Litigating Written Description and Enablement: Understanding the Landscape, Navigating the Pitfalls, and Taking Advantage of the Opportunities

Wednesday, May 10

FISH.

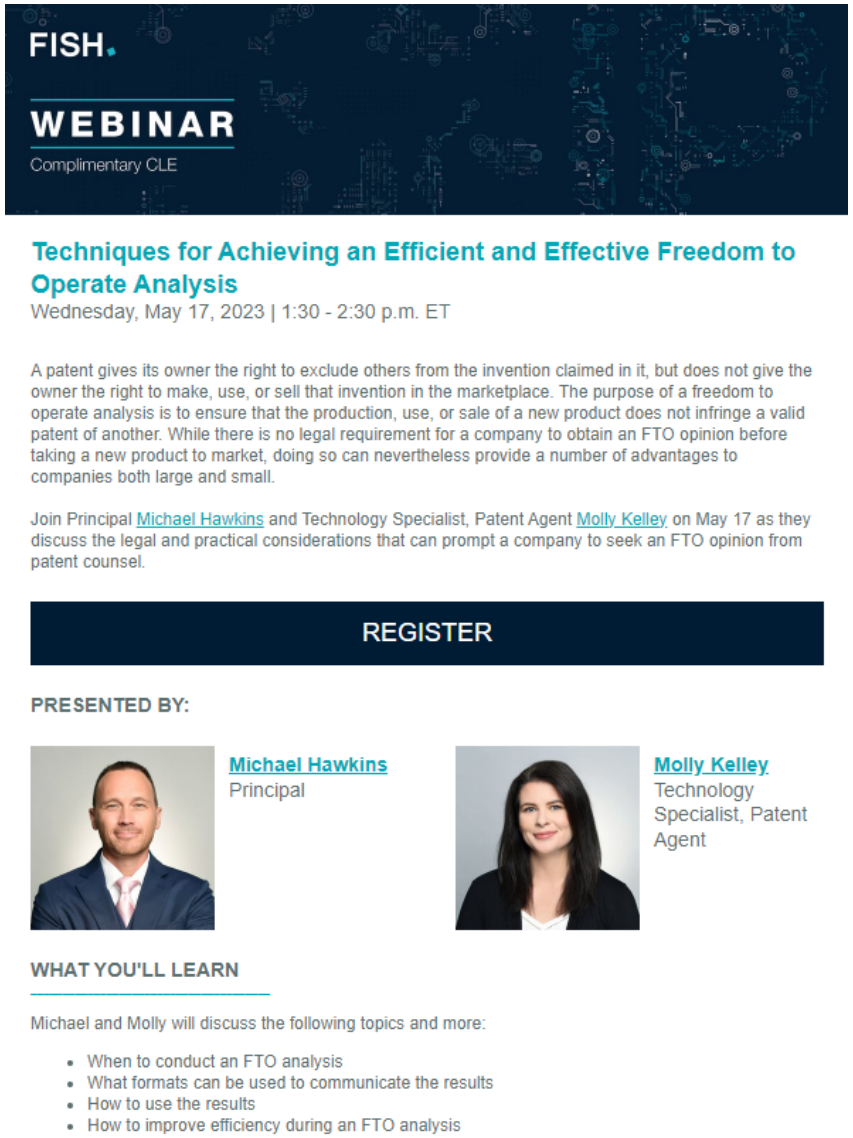
Meet The Speakers

Martina Hufnal
Principal

Chad Shear
Principal

Overview

- **Topics**
  - Important Decisions
  - Practice Tips
- **Housekeeping**
  - CLE
  - Questions
  - Materials
    - **http://www.fr.com/webinars**



Case Discussion Overview

- ***Idenix v. Gilead* (2019): compound claims fail for lack of written description**
- ***Kite v. Juno* (2021): antibody claims fail for lack of written description**
- ***Biogen v Mylan* (2021): therapeutic efficacy claim lacks written description**
- ***Allergan v. Sandoz* (2015): formulation claims have sufficient written description**
- **Recent formulation claims at the district court: *Pernix* (2018)**

§112 as a defense

- **Highly thematic whether a plaintiff or a defendant**
  - Fact witnesses play a crucial role
- **Challenging to succeed on in front of the jury**
  - Compressed time to educate
  - Juries tend to defer to the PTO
  - Remember that enablement is a question of law for the Court to decide regardless of whether the jury is asked for an advisory determination
- **Make your record**

Enablement – *Wands* Factors

1. Breadth of the claims;
2. Nature of the invention;
3. State of the prior art;
4. Level of ordinary skill in the art;
5. Predictability of the art;
6. Amount of direction provided in the specification;
7. Any working examples; and
8. Quantity of experimentation needed relative to the disclosure.

Written Description

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.

Idenix v. Gilead (Fed. Cir. 2019)

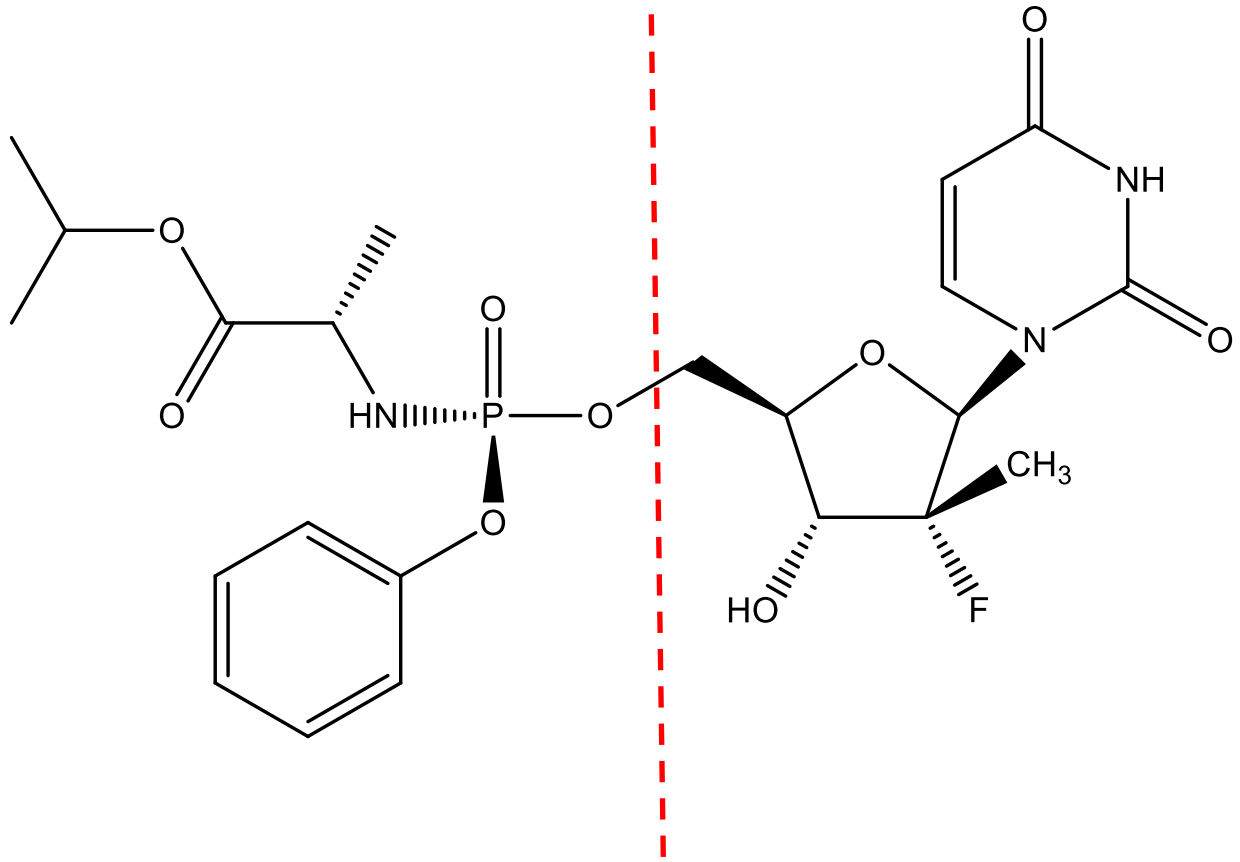
Harvoni® and Sovaldi®

SOVALDI
SOFOSBUVIR

HARVONI
ledipasvir/sofosbuvir

FISH.

