - 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6)
       – 42 USC § 262(k)(6)

ORPHAN DRUGS ACT

Overview

- Provides incentives for developing drugs to treat rare diseases or conditions
- Development incentives
  - Tax credit
  - Grants/contracts
  - Assistance in product development
- 7-year exclusive marketing

ORPHAN DRUG EXCLUSIVITY

Requirements

- Designation as orphan drug prior to submission of a marketing application
- Rare disease or condition
  - Affects less than 200,000 in U.S.; or
  - No reasons reasonable expectation of recovering costs from U.S. sales
- First approval (multiple potential applicants may receive designation prior to approval of first)

ORPHAN DRUG EXCLUSIVITY (CONT'D)

Scope

- 7-year exclusivity period
- Blocks approval of NDAs, 505(b)(2) applications, ANDAs, and Biologics License Applications (BLAs), *even if supported by full clinical trials*
- Limited to "same drug" (i.e., active moiety) for same indication

ORPHAN DRUG EXCLUSIVITY (CONT'D)

- "Same Drug" may "break" pending orphan drug exclusivity and obtain its own if "clinically superior"
  - Superior safety/efficacy based on head-to-head clinical trials
  - Major contribution to patient care (e.g., change from injection to oral, significantly reduced dosing schedule, major improvement in ease of dosing or potential for self administration)
- Recent Controversies
  - Depomed/Eagle/UT
  - Cost Recovery Provisions

PEDIATRIC EXCLUSIVITY

Overview

- Intended to provide an incentive for companies to conduct pediatric studies and generate pediatric labeling
- Granted to innovators who successfully complete FDA-requested clinical trials in pediatric populations

PEDIATRIC EXCLUSIVITY

Scope

- Adds six months to unexpired exclusivity periods, including:
  - Non-patent exclusivity (both 3- and 5-year exclusivity)
  - Orphan drug exclusivity (7 year)
  - Paragraph II, III and IV certifications (if innovator wins)
- Pediatric exclusivity does not:
  - Extend the patent itself; or
  - Extend a 30-month stay
- Umbrella Policy: pediatric exclusivity applies to any drug product that contains the same active moiety as the drug studied

PEDIATRIC EXCLUSIVITY

Requirements

- Written Request from FDA for pediatric studies
  - May require development of pediatric formulation
- NDA holder completes studies within timeframes and submits acceptable reports (usually via NDA supplement)
- Acceptable Reports:
  - Do not need to result in pediatric labeling, but
  - Must fairly respond to the written request and be conducted by accepted scientific principles and reported properly

LABELING IMPLICATIONS OF EXCLUSIVITY

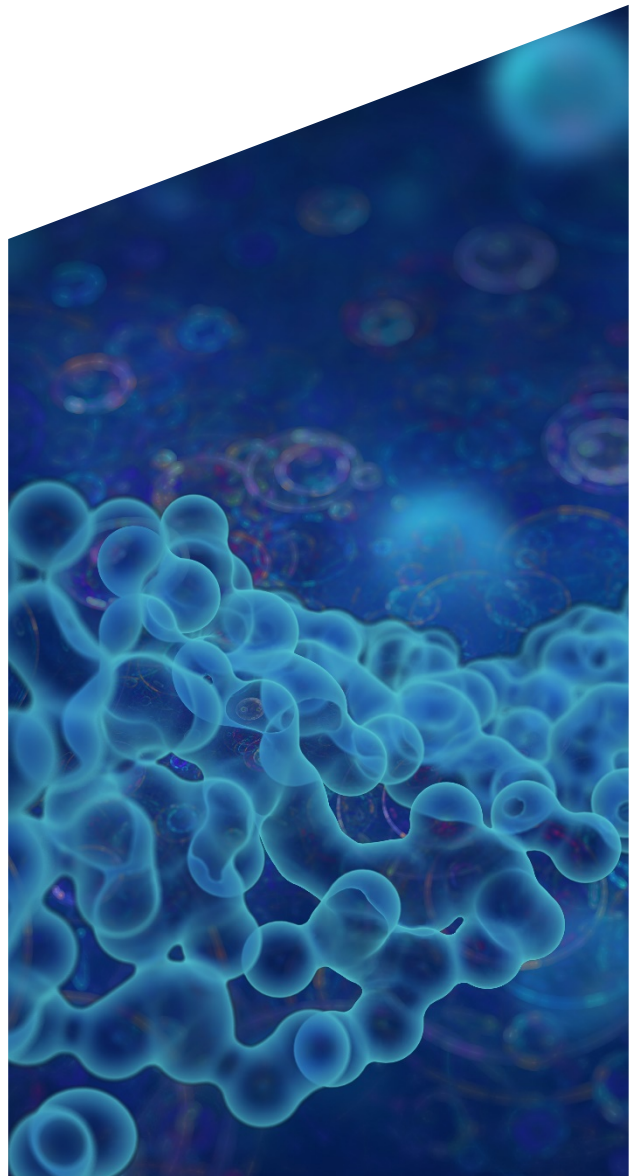
- Avoid carve-outs and design-arounds
- Labeling language should track carefully the exclusivity obtained
- Not an issue for NCE, QIDP
- The more integral the exclusivity-protection is to the safe use of the product, the more difficult it is to design-around
  - Combination products example

