

The logo for FISH, consisting of the word "FISH" in a bold, white, sans-serif font, followed by a small teal square.

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Lessons from Seagen v. Daiichi

September 16, 2026

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University of Chicago Law School

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University of Chicago; Chemistry

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University of Wisconsin, Madison; Chemistry

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- 20+ years of experience helping clients in the life sciences industry resolve complex legal issues involving biologics, small-molecule pharmaceuticals, and medical devices.
- Has provided counseling to innovative life sciences companies across a range of technologies, including those related to immuno-oncology, ophthalmology, cardiovascular health, and innovative platforms.
- Has handled dozens of cases involving biosimilar litigation, brand-side Hatch-Waxman disputes, trade secret disputes, and medical device litigation.
- Represented a biotechnology firm in biosimilar litigation over a drug to aid in post-chemotherapy recovery, in which a victory in District Court and on appeal allowed the company to launch its first-ever product.
- Admitted to practice before the USPTO and has experience representing life science clients in post-grant proceedings.
- Maintains an active practice centered on the intersection of antitrust law and intellectual property, in which he regularly helps clients understand, foresee, and avoid antitrust issues related to exclusive licensing, pay-for-delay, and other matters.



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Harvard Law School

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Washington University in
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- Practice emphasizes patent prosecution and counseling, opinion work, licensing, due diligence studies, and worldwide patent portfolio development and management.
- Advises his clients on patent matters relating to a broad range of technologies, including antibody therapeutics, transgenic animals, CAR-T immunotherapies, TCR-T immunotherapies, microarray technology, diagnostic methods, nanoparticle technology, vaccines, small molecules, medical devices, the application of artificial intelligence in the pharmaceutical industry, and related fields.
- Clients range from large publicly traded biopharmaceutical companies to emerging startup companies around the world.
- Involved at different growth stages of these companies, and he is dedicated to understanding his clients' technology and developing the best intellectual property strategy to maximize the commercial value of his clients' inventions.
- Prior to law school, Peng received his Ph.D. in human and statistical genetics from Washington University in St. Louis. Peng has extensive research experience and training in human genetics, molecular biology, biophysics, and bioinformatics.
- President of Chinese Antibody Society for the 2024-2026 term

Background / History

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35 USC 112(a)

- (a) IN GENERAL.—The specification shall contain a **written description** of the invention, and of the manner and process of **making and using** it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the **best mode** contemplated by the inventor or joint inventor of carrying out the invention.
- MPEP 2162 (Underlying Policy) - The requirement for an adequate written description ensures that **the public receives something in return for the exclusionary rights** that are granted to the inventor by a patent
- To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that **the inventor had possession of the claimed invention**. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

35 USC 112(a)

- **How to show possession of the invention?**
- Generally, a **genus** can be sufficiently disclosed by "either a **representative number of species** falling within the scope of the genus **or structural features common to the members of the genus** so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (emphasis added)

35 USC 112(a)

- One Statutory Standard, Two Frameworks
- **Framework 1: “Broad Genus” Paradigm (Lilly / Juno)**
 - The Question: Are there sufficient representative species or common structural traits to support the full scope of the genus?
- **Framework 2: "Blaze Mark" Paradigm (Ruschig / Duke / Seagen)**
 - The Question: Does the specification explicitly point a POSITA to the specific subgenus or combination of variables claimed?

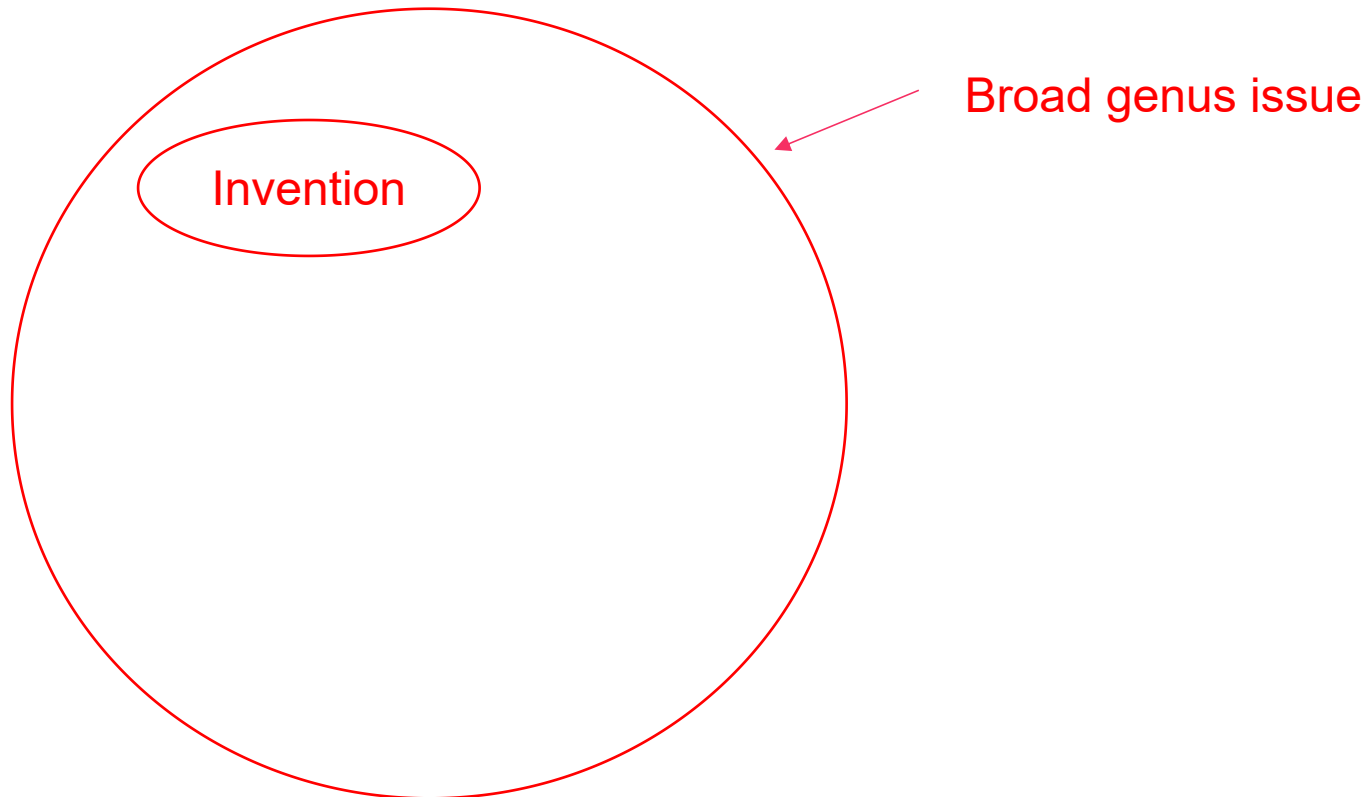
35 USC 112(a)

