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



Wednesday, May 10

Meet The Speakers



Martina Hufnal Principal



Chad Shear Principal

Overview

• Topics

- Important Decisions
- Practice Tips
- Housekeeping
 - CLE
 - Questions
 - Materials
 - <u>http://www.fr.com/webinars</u>



Techniques for Achieving an Efficient and Effective Freedom to Operate Analysis

Wednesday, May 17, 2023 | 1:30 - 2:30 p.m. ET

A patent gives its owner the right to exclude others from the invention claimed in it, but does not give the owner the right to make, use, or sell that invention in the marketplace. The purpose of a freedom to operate analysis is to ensure that the production, use, or sale of a new product does not infringe a valid patent of another. While there is no legal requirement for a company to obtain an FTO opinion before taking a new product to market, doing so can nevertheless provide a number of advantages to companies both large and small.

Join Principal <u>Michael Hawkins</u> and Technology Specialist, Patent Agent <u>Molly Kelley</u> on May 17 as they discuss the legal and practical considerations that can prompt a company to seek an FTO opinion from patent counsel.



PRESENTED BY:





Molly Kelley Technology Specialist, Patent Agent

WHAT YOU'LL LEARN

Michael and Molly will discuss the following topics and more:

- · When to conduct an FTO analysis
- · What formats can be used to communicate the results
- How to use the results
- How to improve efficiency during an FTO analysis



- 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

- 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.

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.

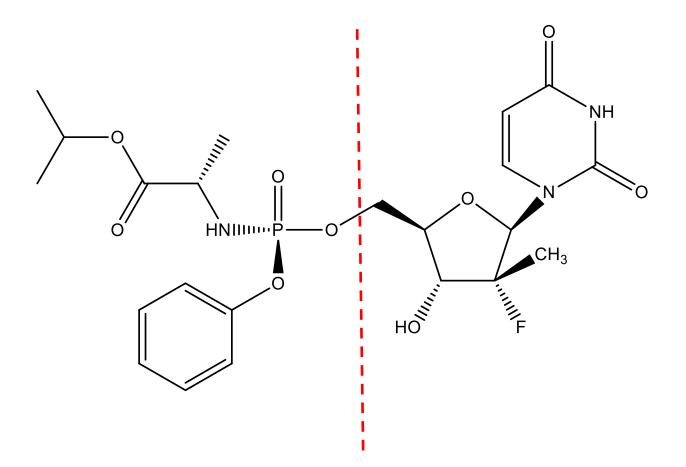
Idenix v. Gilead (Fed. Cir. 2019)