PATENT TERM RESTORATION (EXTENSION)

Brian Malkin

OVERVIEW

- **Patent Term Extensions**
- Where to Sue
- Product Labels



PATENT TERM RESTORATION (EXTENSIONS)

- PTR available to compensate patent holders for loss of term while product is in development and review
- PTR calculation:
  - Regulatory Review Period (RPP) – pre-patent grant regulatory Review Period (pre-patent) – time applicant did not act with due diligence (DD) - 1/2 (Testing phase – Pre-Patent) = PTE
    - “Testing phase” begins on the effective date of an IND, and ends on the date a New Drug Application (“NDA”) is submitted to FDA
    - The “review phase” is the period from NDA submission to the date of FDA’s approval of an NDA
- Maximum of 5 year can be restored to the patent
- Total patent life for the product with extension cannot exceed 14 years (from approval)

PATENT TERM RESTORATION (EXTENSIONS) (CONT'D)

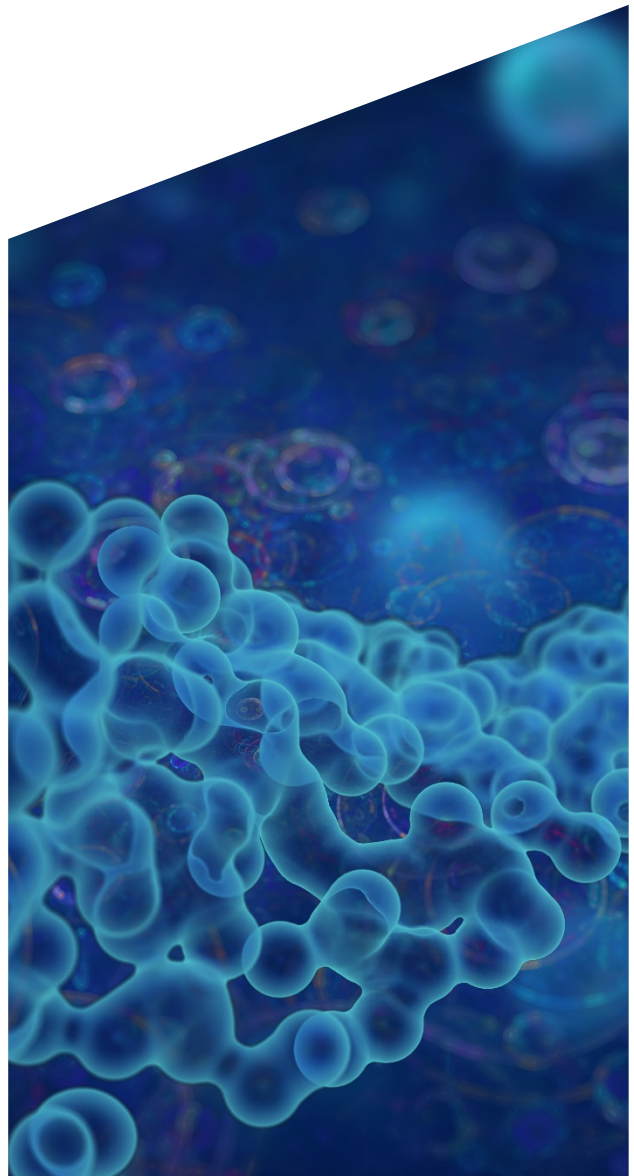
- Eligibility Requirements:
  - Patent must claim the product, method of using product, or method of manufacturing product
  - Patent is not expired
  - Patent term has not previously been extended
  - PTE Application must be submitted within **60 days** of FDA approval
  - Product must have been subject to a regulatory review period prior to commercial marketing or use – available for:
    - Drugs (human and animal), biologics, medical devices, food additives
  - Product must be first permitted commercial marketing of product after regulatory review period:
    - Active ingredient or salt/ester of active ingredient must not have been previously approved