Sofosbuvir



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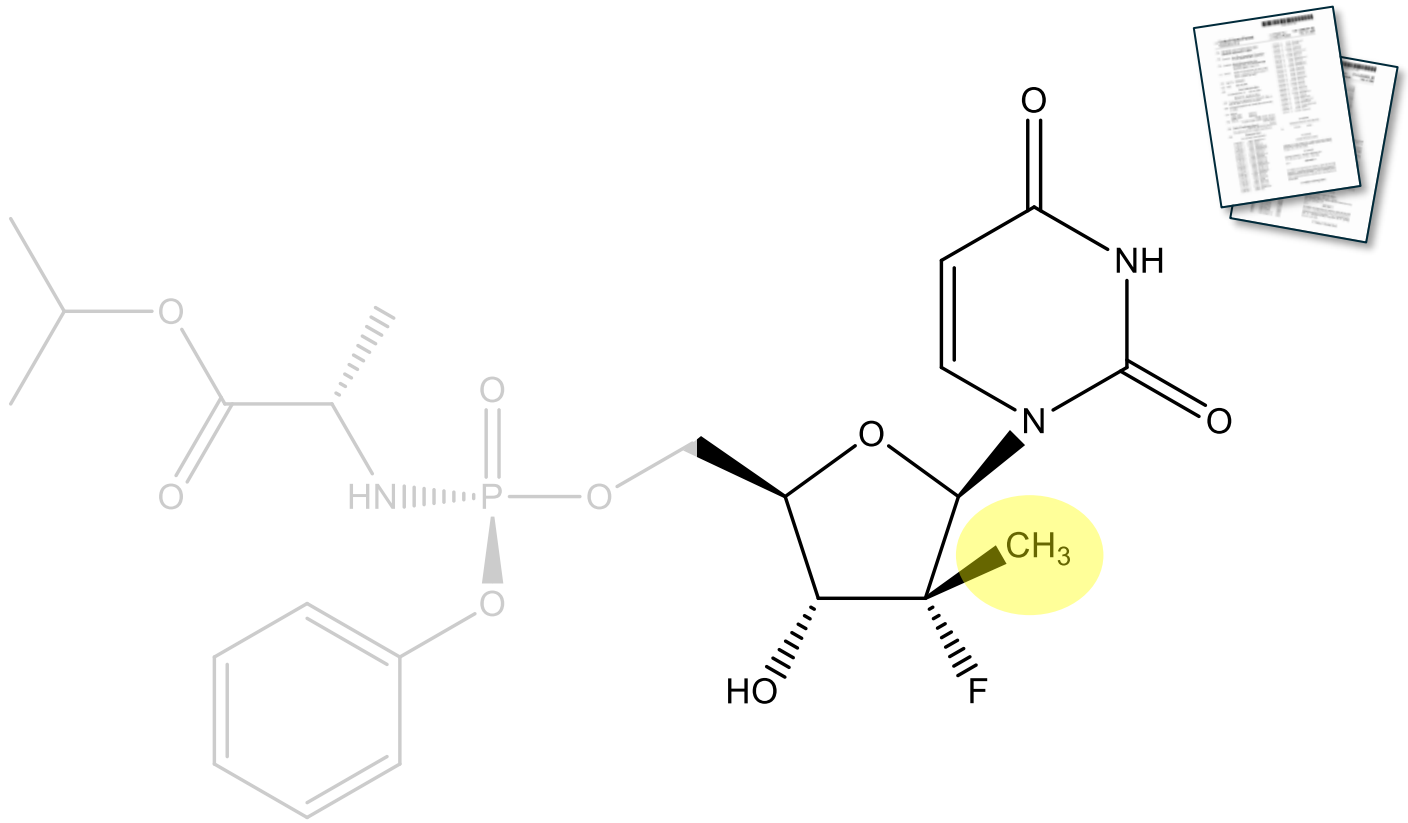
2’ Me-up Nucleosides



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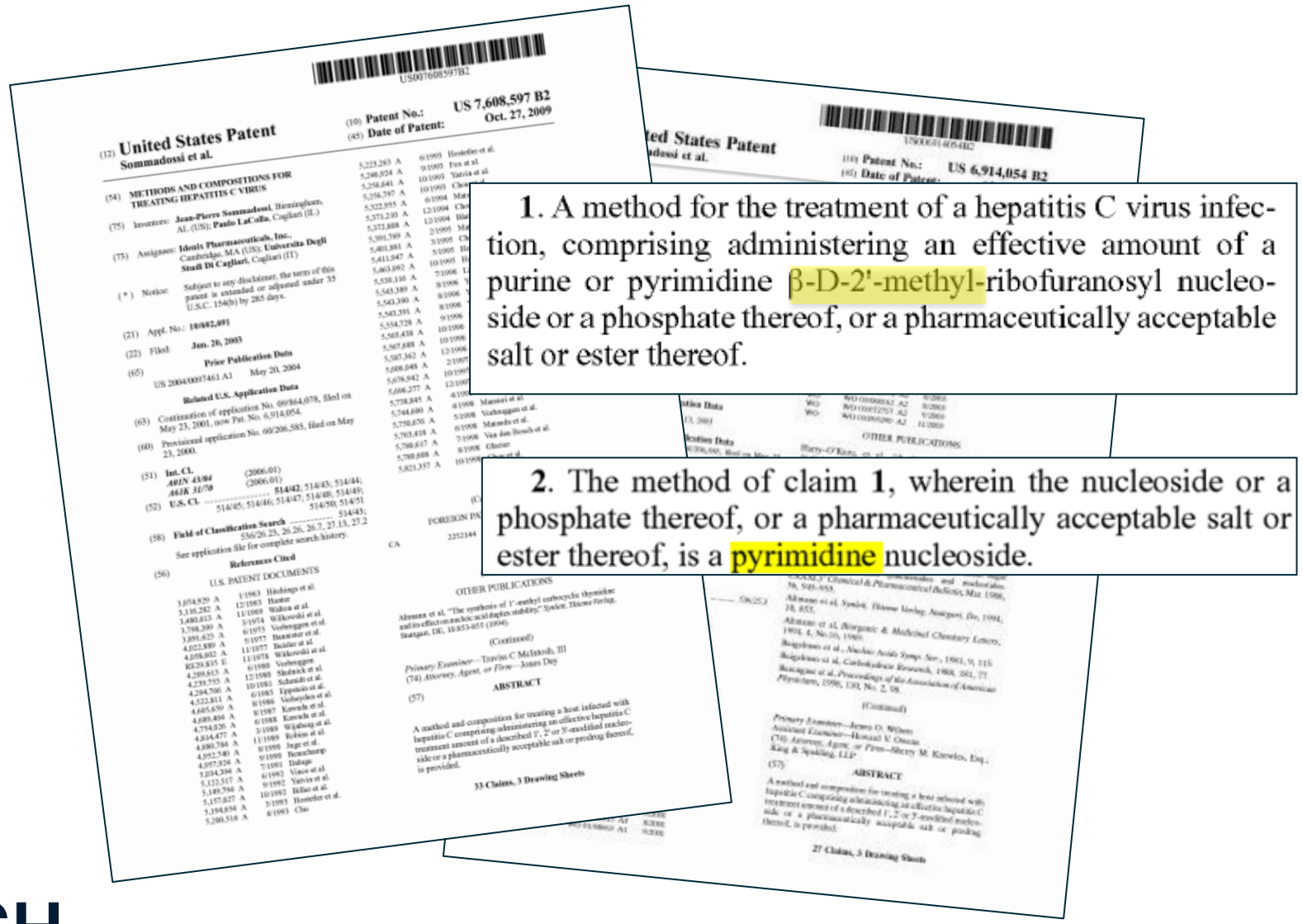
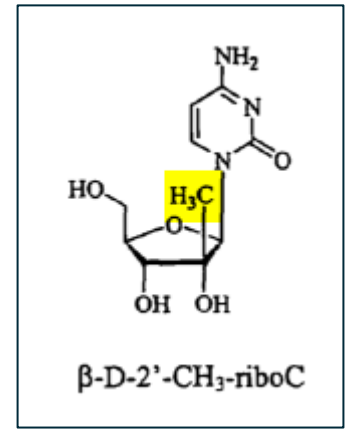
2’ Methyl Up Patents





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Idenix v Gilead

United States Court of Appeals
for the Federal Circuit

IDENIX PHARMACEUTICALS LLC, UNIVERSITA DEGLI STUDI DI CAGLIARI,
Plaintiffs-Appellants

v.

GILEAD SCIENCES INC.,
Defendant-Appellee

2018-1691

Appeal from the United States District Court for the District of Delaware in No. 1:14-cv-00846-LPS, Chief Judge Leonard P. Stark.

Decided: October 30, 2019

GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for plaintiffs-appellants. Also represented by JENNIFER LORAINE SWIZE; LISA LYNN FURBY, Chicago, IL; CALVIN GRIFFITH, RYAN BOYD MCCRUM, Cleveland, OH; ANTHONY INSOGNA, San Diego, CA; JEFFREY A. LAMKEN, SARAH JUSTINE NEWMAN, MICHAEL GREGORY PATTILLO, JR., MoloLamken LLP, Washington, DC.