- **Framework 1:** “Broad Genus” Paradigm (Lilly / Juno)
- **Framework 2:** “Blaze Mark” Paradigm (Ruschig / Duke / Seagen)

Invention

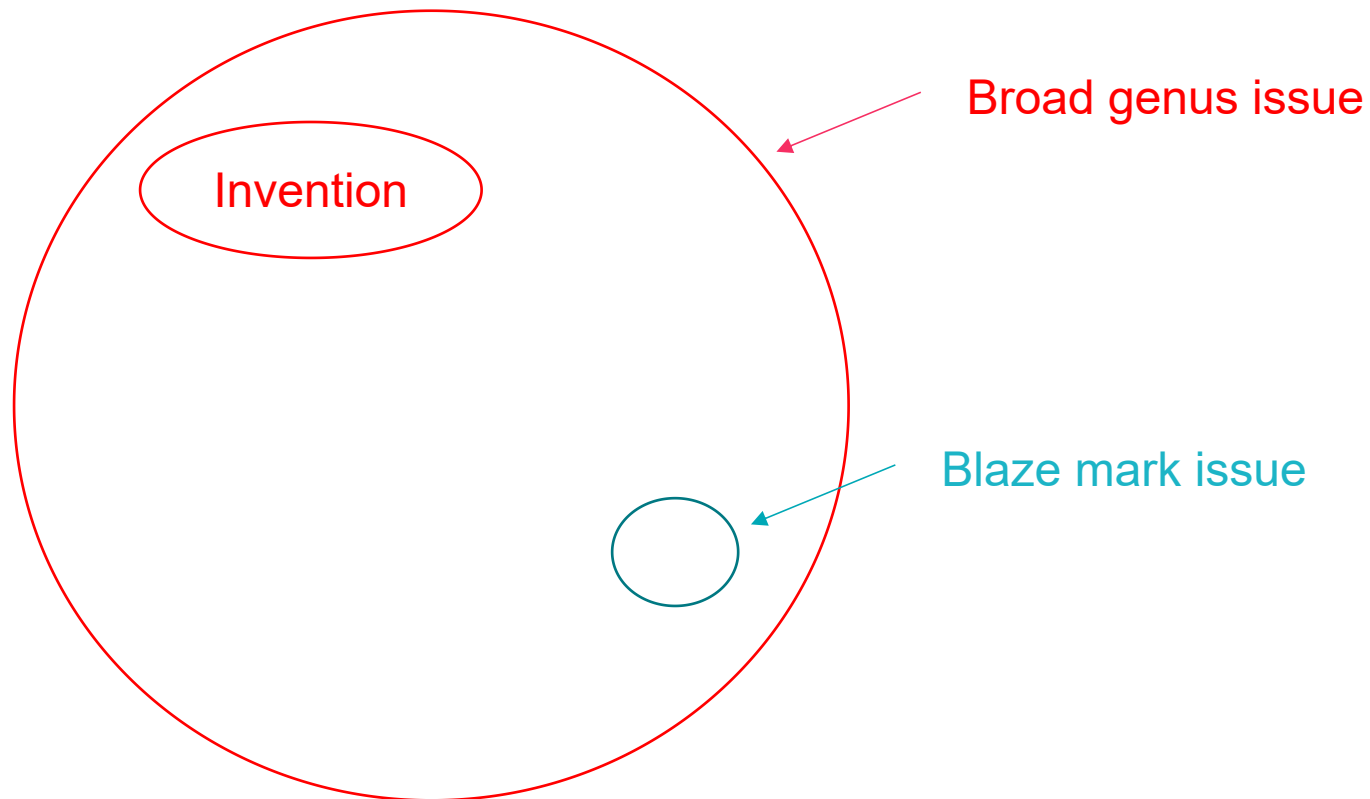
35 USC 112(a)