WHERE TO SUE

Christopher Bruno

OVERVIEW

- **Where to Sue**
  - Venue in ANDA Cases
  - The Hottest Venues
  - Assertions as the New Frontier?
- Product Labels



VENUE IN ANDA CASES

- ***Can*** sue "in districts where actions related to the submission of the ANDA occur" but not where safe-harbor activities occur.
  - Still requires a principal place of business.
- Always ***can*** sue in place of incorporation.
- Foreign entities are amenable to venue everywhere.
- What are actions related to submission?
- Current options
  - MDL
  - Common Tracking

THE HOTTEST VENUES

ANDA – Comparing 2020 with 2021

ANDA Cases Filed in 2020

Courts		
D.Del.	145	55%
D.N.J.	100	38%
N.D.W.Va.	10	4%
D.Colo.	2	1%
N.D.Ill.	2	1%
Other Courts	7	3%

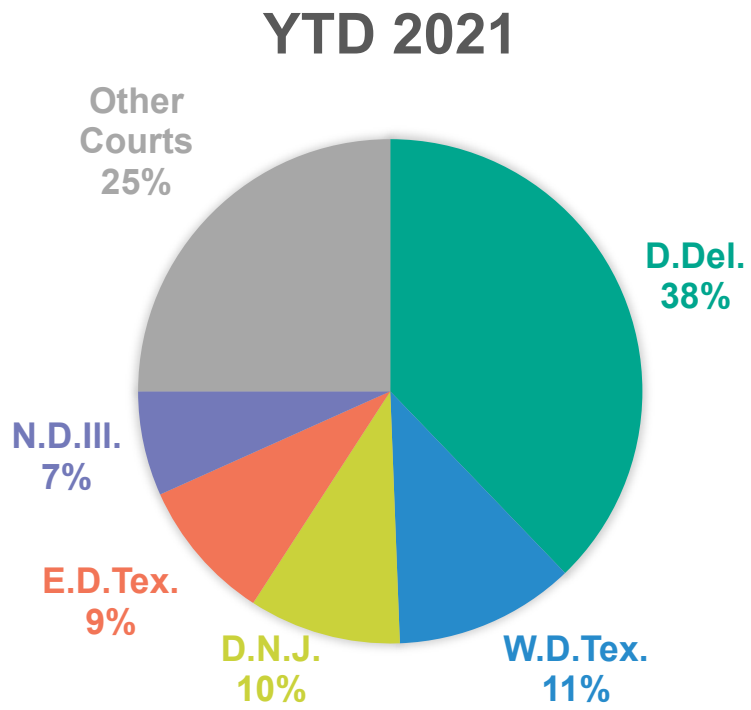
ANDA Cases Filed in 2021 to Date

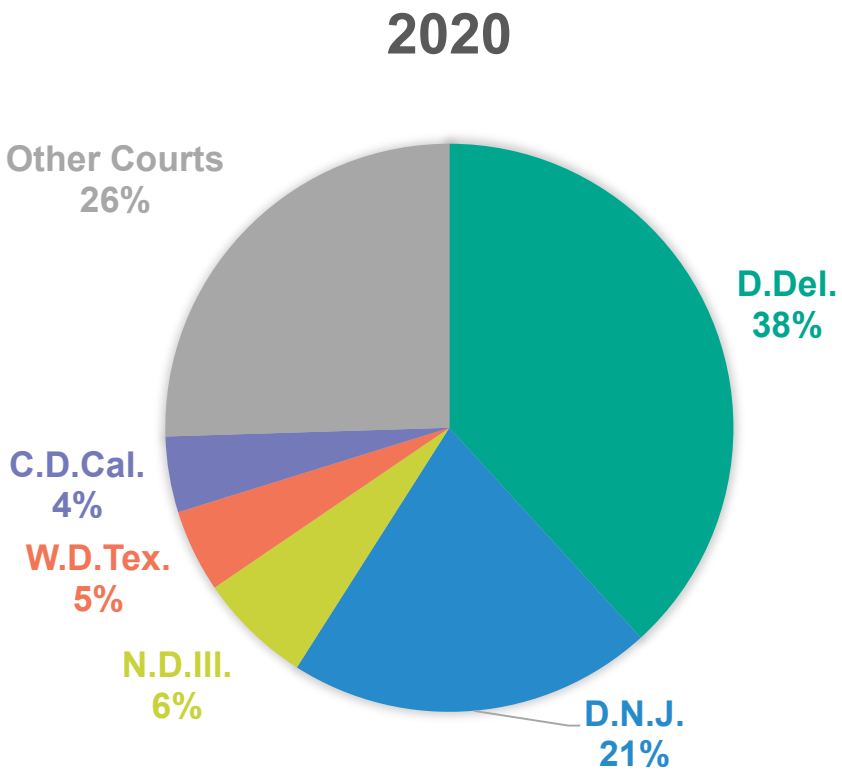
Courts		
D.Del.	48	67%
D.N.J.	16	22%
W.D.Tex.	3	4%
N.D.Ill.	1	1%
M.D.N.C.	1	1%
Other Courts	3	4%