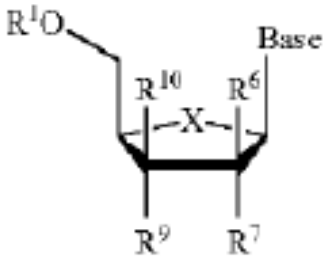
E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY, argued for defendant-appellee. Also represented by EDMUND HIRSCHFELD; ELIZABETH

The only independent claim of the '597 patent recites:

1. A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

a compound of Formula XVII, or a pharmaceutically acceptable salt or prodrug thereof:

(XVII)



wherein:

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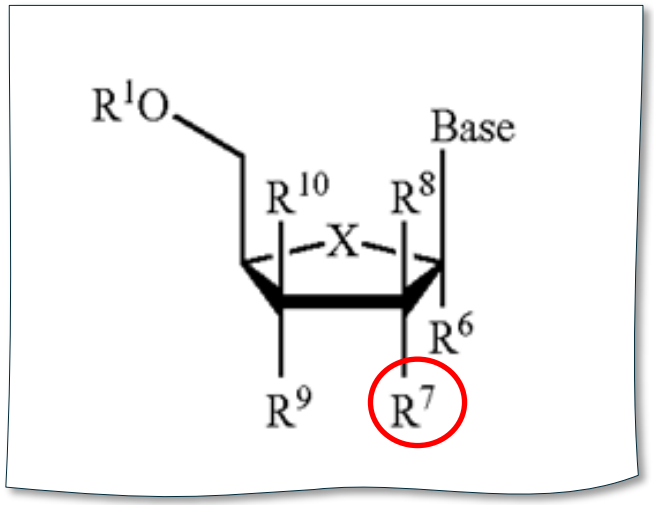
’597 Patent (May 2000)

Specification **Does Not Teach** Fluorine at the 2’-Down Position

Formula XVI

R^7 and R^9 are independently hydrogen, OR^2, hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkyl, Br-vinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —O(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chlorine, bromine, iodine, NO_2, NH_2, —NH(lower alkyl), —NH(acyl), —N(lower alkyl)$_2$, —N(acyl)$_2$;



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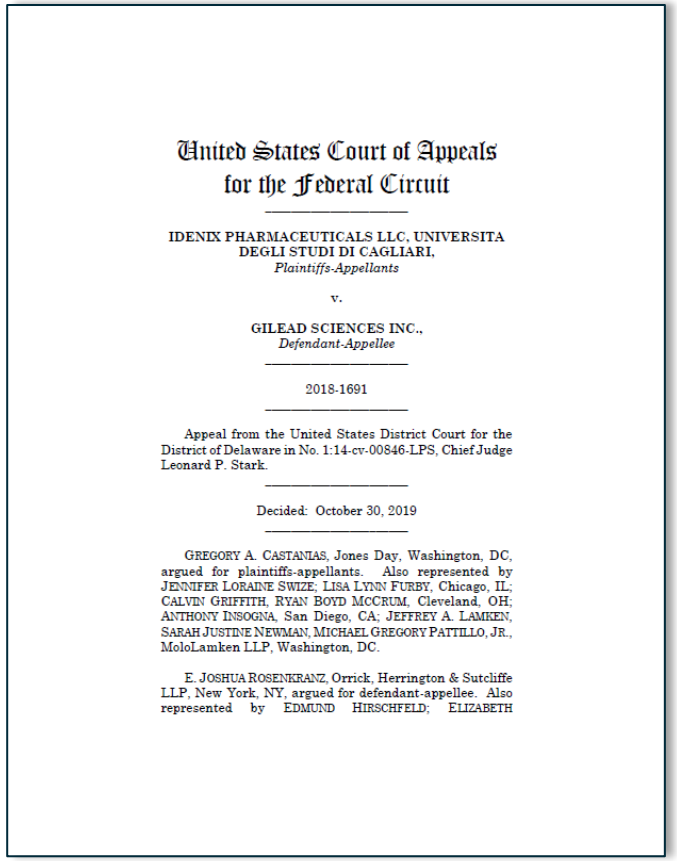
Written Description Requirement



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the enablement requirement. 35 U.S.C. § 112; *see Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). To fulfill the written description requirement, a patent owner "must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (citation omitted) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991)). That test "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351.

Written Description Requirement

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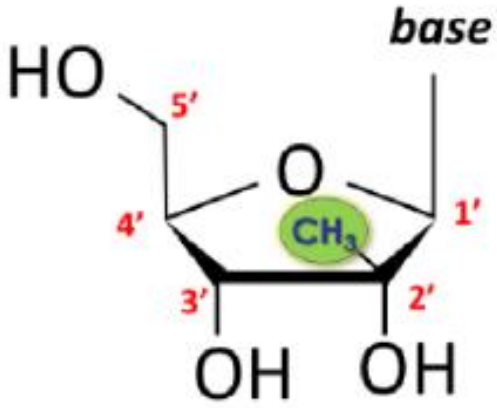
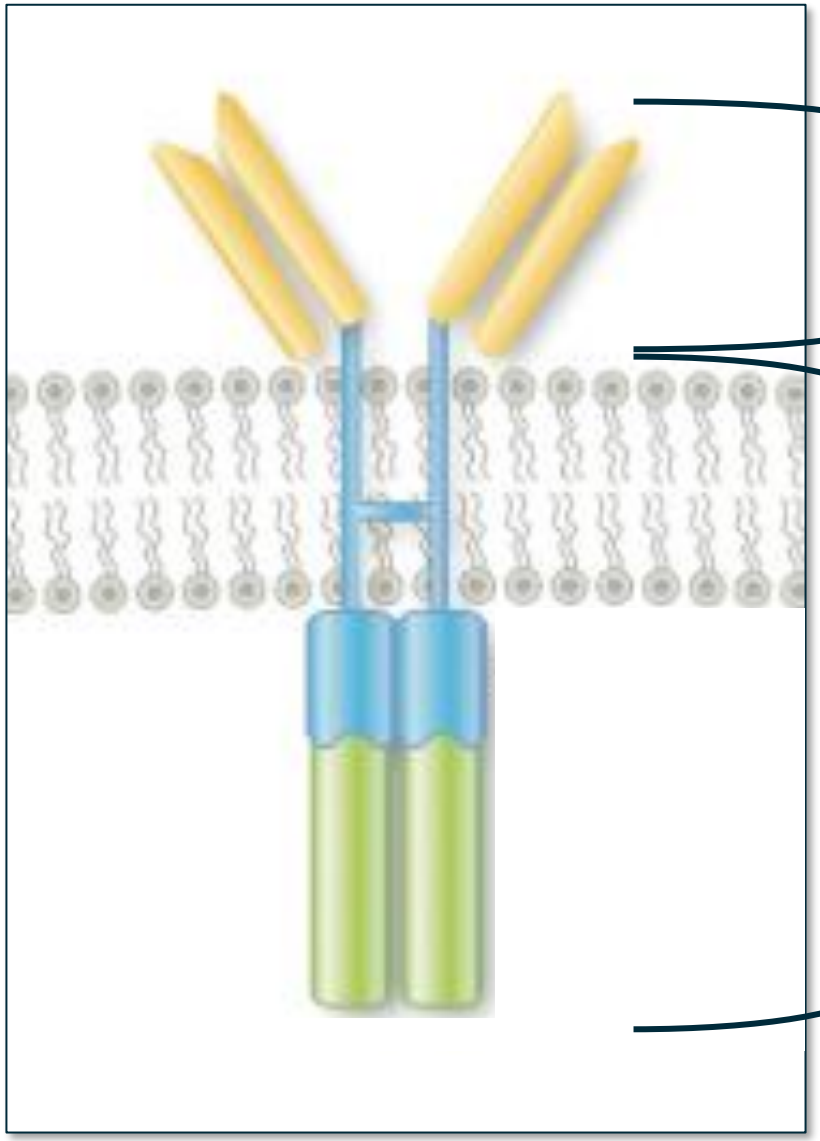
E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY, argued for defendant-appellee. Also represented by EDMUND HIRSCHFELD; ELIZABETH

In this case, we hold that the '597 patent is invalid for lack of written description, as it fails to provide sufficient blaze marks to direct a POSA to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV. The patent provides eighteen position-by-position formulas describing "principal embodiments" of compounds that may treat HCV. *See generally* '597 patent col. 5 l. 29–