- **Framework 1:** “Broad Genus” Paradigm (Lilly / Juno)
- **Framework 2:** “Blaze Mark” Paradigm (Ruschig / Duke / Seagen)



35 USC 112(a)

- **Framework 1:** “Broad Genus” Paradigm (*Ariad* / Juno)
- **Framework 2:** “Blaze Mark” Paradigm (*Ruschig* / *Duke* / *Seagen*)



Broad Genus Paradigm

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Ariad Pharms. v. Eli Lilly (Fed. Cir. 2010)

Representative claim:

80. [A method for modifying effects of external influences on a eukaryotic cell, ... wherein NF- κ B activity in the cell is reduced] wherein **reducing NF- κ B activity** comprises reducing binding of NF- κ B to NF- κ B recognition sites on genes which are transcriptionally regulated by NF- κ B.

- Genus claims encompassing use of all substances that achieve the desired results of reducing the binding of NF- κ B to NF- κ B recognition sites
 - Inventors were first to identify NF- κ B and uncovered mechanism by which NF- κ B activates gene expression underlying the body's immune responses to infection.
- Specification hypothesizes three types of molecules with the potential to reduce NF- κ B activity in cells: decoy, dominantly interfering, and specific inhibitor molecules
 - Does not provide any working or prophetic examples of methods that reduce NF- κ B activity
 - No completed syntheses of any of the hypothesized molecules

Ariad Pharms. v. Eli Lilly (Fed. Cir. 2010)

Representative claim:

80. [A method for modifying effects of external influences on a eukaryotic cell, ... wherein NF-κB activity in the cell is reduced] wherein **reducing NF-κB activity** comprises reducing binding of NF-κB to NF-κB recognition sites on genes which are transcriptionally regulated by NF-κB.

- **Decision:** Invalidated for failing to comply with the written description requirement of § 112.
 - Generic functional language does not automatically satisfy WD requirement
 - Specification fails to disclose a variety of species that accomplish the claimed result
- Reaffirmed rule that written description requirement is in addition to the enablement requirement

AbbVie v. Janssen (Fed. Cir. 2014)

Representative claim:

29. A **neutralizing isolated human antibody**, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a k_{off} rate constant of $1 \times 10^{-2} \text{ s}^{-1}$ or less, as determined by surface plasmon resonance.

- AbbVie claimed a broad genus of antibodies but the specification only described species that were structurally similar to each other
 - Disclosed over 300 examples; within 90% sequence identity
 - Janssen created an antibody that shared the neutralizing function but differed greatly in structure
 - ~50% sequence similarity, different CDR length, different epitopes, different V gene families
- **Decision:** Invalidated for failing to comply with the written description requirement of § 112.
 - A functionally defined genus requires a disclosure of a “representative number of species”
 - Because the claimed genus was structurally diverse, AbbVie’s structurally similar examples were not enough

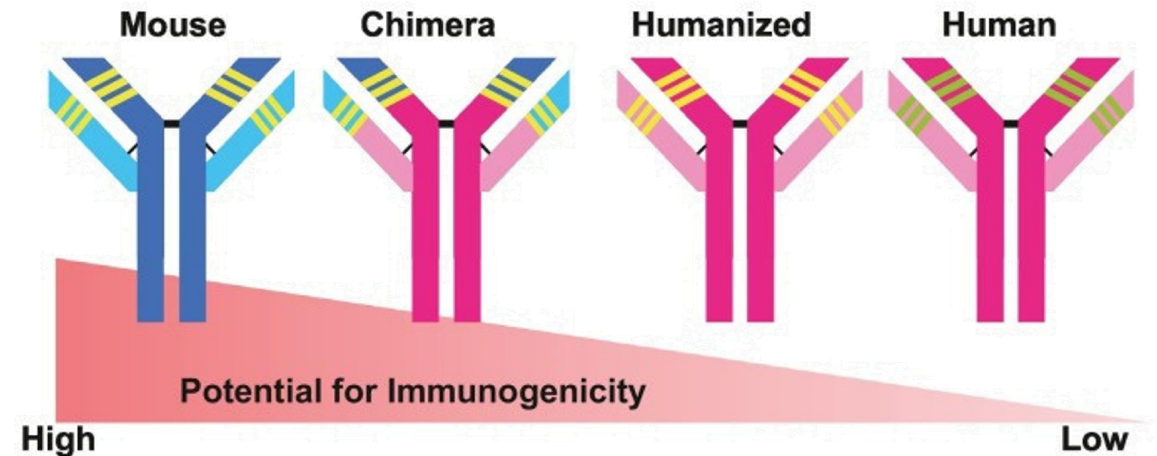
The background of the slide is a light gray technical drawing or blueprint. It features various geometric shapes, lines, and symbols, including circles, rectangles, and crosshairs, arranged in a complex, overlapping pattern. The drawing is centered on the slide, with a large, light gray rectangular area in the middle containing the text.