Source: Lex Machina

THE HOTTEST VENUES

Drug & Medical Patents



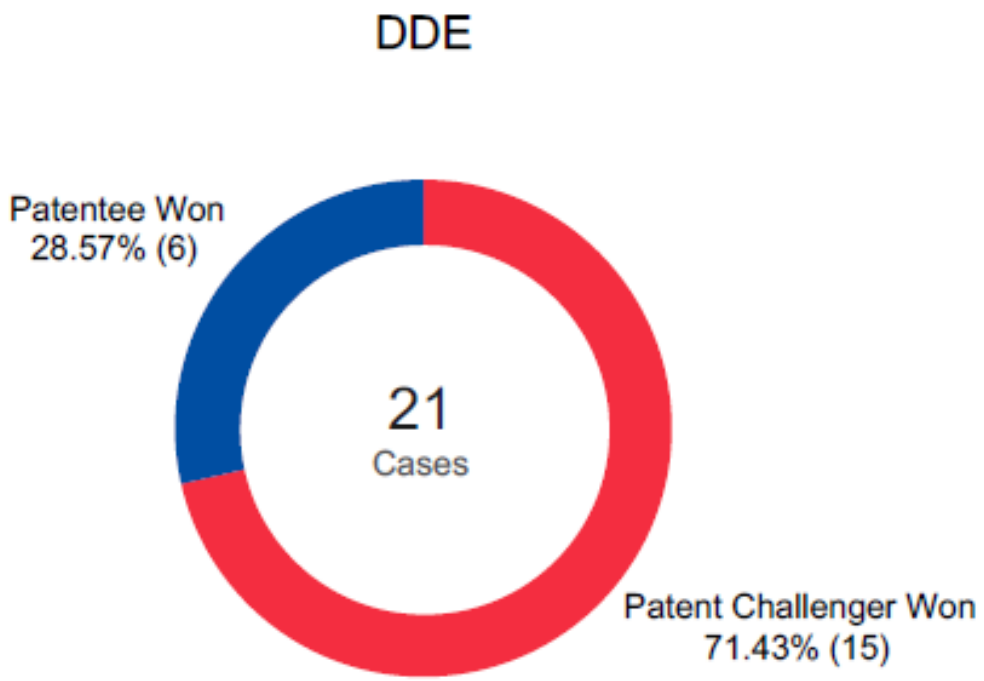


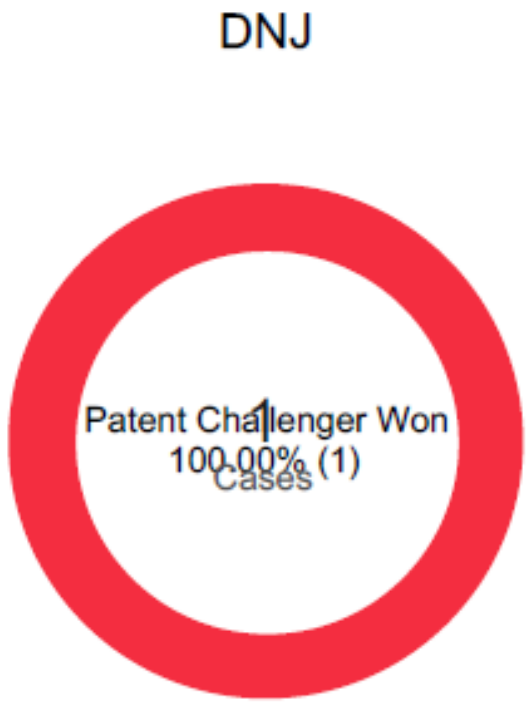
- 164 cases filed this year

Source: Docket Navigator

THE HOTTEST VENUES

2020 Biotech and Organic Chemistry Outcomes





ASSERTIONS AS THE NEW FRONTIER?