Juno Therapeutics v. Kite Pharma

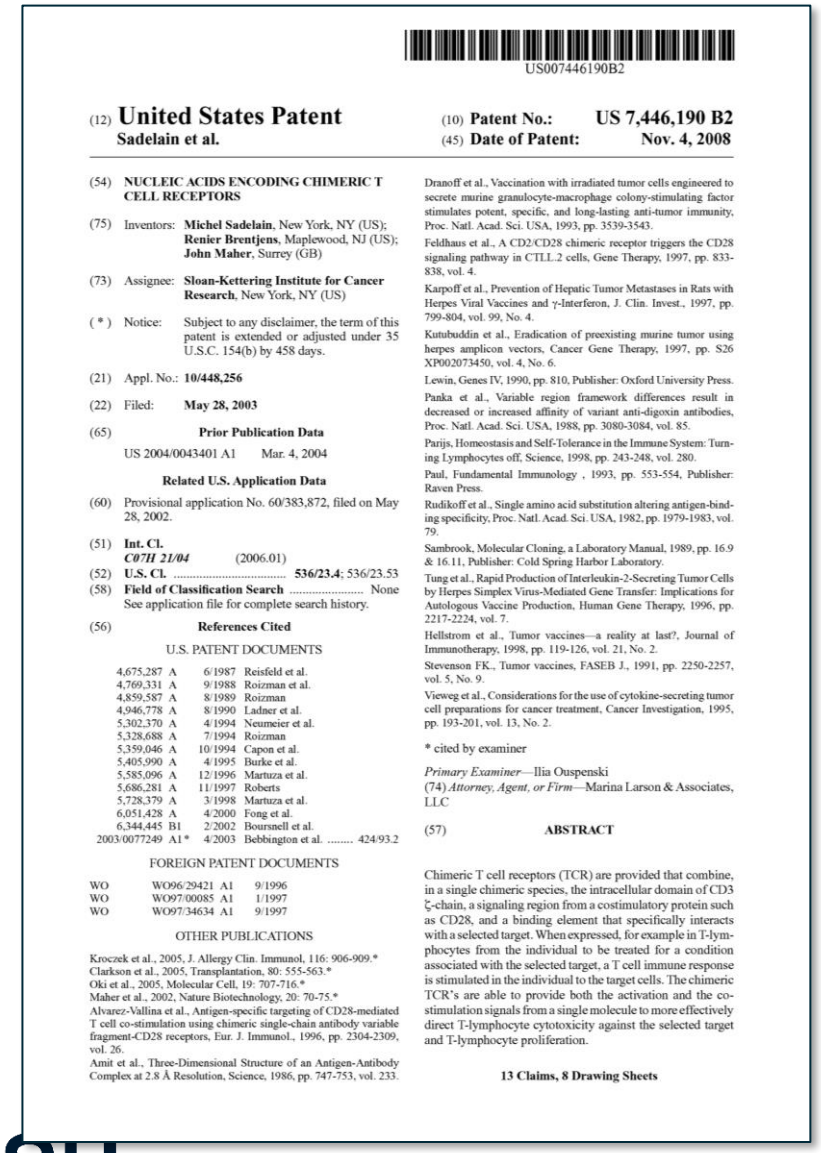
CAR-Ts



Binding Region

The “Backbone”

’190 Patent



US007446190B2

(12) **United States Patent**
Sadelain et al.

(10) **Patent No.: US 7,446,190 B2**
(45) **Date of Patent: Nov. 4, 2008**

(54) **NUCLEIC ACIDS ENCODING CHIMERIC T CELL RECEPTORS**

(75) Inventors: **Michel Sadelain**, New York, NY (US); **Renier Brentjens**, Maplewood, NJ (US); **John Maher**, Surrey (GB)

(73) Assignee: **Sloan-Kettering Institute for Cancer Research**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 458 days.

(21) Appl. No.: **10/448,256**

(22) Filed: **May 28, 2003**

(65) **Prior Publication Data**

US 2004/0043401 A1 Mar. 4, 2004

Related U.S. Application Data

(60) Provisional application No. 60/383,872, filed on May 28, 2002.

(51) **Int. Cl.**
C07H 21/04 (2006.01)

(52) **U.S. Cl.** **536/23.4**; 536/23.53

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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* cited by examiner

Primary Examiner—Ilia Ouspenski
(74) *Attorney, Agent, or Firm*—Marina Larson & Associates, LLC

(57) **ABSTRACT**

Chimeric T cell receptors (TCR) are provided that combine, in a single chimeric species, the intracellular domain of CD3 ζ-chain, a signaling region from a costimulatory protein such as CD28, and a binding element that specifically interacts with a selected target. When expressed, for example in T-lymphocytes from the individual to be treated for a condition associated with the selected target, a T cell immune response is stimulated in the individual to the target cells. The chimeric TCR's are able to provide both the activation and the co-stimulation signals from a single molecule to more effectively direct T-lymphocyte cytotoxicity against the selected target and T-lymphocyte proliferation.

13 Claims, 8 Drawing Sheets

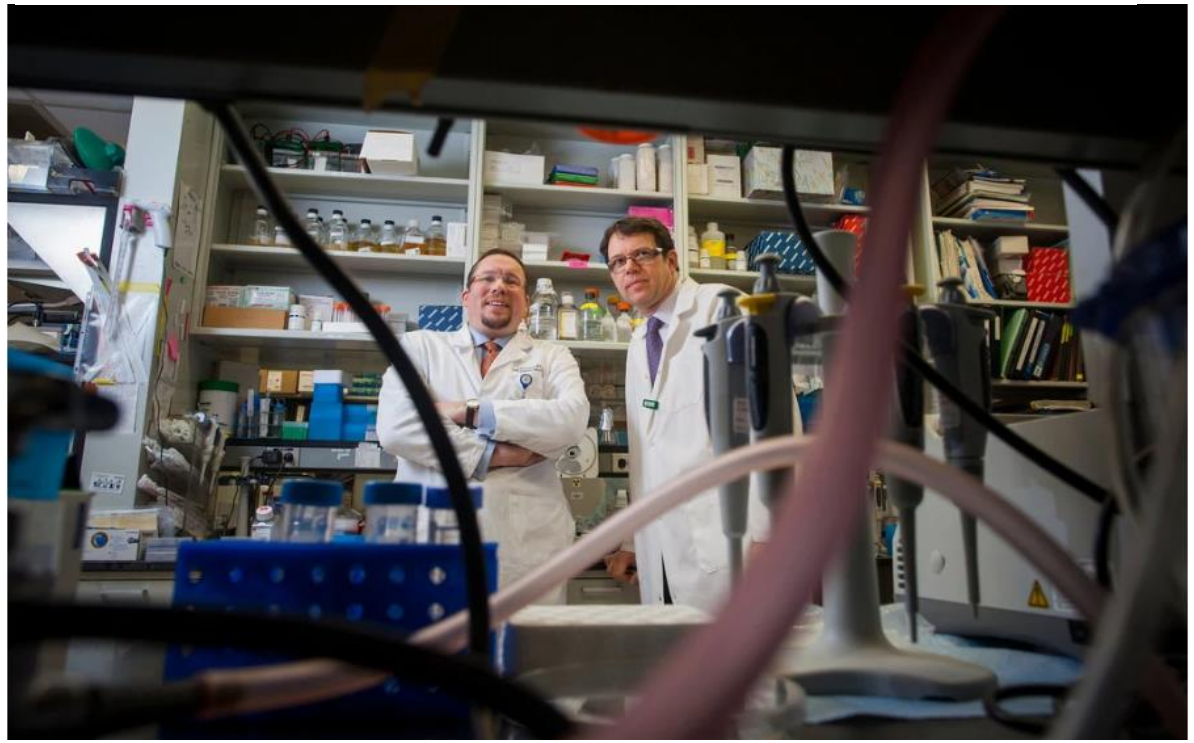
United States Patent
Sadelain et al.

Patent No.: US 7,446,190 B2
Date of Patent: Nov. 4, 2008

FISH.

The New York Times

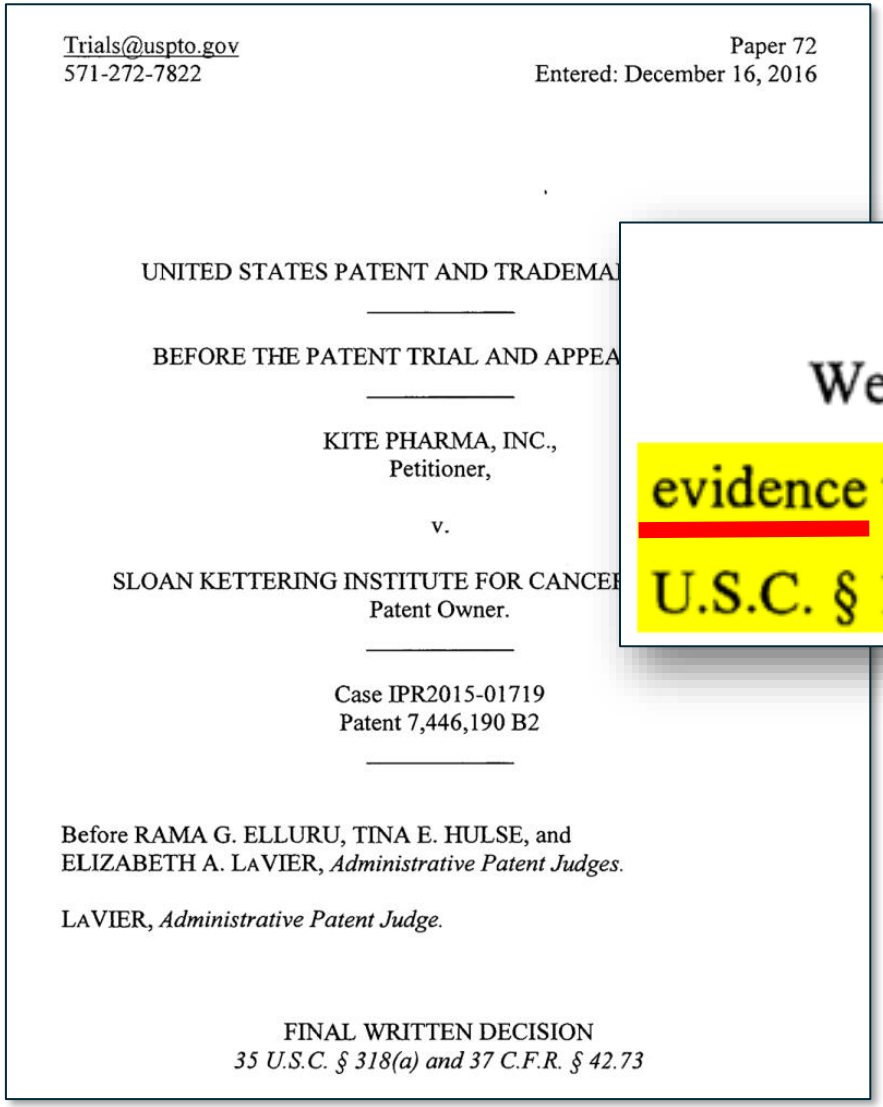
Cell Therapy Shows Promise for Acute Type of Leukemia



Memorial Sloan Kettering Cancer Center

FISH.