Teva Pharms. v. Eli Lilly & Co.
(Fed. Cir. 2026)

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Background

- Calcitonin gene-related peptide (**CGRP**) is a neuropeptide associated with causing headaches by binding to certain cells and causing blood vessel expansion
- Anti-CGRP **antagonist antibodies** block this binding, preventing the headache
- **Humanization** is the process of converting a non-human antibody into a form the human immune system will not reject (humanized antibody)
 - Prior to the application, anti-CGRP antagonist antibodies were known in the art, but no **humanized** versions were known



PTAB & Dist. Ct. challenges

- Lilly filed petitions for IPR with PTAB challenging several of Teva's patents
 - “**Antibody patents**” – claimed humanized anti-CGRP antagonist antibodies themselves
 - Lilly argued anti-CGRP antagonist antibodies and techniques for making them were well known in the art; humanization was an established and routine procedure
 - PTAB determined claims were **unpatentable** as obvious under § 103
 - “**Headache patents**” – claimed method of using humanized anti-CGRP antibodies to treat headache
 - PTAB did not find claims to be unpatentable
- Teva brought suit against Lilly, alleging that Lilly infringed the headache patents
 - Lilly argued that the headache patents are invalid for failure to satisfy both the written description and enablement requirements of § 112

Headache Patents

Representative claim:

30. [A method for reducing incidence of or treating headache in a human, comprising administering to the human an effective amount of an **anti-CGRP antagonist antibody**], wherein said anti-CGRP antagonist antibody is a... **humanized monoclonal antibody**.

- The specification disclosed a single exemplary humanized antibody (“G1”)
 - Described 84 variants of G1 within 95% sequence identity
 - Also disclosed several murine anti-CGRP antagonist antibodies
 - Referenced prior art methods for humanization
- Did the specification disclose a **representative number of species** of the genus of humanized anti-CGRP antagonist antibodies?

Teva & Lilly's products



Teva: AJOVY®

- Fremanezumab (G1)
- Binds to C-terminal end of CGRP antigen¹

- Sequence identity is **50.8-64.5%** between the two
 - Come from different V gene families and have CDRs of different sequences and lengths



Lilly: Emgality®

- Galcanezumab (gmab)
- Binds to mid-region of CGRP antigen¹
- Potency and affinity differences from G1
 - Gmab can treat cluster headache; Teva's G1 was not marked for that purpose

District Court Decision

- Lilly argued that Teva claimed a broad, functionally defined genus (treating headaches) but only possessed one representative species (G1)
 - Discovering others would require extensive screening
 - In vitro assay
 - In vivo tests
 - Obtain animal antibody
 - Humanize (can cost up to \$70k, take ~8-9 weeks)
 - Trial testimony established that there are a “mind-bogglingly large” number of antibodies that could potentially fit within the scope of the asserted claims
- Jury returned \$176.5 million verdict for Teva, finding Lilly willfully infringed
- District Court granted **JMOL** for Lilly
 - Single species insufficient to claim the entire genus
 - Gmab is different from G1 in several ways that are similar to the differences between the antibodies in *AbbVie*
 - Results in an impermissible “research plan”



Federal Circuit Reversal

Claiming a Genus

vs.

Claiming Method of Using a Genus

- The Federal Circuit reversed, reinstating the jury verdict that the patents were valid
- **Distinction:** The claimed invention is the **use** of anti-CGRP antagonist antibodies to treat headache, *not* the antibodies themselves
 - Well-known genus that is not itself the invention
 - Similar to *Ajinomoto* and *Herschler*, fits within precedent
 - Skilled person would be able to understand the genus, already well explored
- District Court acknowledged POSITA would have:
 - Known methods for making murine anti-CGRP antagonist antibodies
 - Known that humanizing antibodies was routine
 - Understood from the specification that all humanized anti-CGRP antagonist antibodies would treat headache

Impact of Lilly's PTAB Admissions

- In IPR proceedings, Lilly successfully invalidated Teva's COM antibody patents for obviousness
 - Argued anti-CGRP antagonist antibodies were “**well-known**” and “**replete**” in the art
 - Argued that humanization was a well-established and **routine procedure**
- Federal Circuit **used these admissions against Lilly** to establish that the background knowledge of a skilled person was sufficient to satisfy § 112
- Without Lilly's admissions, Teva would have to establish that murine CGRP antagonist antibodies were well known and that humanization was routine
 - Lilly would likely have argued that humanizing these specific antibodies was unpredictable
- Teva still had strong scientific narrative that ***all*** humanized anti-CGRP antagonist antibodies would accomplish claimed function (treating headache)