- **Old Standard**: Patent assertion letters could not create a basis for personal jurisdiction in the sender's jurisdiction for a declaratory judgment action.

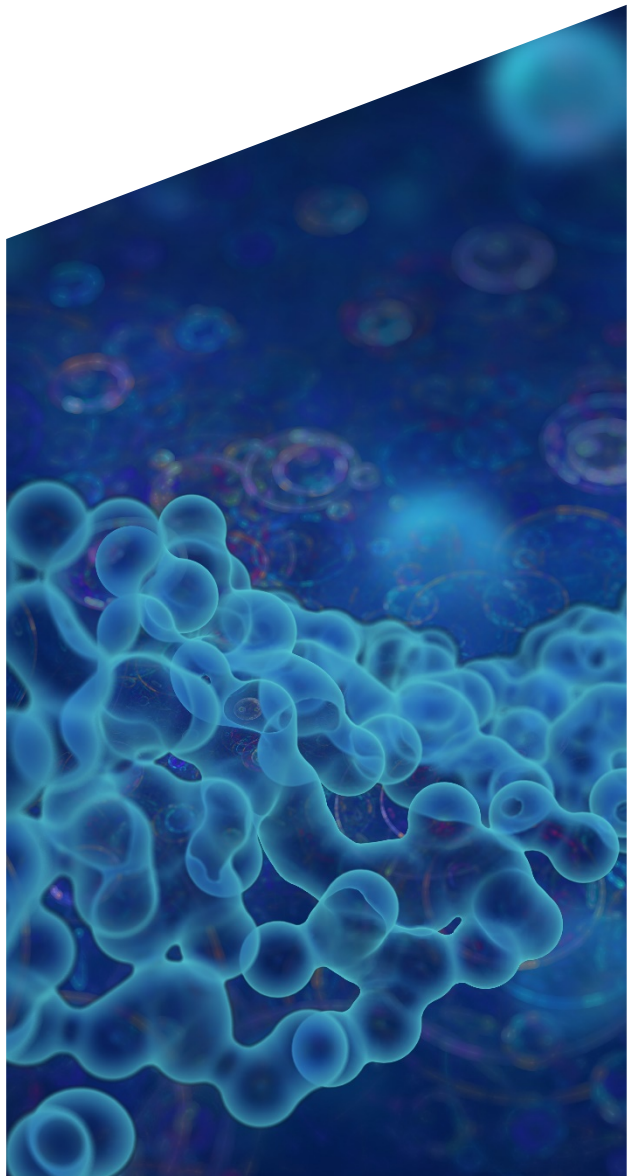
- **New Standard:** No bright line rules; the nature of the patent assertion activity matters