Kite Tried to Kill the Patent, but Failed



Trials@uspto.gov
571-272-7822

Paper 72
Entered: December 16, 2016

UNITED STATES PATENT AND TRADEMA

BEFORE THE PATENT TRIAL AND APPEA

KITE PHARMA, INC.,
Petitioner,

v.

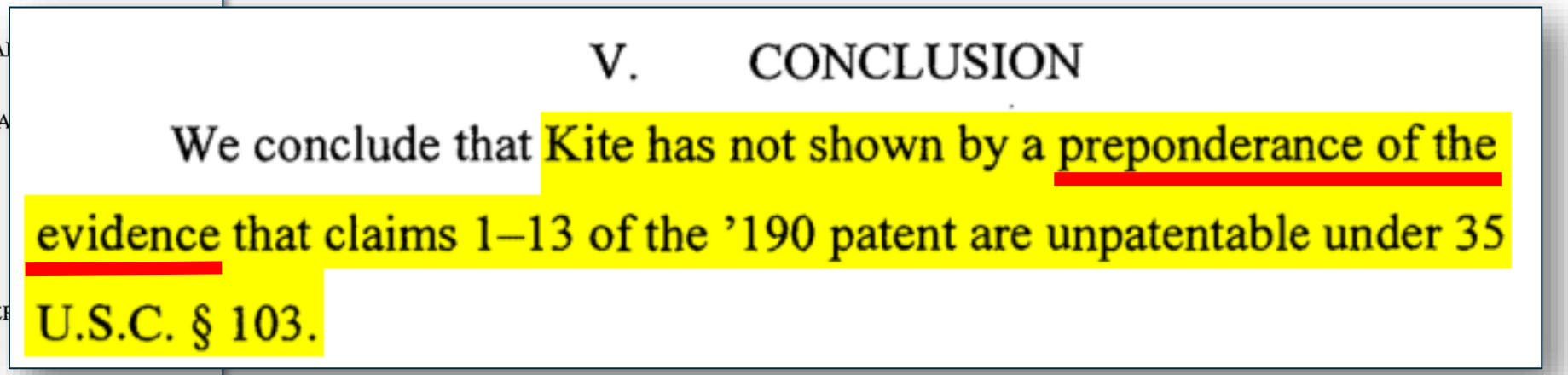
SLOAN KETTERING INSTITUTE FOR CANCE
Patent Owner.

Case IPR2015-01719
Patent 7,446,190 B2

Before RAMA G. ELLURU, TINA E. HULSE, and
ELIZABETH A. LAVIER, *Administrative Patent Judges.*

LAVIER, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73



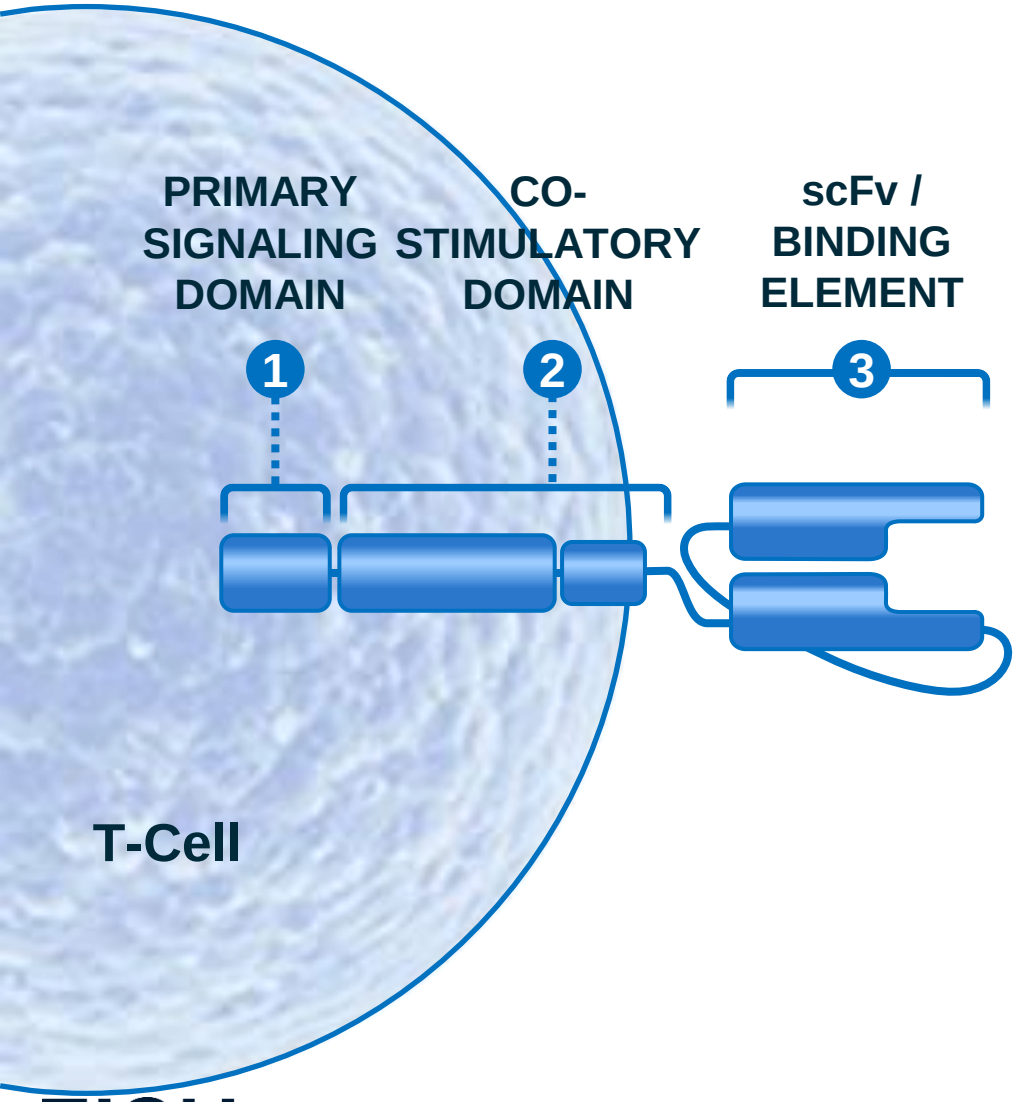
V. CONCLUSION

We conclude that Kite has not shown by a preponderance of the evidence that claims 1–13 of the '190 patent are unpatentable under 35 U.S.C. § 103.

Leading up to trial . . .

- **Kite was estopped from arguing invalidity under either §102 or §103 because of earlier IPR loss**
- **Kite stipulated to infringement under Court's claim construction**
- **Left with two defenses:**
  - §112
  - Invalid Certificate of Correction
- **Damages**

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)



The invention claimed is:

1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising

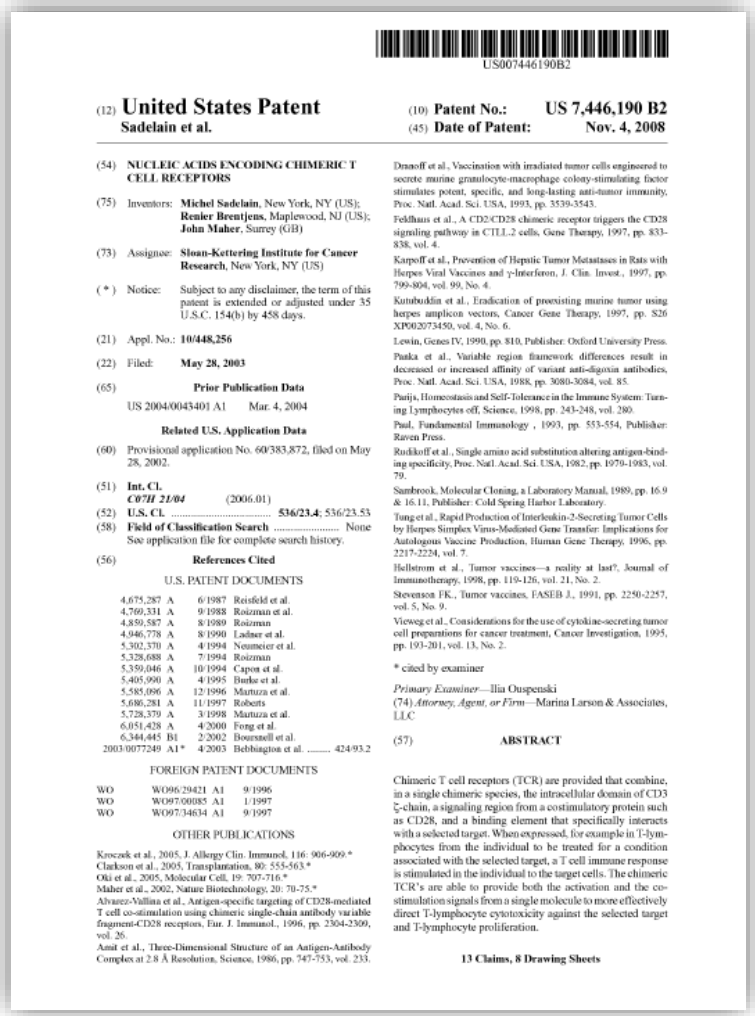
1 (a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,