Harvoni® and Sovaldi®



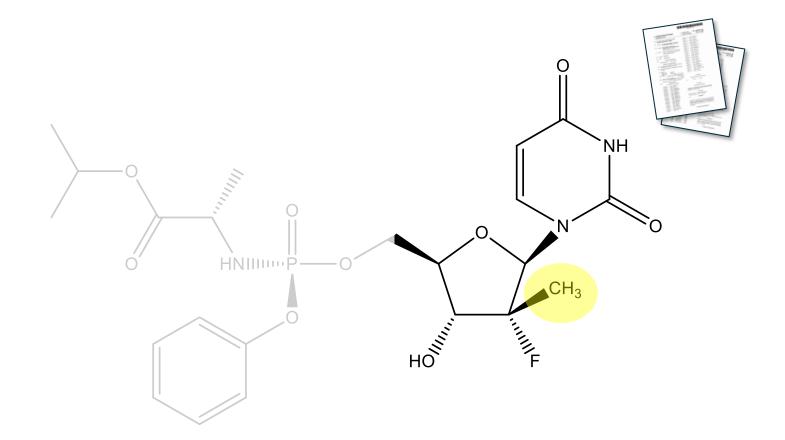


Sofosbuvir



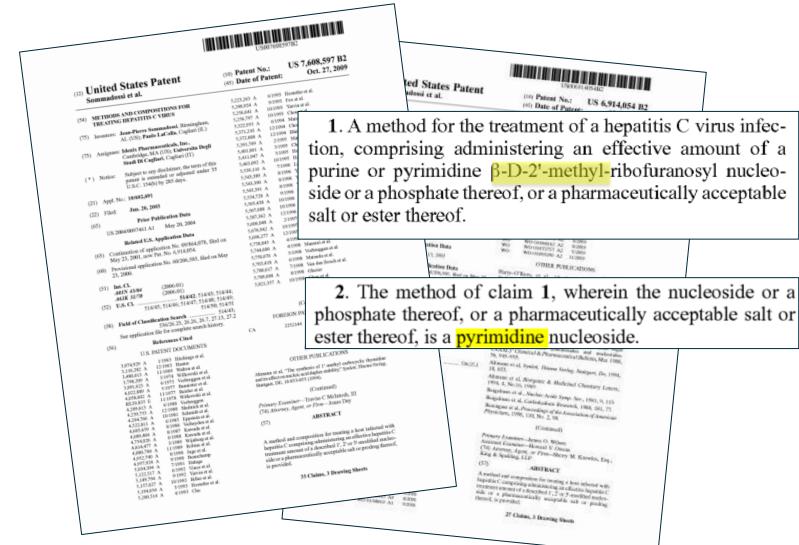


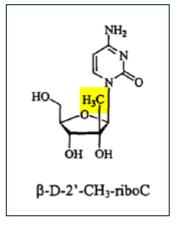
2' Me-up Nucleosides

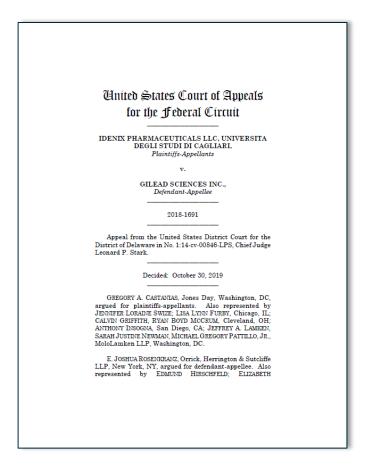




2' Methyl Up Patents

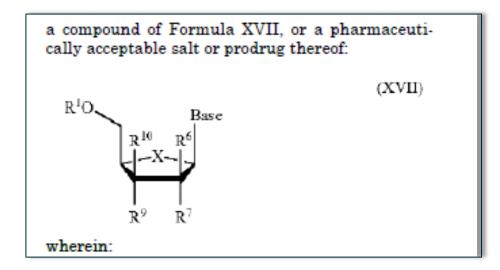






The only independent claim of the '597 patent recites:

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'-methylribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

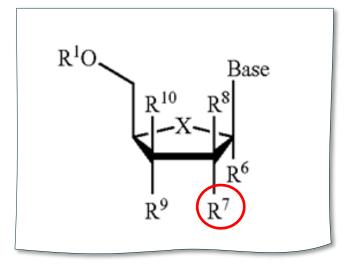


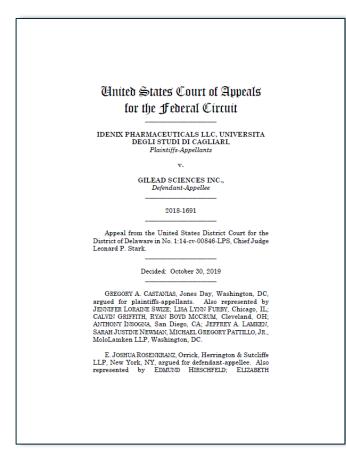
'597 Patent (May 2000)

Specification **Does Not Teach** Fluorine at the 2'-Down Position Formula XVI

R⁷ and R⁹ are independently hydrogen, OR², hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkyl, Brvinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —O(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chlorine, bromine, iodine, NO₂, NH₂, —NH(lower alkyl), —NH(acyl), —N(lower alkyl)₂, —N(acyl)₂;