PRODUCT LABELS

April Weisbruch

OVERVIEW

- **Product Labels**



PRODUCT LABELS: A BROAD TOPIC

- What is the § 271(b) risk associated with my product label?
- What has really changed for section viii label carve-outs as a result of the Federal Circuit's decision in *GSK v. Teva?*
- Have other types of product labels been implicated?
- What has the district court reaction been to these changes in the law?

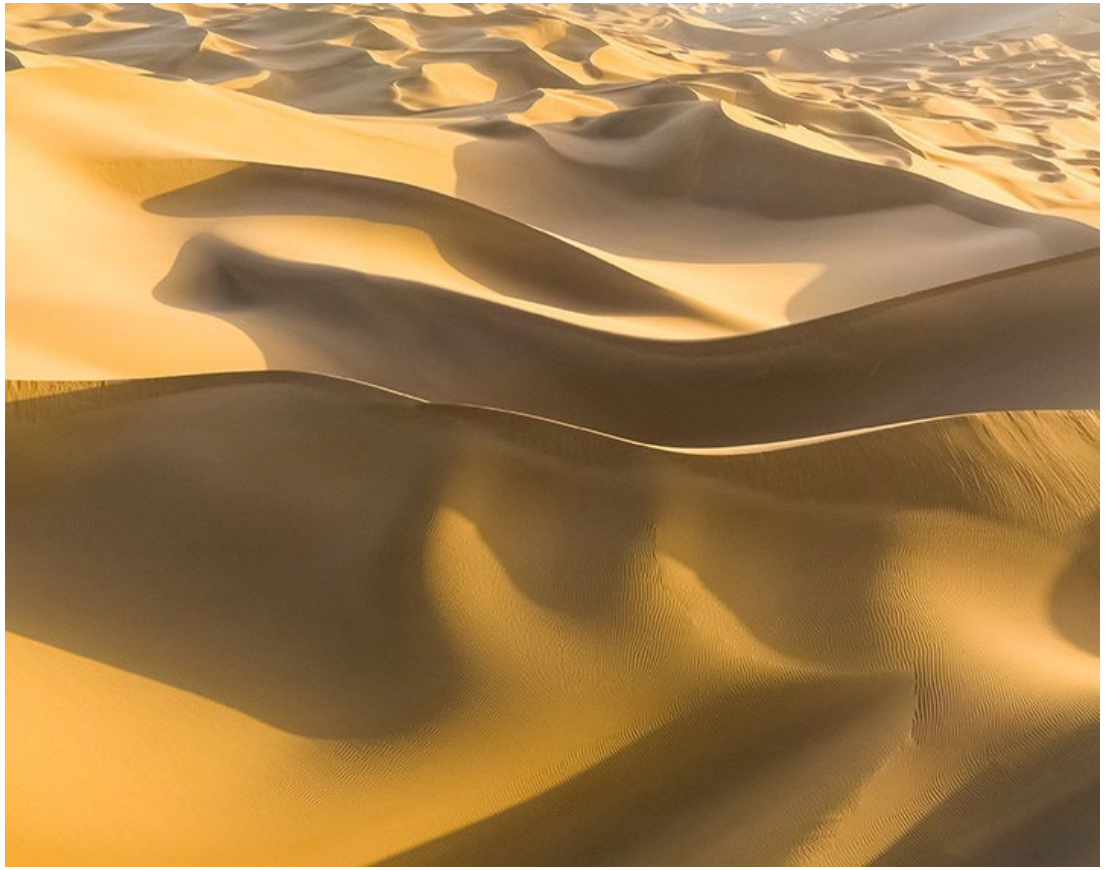
INDUCED INFRINGEMENT

- A defendant is liable for induced infringement under § 271(b) if it:
  - (A) took certain affirmative acts to bring about the commission by others of acts of infringement and
  - (B) had knowledge that the induced acts constitute patent infringement.
    - The intent element requires knowledge that the induced acts constitute patent infringement can be established by circumstantial evidence (*Warsaw Orthopedic*) or willful blindness (*Global-Tech*)

Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 765-66, 131 S. Ct. 2060, 179 L. Ed. 2d 1167 (2011); *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632, 135 S. Ct. 1920, 1928, 191 L. Ed. 2d 883 (2015); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016).

INDUCED INFRINGEMENT

- ***GSK v. Teva*** has introduced some uncertainty into the already 'fuzzy' realm of induced infringement
- Conversation has focused largely on whether the decision has sounded the 'death knell' of section viii carve-outs
- This misses a critical part of the GSK holding: induced infringement may be proven with circumstantial evidence "that the accused inducer promoted the infringing use with knowledge that such use directly infringes the patent claims."



INDUCED INFRINGEMENT: *GSK*

- The Federal Circuit's October 2020 decision in ***GSK v. Teva*** was rooted in circumstantial evidence, such as, *e.g.*:
  - “Teva’s promotional materials [referring] to Teva’s carvedilol tablets as AB rated equivalents of the Coreg® tablets”
  - "Teva’s press releases identifying their product as “Generic Coreg® Tablets”
  - Expert testimony that doctors are completely reliant on information provided by generic companies
  - Teva's Prescribing Reference Editions