2 (b) a costimulatory signaling region, and

3 (c) a binding element that specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

DX0073, '190 Patent at Claim 1

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)



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Primary Examiner—Ilia Ouspenski
(74) *Attorney, Agent, or Firm*—Marina Larson & Associates, LLC

(57) **ABSTRACT**

Chimeric T cell receptors (TCR) are provided that combine, in a single chimeric species, the intracellular domain of CD3 ζ-chain, a signaling region from a costimulatory protein such as CD28, and a binding element that specifically interacts with a selected target. When expressed, for example in T-lymphocytes from the individual to be treated for a condition associated with the selected target, a T cell immune response is stimulated in the individual to the target cells. The chimeric TCR's are able to provide both the activation and the co-stimulation signals from a single molecule to more effectively direct T-lymphocyte cytotoxicity against the selected target and T-lymphocyte proliferation.

13 Claims, 8 Drawing Sheets

1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising

(a) a zeta chain portion comprising the intracellular domain of human CD3ζ chain,

(b) a costimulatory signaling region, and

(c) a binding element that specifically interacts with a selected target,

wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

2. The nucleic acid polymer of claim 1, wherein the binding element is an antibody.

3. The nucleic acid polymer of claim 2, wherein the antibody is a single chain antibody.

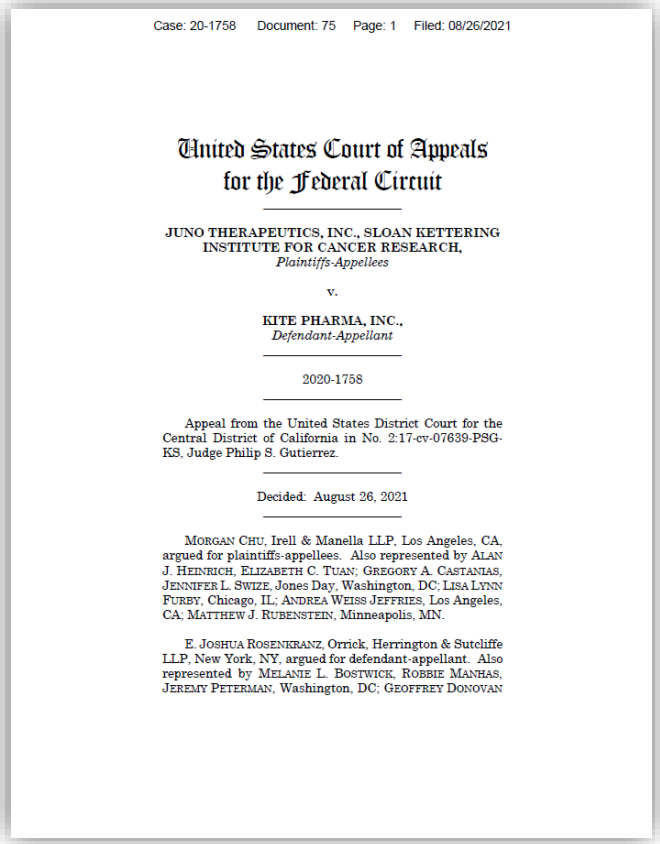
5. The nucleic acid polymer of claim 3, wherein the single chain antibody binds to CD19.

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)

- **Kite arguments on appeal**
  - Claims cover an enormous number (millions of billions) of scFv candidates
  - Only a fraction of which satisfy the functional binding limitation for any given target
  - Field is unpredictable since an scFv's binding ability depends on a variety of factors
  - The '190 patent discloses neither (1) representative number species or (2) common structural features of the claimed scFv genus adequate to identify which scFvs would function as claimed

- **Juno arguments on appeal**
  - scFvs and how to make them were well-known
  - The '190 patent describes two working scFv embodiments that are representative of all scFvs
  - scFvs had been incorporated in CARs well before the '190 patent's priority date
  - scFvs are interchangeable and have common structural features
  - *Ariad* was irrelevant because the real invention was the combination of the signaling domains, not the scFv portion

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)



United States Court of Appeals
for the Federal Circuit

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Plaintiffs-Appellees

v.

KITE PHARMA, INC.,
Defendant-Appellant

2020-1758

Appeal from the United States District Court for the Central District of California in No. 2:17-cv-07639-PSG-KS, Judge Philip S. Gutierrez.

Decided: August 26, 2021

MORGAN CHU, Irell & Manella LLP, Los Angeles, CA, argued for plaintiffs-appellees. Also represented by ALAN J. HEINRICH, ELIZABETH C. TUAN; GREGORY A. CASTANIAS, JENNIFER L. SWIZE, Jones Day, Washington, DC; LISA LYNN FURBY, Chicago, IL; ANDREA WEISS JEFFRIES, Los Angeles, CA; MATTHEW J. RUBENSTEIN, Minneapolis, MN.

E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY, argued for defendant-appellant. Also represented by MELANIE L. BOSTWICK, ROBBIE MANHAS, JEREMY PETERMAN, Washington, DC; GEOFFREY DONOVAN

While it is true that scFvs in general were known, and even known to bind, the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most). The '190 patent, however, provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19. Without this guidance, under our controlling *Ariad* decision, no reasonable jury could find the '190 patent satisfies the written description requirement.

CONCLUSION

Substantial evidence does not support the jury's verdict in Juno's favor on the issue of written description. For the claimed functional scFv genus, the '190 patent does not disclose representative species or common structural features to allow a person of ordinary skill in the art to distinguish between scFvs that achieve the claimed function and those that do not. Accordingly, we reverse.

REVERSED

Biogen v. Mylan

35 U.S.C. § 112(a)

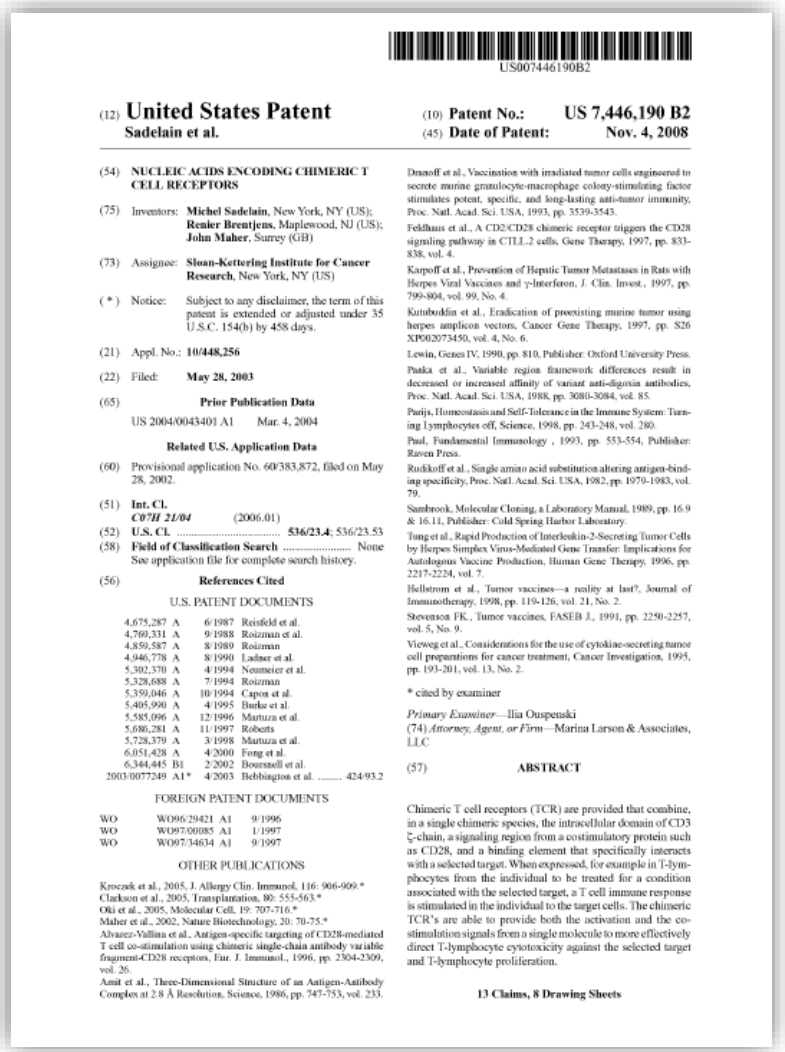
§ 112. Specification

(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.