Takeaways

- There are **different § 112 standards** for claiming a novel genus of compounds versus claiming a method of using a well-known genus for a specific therapeutic purpose
 - When a genus is well-understood, background knowledge can provide § 112 support
 - When genus is auxiliary to the novel method claimed
- Patents may still face intense scrutiny if evidence suggests that less than **all members of a known genus** are useful in carrying out the method
 - Written description and enablement are easier to defend if the specification and prior art demonstrate that all members of a genus will achieve the claimed functional result
- Characterizations of prior art in § 103 arguments as “well-known” and “routine” can act as **fatal admissions** for § 112
 - Lilly’s own obviousness arguments were difficult to reconcile with its § 112 defense
- Drafting strategy
 - Layer composition of matter claims with method-of-use claims
 - Tie function to genus-wide efficacy if possible
 - Cite prior art for “routine” procedures

Blaze Mark Paradigm

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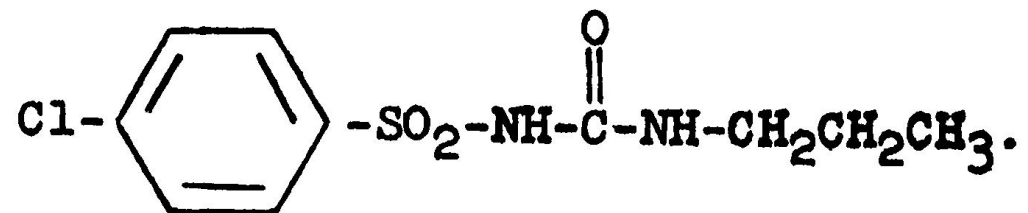
Framework 2: "Blaze Mark" Paradigm

In re Ruschig, 379 F.2d 990 (CCPA 1967)

- The origin of the concept of **blaze marks**
- Court affirmed rejection of newly claimed species claim for lack of written description
- A genus will not provide adequate written description for a species that is not otherwise specifically disclosed.
- The specification contained no disclosure of the name or structure

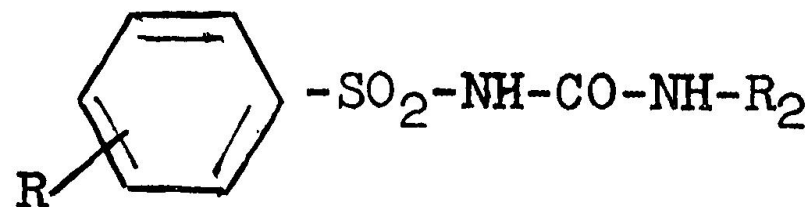
History: In re Ruschig

- New claim introduced to chlorpropamide



- Not exemplified or otherwise disclosed in the application
- Argued that it was supported by the disclosed genus and analog compounds

- Genus:



- R is Cl or Br, and
- R₂ is alkyl, alkenyl, cycloalkyl, or cycloalkylalkyl
- Specification also disclosed a homolog of chlorpropamide, where butyl was in place of propyl.

History: In re Ruschig

- No written description for the newly claimed species
- “It is an old custom in the woods to mark trails by making **blaze marks** on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared- or have not yet been made, which is more like the case here- to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for **blaze marks** which single out particular trees. We see none.”



Seagen v. Daiichi

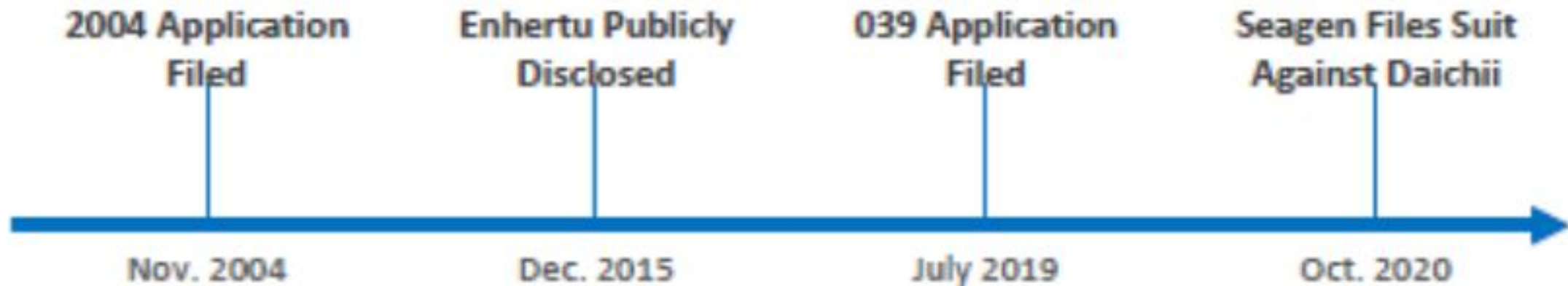
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Seagen v. Daiichi

- *Seagen Inc. v. Daiichi Sankyo Co.*, 160 F.4th 1322 (Fed. Cir. 2025)
- Seagen's patent is US 10,808,039
- Relating to Daiichi's ADC drug Enhertu®, used to treat various types of cancer
- Seagen sued Daiichi for infringement as soon as the patent issued
- District Court jury trial found claims **not** invalid for lack of written description or enablement, denied JMOL, and awarded \$42 million
- Fed Cir reversed
 - No written description
 - No enablement