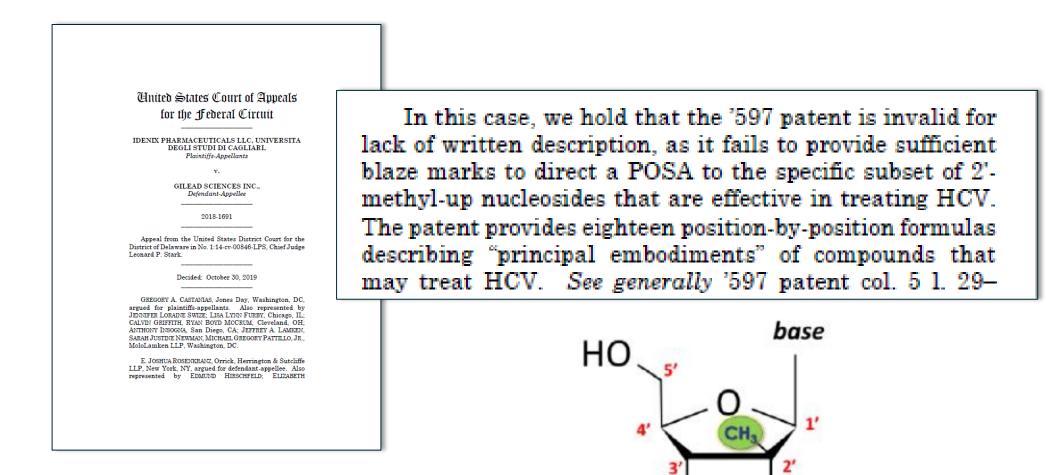






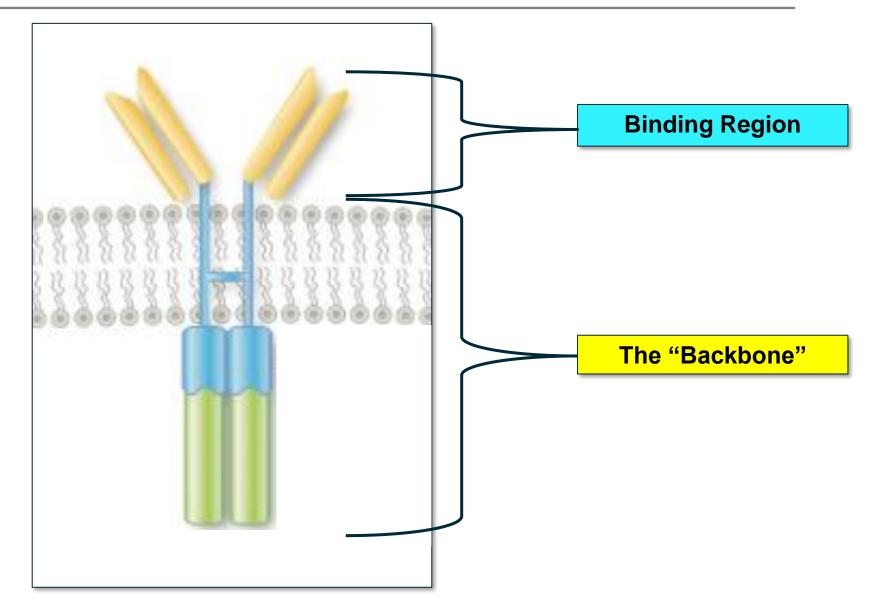
the enablement requirement. 35 U.S.C. § 112; see Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). To fulfill the written description requirement, a patent owner "must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, 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