INDUCED INFRINGEMENT: *TECSEC*

- The ***GSK v. Teva*** decision came down at around the same time as ***TecSec v. Adobe***, which (while not a life sciences/pharmaceutical case) also fuels questions of what can form the basis for intent to induce infringement.

> "...[W]e have held that, under [*Halo*], a finding of willfulness may rest on the ***subjective bad faith*** of the infringer ***even if it would be objectively reasonable to view the conduct at issue as non-infringing***... That logic applies equally to the intent element of inducement, as we concluded in [*Smith & Nephew Inc. v. Arthrex, Inc.*, 603 F. App'x 981 (Fed Cir. 2015)], where we explained that a district court's prior judgment of noninfringement, and statement to the parties that the plaintiff's inducement claim was objectively weak, did not prevent the plaintiff, as a matter of law, from proving the subjective intent element of induced infringement, which is a fact issue."
>
> *TecSec, Inc. v. Adobe, Inc.*, 978 F.3d 1278, 1287 (Fed. Cir. 2020) (emphasis added).

INDUCED INFRINGEMENT AND SECTION VIII CARVE-OUTS

- The inducement issue intersected with the issue of section viii carve-outs in *GSK* because Teva had carved out the infringing use on its label:
  - Coreg® was FDA-approved for treatment of three separate indications: hypertension; congestive heart failure ("CHF"); left ventricular dysfunction following a myocardial infarction ("post-MI LVD").
  - After March 2007, no GSK Orange-Book-listed patent covered the hypertension or post-MI LVD indications
  - A reissue patent (RE40,000) remained in force for CHF.

RELEVANT TRIAL TESTIMONY

Question: So is the expectation of Teva that when you carve out a particular indication, that Teva will still get sales of that drug for that indication once it's launched its product?

Answer: It's a legal strategy, not a commercial strategy.

***

Question: And so to make it specific to the issues here, if Teva has carved out congestive heart failure, but not hypertension and not post MILVD, Teva still expects to get sales where the doctor prescribed carvedilol for congestive heart failure, correct?