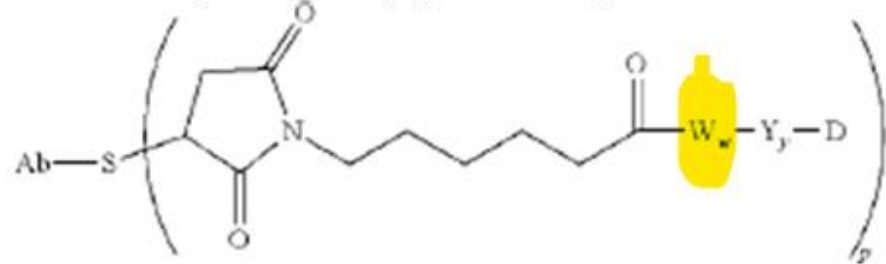
Seagen v. Daiichi

- “One cannot avoid the suspicion that the '039 patent was filed specifically to encompass Enhertu”



Seagen v. Daiichi

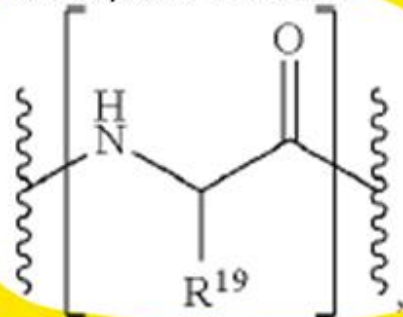
An antibody-drug conjugate having the formula:



or a pharmaceutically acceptable salt thereof, wherein:

Ab is an antibody,
S is sulfur,

each $—WW—$ unit is a tetrapeptide; wherein each $—W—$ unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl,

Y is a Spacer unit,
y is 0, 1 or 2,

D is a drug moiety, and
p ranges from 1 to about 20,

wherein the S is a sulfur atom on a cysteine residue of the antibody, and

wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

81 linker possibilities (3^4)

Seagen v. Daiichi

- A specification adequately describes an invention when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation omitted).
- "[T]he hallmark of written description is disclosure" in the "four corners of the specification." *Id.* Whether a patent complies with the written description requirement is a question of fact, and "we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335-36 (Fed. Cir. 2021) (quoting *Ariad*, 598 F.3d at 1355).

Seagen v. Daiichi

- The court agreed with Daiichi that no reasonable jury could have found that the original application sufficiently disclosed the claimed 81-member linker subgenus of Gly/Phe-only tetrapeptides.
- The specification states that "when present," the peptide unit " W_w " can be any of "a dipeptide, tripeptide, tetrapeptide, pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide, decapeptide, undecapeptide or dodecapeptide unit."
- 39 different amino acids that can constitute the R19 group
- Estimated **47 million** possibilities for the linker

Seagen v. Daiichi

- **Reasonably specific supporting disclosure needed for WD**
- “A patent's disclosure of a "broad genus," without more, is inadequate to satisfy the written description requirement for claims directed to a "particular subgenus or species contained therein." See, e.g., *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).”
- Our predecessor court's decision in *In re Ruschig* is instructive. 379 F.2d 990, 54 C.C.P.A. 1551 (CCPA 1967). There, the claim recited a single compound, which was "encompassed" in the application's "general disclosure of . . . something like half a million possible compounds." *Id.* at 993, 996. The Court of Customs and Patent Appeals ("CCPA") rejected that argument, explaining that claims to a particular species or subgenus require "reasonably specific supporting disclosure" to show that the inventor possessed the specific compound.
- Even the inventors testified they had never contemplated the claimed Gly/Phe (G/F) linkers until they learned of Enhertu

Seagen v. Daiichi

- **Blaze marks (the lack thereof)**
- Seagen argued the specification directed toward the G/F tetrapeptide linkers
- Expert witness Carolyn Bertozzi testified that it would be a "straightforward leap" for a skilled artisan "to go from GFLG . . . to a [tetra]peptide that's all G and F."
- Court had a problem with the word "leap".
 - "But that testimony dooms Seagen's case. That which one must leap to is obviously not there."
- "There are no adequate blaze marks that would lead a skilled artisan to the 81-member Gly/Phe-only tetrapeptide subgenus or any species within it."

Seagen v. Daiichi

- **Enablement**
- Claims also failed enablement
- D can be any drug moiety
- Functional limitation: "the drug moiety is intracellularly cleaved in a patient from the antibody"
- "It is undisputed that ADC science was so unpredictable that a skilled artisan would be required to use an assay to test whether any given ADC with a given drug moiety meets that functional limitation."
- "...the scale of trial and error is so vast and the science so unpredictable, such experimentation is undue under *Amgen*" (following *Amgen v. Sanofi*, 598 U.S. 594, 610, 612, 143 S. Ct. 1243, 215 L. Ed. 2d 537 (2023))