The test for adequate written description "is whether the disclosure of the application relied upon 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)

Biogen v. Mylan (Fed. Cir. 2021)



US007446190B2

(12) **United States Patent**
Sadelain et al.

(10) **Patent No.: US 7,446,190 B2**
(45) **Date of Patent: Nov. 4, 2008**

(54) **NUCLEIC ACIDS ENCODING CHIMERIC T CELL RECEPTORS**

(75) Inventors: **Michel Sadelain**, New York, NY (US); **Renier Brentjens**, Maplewood, NJ (US); **John Maher**, Surrey (GB)

(73) Assignee: **Sloan-Kettering Institute for Cancer Research**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 458 days.

(21) Appl. No.: **10/448,256**

(22) Filed: **May 28, 2003**

(65) **Prior Publication Data**

US 2004/0043401 A1 Mar. 4, 2004

Related U.S. Application Data

(60) Provisional application No. 60/383,872, filed on May 28, 2002.

(51) **Int. Cl.**
C07H 21/04 (2006.01)

(52) **U.S. Cl.** **536/23.4**; 536/23.53

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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Primary Examiner—Ilia Ouspenski
(74) *Attorney, Agent, or Firm*—Marina Larson & Associates, LLC

(57) **ABSTRACT**

Chimeric T cell receptors (TCR) are provided that combine, in a single chimeric species, the intracellular domain of CD3 ζ-chain, a signaling region from a costimulatory protein such as CD28, and a binding element that specifically interacts with a selected target. When expressed, for example in T-lymphocytes from the individual to be treated for a condition associated with the selected target, a T cell immune response is stimulated in the individual to the target cells. The chimeric TCR's are able to provide both the activation and the co-stimulation signals from a single molecule to more effectively direct T-lymphocyte cytotoxicity against the selected target and T-lymphocyte proliferation.

13 Claims, 8 Drawing Sheets

1. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of

(a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and

(b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

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Biogen v. Mylan (Fed. Cir. 2021)

Court assumed disclosure of connection between treatment of MS and DMF

> "Thus, assuming that a skilled artisan would understand the disclosure to be unambiguously focused on MS despite its inclusion among approximately three-dozen neurological disorders—a determination we need not reach in this case—the specification may arguably provide adequate information to convey to a skilled artisan that the invention supports method-of-treatment claims directed to MS and, perhaps, that the use of DMF may be therapeutically linked to MS treatment."

Court focused on the fact the 480 mg/day was mentioned only once and specification's focus was on drug discovery and basic research

> "[T]he district court did not clearly err in finding that a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure, that DMF480 would have been efficacious in the treatment of MS, particularly because the specification's only reference to DMF480 was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose."

Biogen v. Mylan (Fed. Cir. 2021): Dissent (O'Malley)

Discussed distinction between clinical efficacy and therapeutic effects

- "[T]he district court's refusal to acknowledge the difference between ***therapeutic*** and ***clinical*** effects evinces a fundamental misunderstanding of what is claimed—and, thus, what requires written description support—in the '514 patent."
- "The district court's conflation of therapeutic and clinical efficacy caused it to erroneously require clinical data, rather than therapeutic effects."
  - DCT had referred to expert's testimony in IPR that a POSITA would not have expected the DMF480 dose to clinically treat MS
  - DCT should not have used Patent Owner's obviousness defense against it in the written description context

Rejected the district court's "blaze marks" analysis to a disclosed range

"[The court's] 'blaze marks' jurisprudence does not apply in every case concerning written description; it, instead, provides a useful framework to analyze whether written description has been met in cases involving patents containing laundry list disclosures."

Biogen v. Mylan (Fed. Cir. 2022): Denial *En Banc* Dissent

- **Lourie, joined by Moore and Newman**

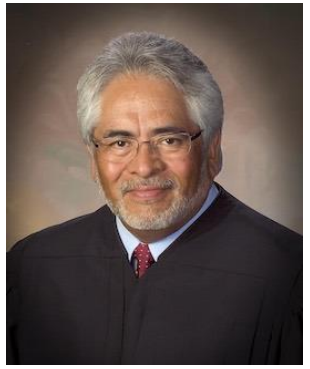


- **O'Malley, Stoll, and Cunningham did not participate**



- **Dyk, Prost, Reyna, Taranto, Chen, Hughes voted not to take the case *en banc***



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Biogen v. Mylan (Fed. Cir. 2022): Denial *En Banc* Dissent

Extraordinary Case

- "[T]his case, in which every claim limitation is expressly described in the disclosure of the patent specification, is at the farthest end of the spectrum of case where written description has not been found."
- "I recognize the hesitance to go en banc simply to correct errors in one case. . . . [T]he panel majority has affirmed a district court's erroneous broadening of the written description inquiry."

Four Errors by Panel Majority & DCT

- Overly emphasized unclaimed disclosures in the specification
- Erroneously imposed a heightened burden on the patentee to show that the specification proves efficacy
- Imported legal factors from other patentability requirements
- Were influenced by irrelevant extrinsic evidence

Allergan v. Sandoz, 796 F.3d 1293 (Fed. Cir. 2015)


ALLERGAN
NDC 0023-9187-05
LUMIGAN®
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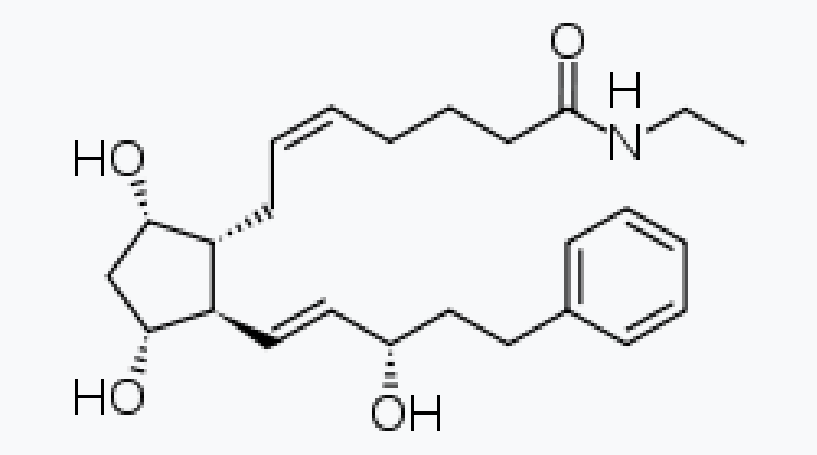
ophthalmic solut
0.03%
3 ml
sterile
LUMIGAN®
(bimatoprost ophthalmic
solution) 0.03%
3 ml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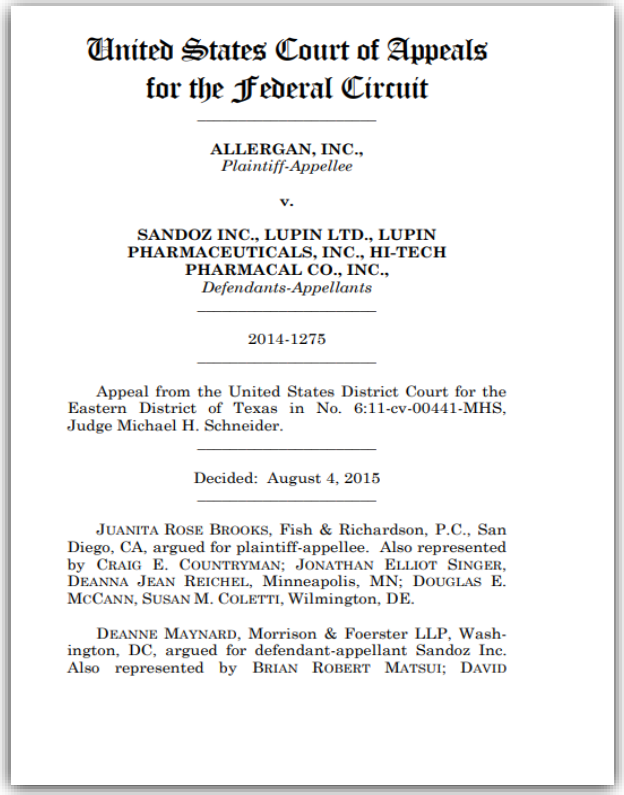
ALLERGAN
NDC 0023-3205-03
LUMIGAN®
(bimatoprost
ophthalmic solution)
0.01%
2.5 mL
Rx only
sterile
NDC 0023-3205-03
LUMIGAN®
(bimatoprost
ophthalmic solution)
2.5 mL
sterile

Allergan v. Sandoz (Fed. Cir. 2015)



United States Court of Appeals
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ALLERGAN, INC.,
Plaintiff-Appellee

v.