Answer: Yes, unless the doctor feels strongly.

Question: Writes brand only?

Answer: Yes.

Trial Tr., June 13, 2017, at 488.

In response to the question whether "[b]ased on what Teva said in 2004 and 2007, any time after that . . . , did you ever come to believe that Teva's generic carvedilol had not been approved for the treatment of heart failure?" Dr. McCullough answered: "No, I never knew it." Trial Tr., June 19, 2017, at 1661.

GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1354 (Fed. Cir. 2020).

INDUCED INFRINGEMENT AND SECTION VIII CARVE-OUTS

- Strong dissent authored by Chief Judge Prost:

"When Teva launched its product, Teva's carvedilol label did not suggest that it was approved to treat CHF at all, much less the '000 patent's narrow method of treating CHF... And there is *no dispute* that the only two uses included on Teva's label...*were not patented*... Teva's skinny label therefore did not infringe.

To hold otherwise, as the Majority does, undermines Congress's provision for skinny labels by substantially nullifying section viii. According to the Majority, a generic company that carves out from its label a patented method of use can nonetheless be found to infringe that patented method based on the content of the FDA-approved label... By finding inducement based on Teva's skinny label, which was not indicated for—and did not otherwise describe—the patented method, the Majority invites a *claim of inducement* for almost *any generic* that legally enters the market *with a skinny label*. That is directly contrary to Congress's intent."

GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1367 (Fed. Cir. 2020) (emphasis in original) (Prost, C.J., dissenting)

INDUCED INFRINGEMENT AND SECTION VIII CARVE-OUTS

- Amicus briefs have been filed by…
  - Novartis
  - Sandoz
  - Knowledge Ecology Intl. and James Packard Love
  - 57 Law, Economics, Business, Health, and Medicine Professors
  - Former Rep. Henry A. Waxman
  - Mylan
  - Apotex Inc.
  - Association for Accessible Medicine
  - R Street Institute

INDUCED INFRINGEMENT: STATUS OF *GSK*

- On February 9, 2021, the panel issued an order granting Teva's petition for rehearing
- The prior October 2, 202 judgment was vacated and the opinion withdrawn.
- On February 23, 2021, the panel reheard oral argument in the case.
  - Oral argument limited to the issue of whether there was substantial evidence to support the jury's verdict of induced infringement during the "Skinny Label" period
  - The panel geared its questions towards the labels, the accessibility of Teva's press releases, and the trial testimony of the parties' experts.

INDUCED INFRINGEMENT: DISTRICT COURT REACTION

- Distinction between ***FDA-required labeling*** and non-FDA required labeling
  - “Unlike in the Hatch-Waxman cases on which Roche relies...the pertinent language on Roche's labels was not placed there (nor removed from there) due to FDA regulations. It would have been reasonable, therefore, for the jury to base a finding of intent on (at least in part) Roche's removal of field restrictions from its labelling."
  - *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC,* 2020 U.S. Dist. LEXIS 223968 (D.Del. Nov. 20, 2020).
- Some instruction manuals insufficient to prove inducement even as circumstantial evidence.
  - "….[W]hen, as here, an alleged infringer's instruction manuals do not 'teach all of the steps of the claimed method together, much less in the required order,' a patentee's circumstantial evidence of infringement 'requires too speculative a leap to conclude that any customer actually performed the claimed method.'”
  - *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 2021 U.S. Dist. LEXIS 54618 (D.Minn. Mar. 23, 2021).

PRODUCT LABELS: A BROAD TOPIC

- What is the § 271(b) risk associated with my product label? **The law is currently evolving towards promoting findings of induced infringement; exposure is heightened**
- What has really changed for section viii label carve-outs as a result of the Federal Circuit's decision in *GSK v. Teva?* **The law has changed; but the question of impact depends on whether there is any course correction (panel rehearing)**
- Have other types of product labels been implicated? **Not yet**
- What has the district court reaction been to these changes in the law? **Limited so far, but what we have seen has offered bright line guidance**