Duke (Allergan) v Sandoz

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Duke (Allergan) v. Sandoz

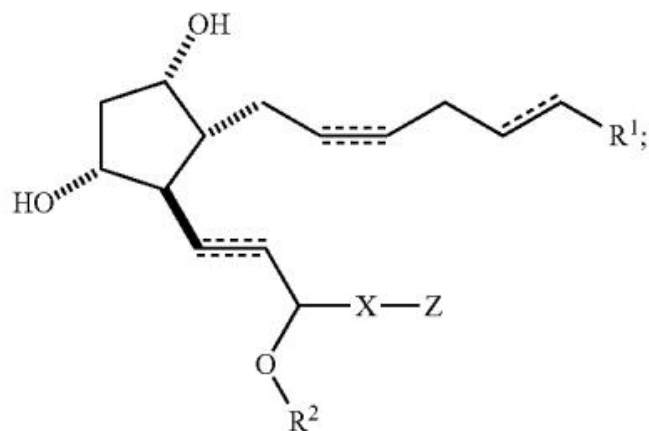
- *Duke Univ. v. Sandoz Inc.*, 160 F.4th 1305 (Fed. Cir. 2025)
- Before DYK, STOLL, and STARK
- US 9579270
- Relating to Latisse® - Allergan's product containing bimatoprost for growing eyelashes
- Claims a method for treating hair loss using prostaglandin F (PGF) analogs (including bimatoprost)
- District Court jury trial found claims valid, enforceable and awarded \$39 million
- Appealed
- Fed Cir reversed – no written description

Duke (Allergan) v. Sandoz

- Claim at issue (claim 30)

17. A method of growing hair, wherein the method comprises topically applying to mammalian skin a safe and effective amount of a composition comprising:

A) an active ingredient selected from the group consisting of a prostaglandin F analog of the following structure:



and pharmaceutically acceptable salts thereof;
 wherein R¹ is selected from the group consisting of C(O)NHOH, C(O)NHR³, and C(O)NHS(O)₂R⁴;
 R² is a hydrogen atom;
 R³ is methyl, ethyl or isopropyl;
 R⁴ is phenyl or methyl;

X is selected from the group consisting of —C≡C—, a covalent bond, —CH=C=CH—, —CH=CH—, —CH=N—, —C(O)—, —C(O)Y—, and —(CH₂)_n—, wherein n is 2 to 4;

Y is selected from the group consisting of a sulfur atom, an oxygen atom, and NH; and

Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group.

24. The method of claim 17, wherein Z is an aromatic group.

25. The method of claim 24, wherein Z is phenyl.

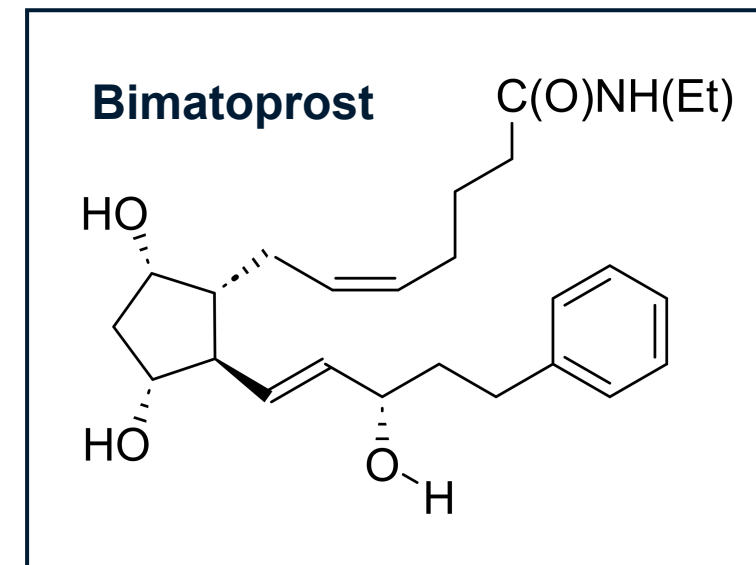
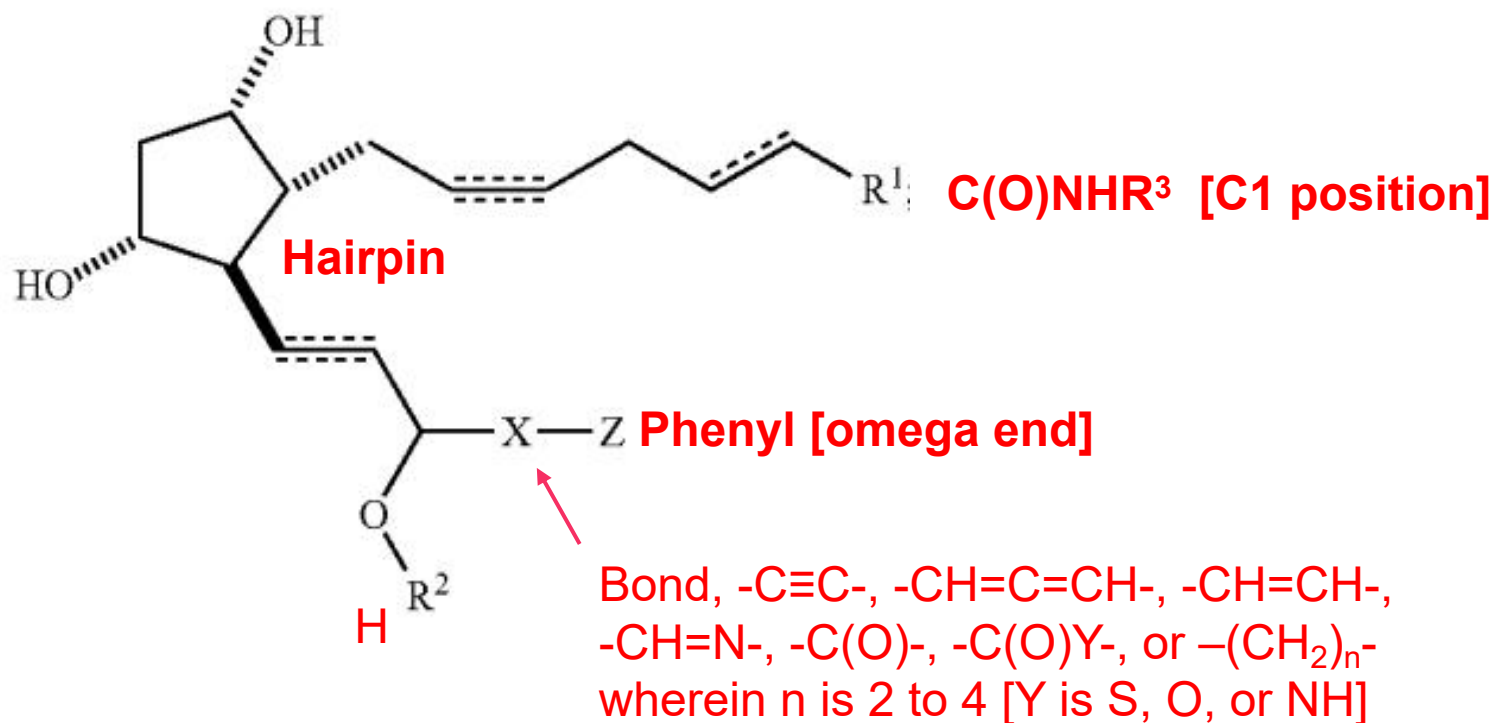
30. The method of claim 25, wherein R¹ is C(O)NHR³.