SANDOZ INC., LUPIN LTD., LUPIN PHARMACEUTICALS, INC., HI-TECH PHARMACAL CO., INC.,
Defendants-Appellants

2014-1275

Appeal from the United States District Court for the Eastern District of Texas in No. 6:11-cv-00441-MHS, Judge Michael H. Schneider.

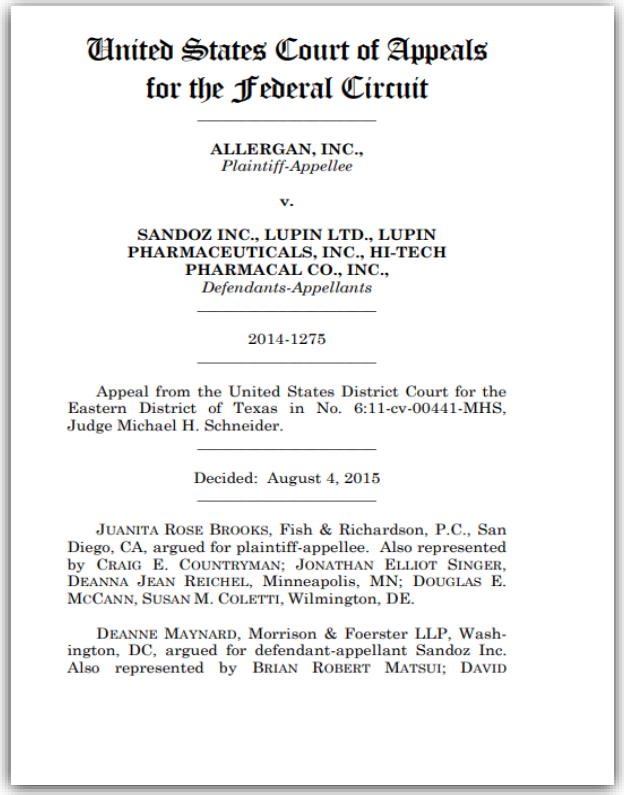
Decided: August 4, 2015

JUANITA ROSE BROOKS, Fish & Richardson, P.C., San Diego, CA, argued for plaintiff-appellee. Also represented by CRAIG E. COUNTRYMAN; JONATHAN ELLIOT SINGER, DEANNA JEAN REICHEL, Minneapolis, MN; DOUGLAS E. MCCANN, SUSAN M. COLETTI, Wilmington, DE.

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendant-appellant Sandoz Inc. Also represented by BRIAN ROBERT MATSUI; DAVID

1. A first composition administered once daily for lowering intraocular pressure in a person with glaucoma or ocular hypertension, the first composition comprising about 0.01% w/v bimatoprost and about 0.02% w/v benzalkonium chloride, wherein the first composition *lowers intraocular pressure and results in less hyperemia* as compared to the once daily administration of a second composition comprising 0.03% w/v bimatoprost and 0.005% w/v benzalkonium chloride.

Allergan v. Sandoz (Fed. Cir. 2015)



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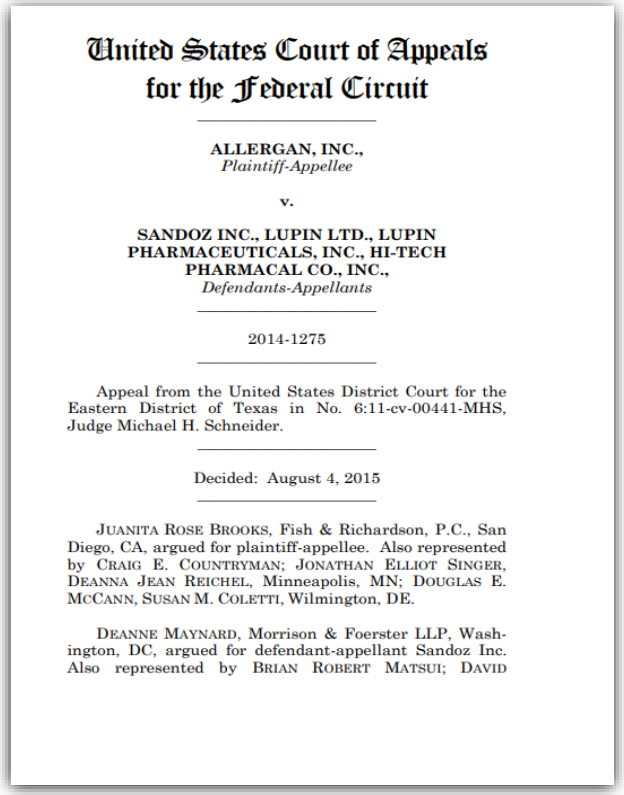
DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendant-appellant Sandoz Inc. Also represented by BRIAN ROBERT MATSUI; DAVID

Specifically, the defendants alleged that the Group II claims, which recite clinical profile limitations, were invalid for lack of an adequate written description. The district court found, however, that the patents explicitly describe the formulation of Lumigan 0.01%, and that Lumigan 0.01% has the clinical profile recited in the Group II claims. *Id.* at 78. The court also found additional support in the titles of the patents, the disclosed *in vitro* and *in vivo* permeability data of bimatoprost, as well as the constructive example comparing the IOP-lowering efficacy and hyperemia profile of a test formulation to that of Lumigan 0.03%. The court therefore found that the Group II claims have adequate written description support, "especially given the express disclosure that Lumigan 0.01% is an example of the best mode of the invention." *Id.* The

Allergan v. Sandoz (Fed. Cir. 2015)



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DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendant-appellant Sandoz Inc. Also represented by BRIAN ROBERT MATSUI; DAVID

The district court also rejected the defendants' invalidity challenges based on the written description and enablement requirements, which they raised only in pre-and post-trial briefings. *Id.* at 77–81. The court noted that the defendants "did not present any evidence or argument" on those issues at trial. *Id.* at 77, 79.

Pernix v. Alvogen, 323 F.Supp.3d 566 (D. Del. 2018)

Pernix v. Alvogen

- **Zohydro ER – extended release hydrocodone product that contains no other active ingredient.**
- **Formulation was in the prior art.**
- **As part of FDA approval, a hepatic impairment study showed concentration did not change for patients with hepatic impairment.**

A method of treating pain in a patient having mild or moderate hepatic impairment, the method comprising:

Administering to the patient having mild or moderate hepatic impairment a starting dose of an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate, and wherein the starting dose is not adjusted relative to a patient without hepatic impairment.

A method of treating pain in a patient having mild or moderate haptic impairment, the method comprising:

administering to the patient having mild or moderate hepatic impairment an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate,

wherein the dosage unit provides a release profile of hydrocodone that:

does not increase average hydrocodone $AUC_{0\text{-inf}}$ in subjects suffering from mild hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 14%; and

does not increase average hydrocodone $AUC_{0\text{-inf}}$ in subjects suffering from moderate hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 30%.

Claims Are Generic And Functional

- **“The asserted claims are broadly cast in generic form.”**
- **“[The claims] do not recite methods of treatment involving the use of a particular identified formulation, or even a group of identified formulations. Instead, the formulation limitations recited in the claims read on all oral dosage unites comprising extended-release hydrocodeon in which hydrocodone is the only active ingredient.”**
- **“The claims are largely functional, and the only nonfunctional limitations are generic.”**

The Specification Was Limited

3. Example 8 in the common specification is a species falling within the genus defined by the limitations of each of the asserted claims. The common specification does not disclose any other operative species that was shown to satisfy the functional claim limitations.

4. Example 8 is the formulation disclosed in the prior art Devane reference and is the formulation used in Pernix's opioid product, Zohydro ER. The inventors of the '760 and '499 patents did not invent the Devane composition, but instead merely determined that Devane's formulation has certain pharmacokinetic properties that permit it to be administered to persons with mild and moderate hepatic impairment at the same dosage level as for ***623** persons without hepatic impairment. They made that discovery after conducting a clinical hepatic impairment study to obtain FDA approval for Zohydro ER.

6. Neither the specification nor any evidence offered at trial points to any structural features that would assist a person of ordinary skill in the art in identifying species falling within the asserted generic claims. The pharmacokinetic data and dissolution profile for the Devane formulation provide no guidance as to whether other formulations would satisfy the functional limitations of the claims, and the sample components for the immediate release hydrocodone and modified release coating solutions in Table 1 and Table 2 would contain candidate components for the formulation, *see* Trial Tr. 615:13–616:16, but no assurance that any particular formulation using those components would work.

Other Evidentiary Considerations

- Expert admitted on cross that he would not know whether a particular formulation would practice the functional limitations recited in the claims without conducting a hepatic impairment study.
- The inventors did not know why the formulation functioned in the way it did.
- “Here, the efficacy of the claimed treatment method depends entirely on whether the particular formulation functions in the manner recited in the claims. It is therefore critical that the formulation be described with sufficient specificity to ensure that the inventors have invented the full scope of the formulations received in the claims and not simply a single operative embodiment within that class.”

Thank You!

Chad Shear
Principal
shear@fr.com

Martina Hufnal
Principal
hufnal@fr.com

Please send your NY CLE forms to mcleteam@fr.com

Any questions about the webinar, contact the events team at eventsteam@fr.com

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