Duke (Allergan) v. Sandoz

- Prosecution History highlights
- Claims introduced by preliminary amendment prior to examination and remained essentially unchanged through prosecution
 - No indication of where support for the amendments could be found in the spec
 - Very few embodiments, subgenera, or backup positions for each variable were provided in application
 - 95 example compounds provided, none of which fell in the scope of claim 30
 - None with combination of unsubstituted phenyl for Z and amide for R1

Duke (Allergan) v. Sandoz

- Claim at issue (claim 30)



Duke (Allergan) v. Sandoz

- Sandoz alleges inventors did not have possession of the claimed subgenus or bimatoprost
 - NO EXAMPLES: The specification does not provide a single example of an actual compound within the claimed genus
 - NO BLAZE MARKS: The specification also fails to identify sufficient commonalities of structure to provide a skilled artisan with the necessary “blaze marks” to lead them to the claimed compounds.
- Court agreed with Sandoz and reversed the District Court

Duke (Allergan) v. Sandoz

- Sandoz contends that the specification of the '270 patent is written so broadly that it encompasses a “universe of billions of compounds,” while claim 30 is limited to roughly 1,620-4,230 of these potential compounds.
- According to Sandoz, the patent fails to provide skilled artisans with the information they need to identify and obtain this subgenus of claimed compounds.
- In order to have adequate written description, the specification of the '270 patent needs to allow a skilled artisan to understand how to identify this subgenus of claimed compounds (1620-4230 estimated compounds) from the billions of compounds in the broad genus described.
- The specification must provide sufficient indication as to how a skilled artisan would narrow the disclosed universe of billions of compounds described in the specification to the subset of just 1,620-4,230 compounds actually claimed (in claim 30).

Dilemma

- The Claims "Goldilocks Zone" Dilemma
- Trap 1: Claiming Too Broadly (The *Juno* / *Amgen* Trap)
 - **Objective:** Drafting broad or functionally defined genus claims to block competitors and prevent design-arounds.
 - **Invalidity Risk:** Invalidated for lacking a representative number of species or common structural traits under written description (*Juno*), or failing full-scope enablement under § 112 (*Amgen*).
- Trap 2: Claiming Narrowly to cover others' products (The "Blaze Mark" / *Duke* Trap)
 - **Objective:** Selecting a narrower subgenus or specific variable combination to cover other's products
 - **Invalidity Risk:** Invalidated because the specification contains generic "laundry lists" of substituents without explicit "blaze marks" leading a POSITA directly to that specific combination (*Duke* / *Seagen*).

Conclusion

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Take Aways

- Courts are tough on WD!
- Satisfying written description for a new genus claim, however broad or narrow, can be difficult, especially if the specification provides inadequate direction
- Leverage Method-of-Use Claims as a Safe Haven (*Teva v. Lilly*)
- Picking components from laundry lists to craft a subgenus is not permitted when making amendments – unless there are sufficient blaze marks (or supporting examples)
- Be careful crafting new claims when piecing together multiple, separate embodiments – try to be cognizant of, and take advantage of, potential blaze marks to support the new claims
- When drafting applications, include lots of embodiments for each variable (and combinations) to provide support for future narrower subgenera
- What constitutes a blaze mark? Number of examples, preference language, maybe data...
- Avoid “preferred” or “more preferred” language.

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