Juno Therapeutics v. Kite Pharma

CAR-Ts



'190 Patent

FISH

(12) United States Patent			tes Patent	(10) Patent No.: US 7,446,190 B (45) Date of Patent: Nov. 4, 200		
(54)	CELL RECEPTORS			Dranoff et al., Vaccination with irradiated tumor cells engineered secrete murine granulocyte-macrophage colony-stimulating fact stimulates potent, specific, and long-lasting anti-tumor immunit		
(75)	Inventors: Michel Sadelain, New York, NY (US); Renier Brentjens, Maplewood, NJ (US); John Maher, Surray (GB) 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.		entjens, Maplewood, NJ (US);	Proc. Natl. Acad. Sci. USA, 1993, pp. 3539-3543. Feldhaus et al., A CD2/CD28 chimeric receptor triggers the CD signaling pathway in CTLL.2 cells, Gene Therapy, 1997, pp. 83		
(73)				838, vol. 4. Karpoff et al., Prevention of Hepatic Turner Metastases in Rats wi Heppes Viral Vaccines and γ-Interferon, J. Clin. Invest., 1997, p 799-304, vol. 99, No. 4. Kutubudin et al., Endication of preexisting murine turnor usi herpes amplicon vectors, Cancer Gene Therapy, 1997, pp. S. XP002071440, vol. 4, No. 6.		
*)			extended or adjusted under 35			
(21)	Appl. No.:	10/448,250	5	Lewin, Genes IV, 1990, pp. 810, Publisher: Oxford University Pre- Panka et al., Variable region framework differences result decreased or increased affinity of variant anti-digoxin antibodi Proc. Natl. Acad. Sci. USA., 1988, pp. 3080-3084, vol. 85.		
22)	Filed:	May 28, 2	003			
65)			ublication Data	Proc. Natl. Acad. Sci. USA, 1988, p Parijs, Homeostasis and Self-Toleran		
		043401 A1	Mar. 4, 2004	ing Lymphocytes off, Science, 1998, pp. 243-248, vol. 280. Paul, Fundamental Immunology, 1993, pp. 553-554, Publish		
Related U.S. Application Data			•••	Raven Press.		
60)	Provisional application No. 60/383,872, filed on May 28, 2002.		a No. 60/383,872, filed on May	Rudikoff et al., Single amino acid su ing specificity, Proc. Natl. Acad. Sci. 79.		
	1) Int. Cl. <i>C07H 21/04</i> (2006.01)			Sambrook, Molecular Cloning, a Lal & 16.11, Publisher: Cold Spring Ha		
(52) (58)	Field of Classification Search None See application file for complete search history.			Tung et al., Rapid Production of Interleukin-2-Secreting Tumor Ce by Herpes Simplex Virus-Mediated Gene Transfer: Implications 1 Autologous Vaccine Production, Human Gene Therapy, 1996, p 2217-2224, vol. 7.		
56)				Hellstrom et al., Tumor vaccines—a reality at last?, Journal Immunotherapy, 1998, pp. 119-126, vol. 21, No. 2.		
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	5,359,046 A	10/1994	Capon et al.	* cited by examiner		
5,585,096 A 12/1996 Martuza et al. 5,686,281 A 11/1997 Roberts 5,728,379 A 3/1998 Martuza et al.			Roberts Martuza et al.	Primary Examiner—Ilia Ousper (74) Attorney, Agent, or Firm—M LLC		
6,051,428 A 4/2000 Fong et al. 6,344,445 B1 2/2002 Boursnell et al. 2003/0077249 A1* 4/2003 Bebbington et al.			Boursnell et al.	(57) ABSTR	ACT	
	FORI	EIGN PATE	NT DOCUMENTS			
WO WO	WO9 WO9	5/29421 A1 7/00085 A1	9/1996 1/1997	Chimeric T cell receptors (TCR) in a single chimeric species, the ζ-chain, a signaling region from	intracellular domain of CD	
WO		7/34634 AI	9/1997 BLICATIONS	as CD28, and a binding element with a selected target. When expr	nt that specifically interac	
OTHER PUBLICATIONS Kroczek et al., 2005, J. Allergy Clin. Immunol, 116: 906-909.* Clarkson et al., 2005, Transplantation, 80: 555-563.* Oki et al., 2005, Molecular Cell, 19: 707-716.*				phocytes from the individual to associated with the selected target is stimulated in the individual to	be treated for a condition et, a T cell immune response	

Krocze Clarkse Oki et al., 2005, Molecular Cell, 19: 707-716. Maher et al., 2002, Nature Biotechnology, 20: 70-75.* Alvarez-Vallina et al., Antigen-specific targeting of CD28-mediated T cell co-stimulation using chimeric single-chain antibody variable stimulation signals from a single molecule to more effectively direct T-lymphocyte cytotoxicity against the selected target fragment-CD28 receptors, Eur. J. Immunol., 1996, pp. 2304-2309, vol 26

Amit et al., Three-Dimensional Structure of an Antigen-Antibody Complex at 2.8 Å Resolution, Science, 1986, pp. 747-753, vol. 233.

TCR's are able to provide both the activation and the co-

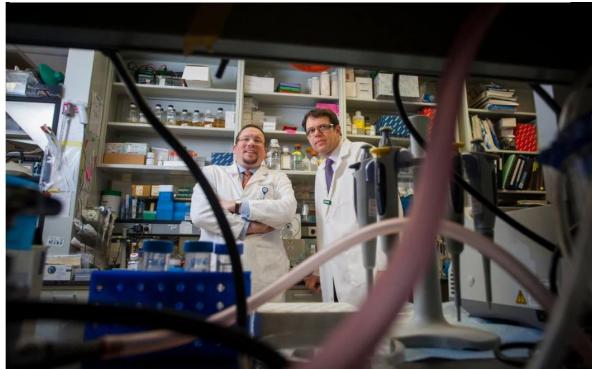
13 Claims, 8 Drawing Sheets

and T-lymphocyte proliferation.

United States Patent Sadelain et al.

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

The New York Times Cell Therapy Shows Promise for Acute Type of Leukemia

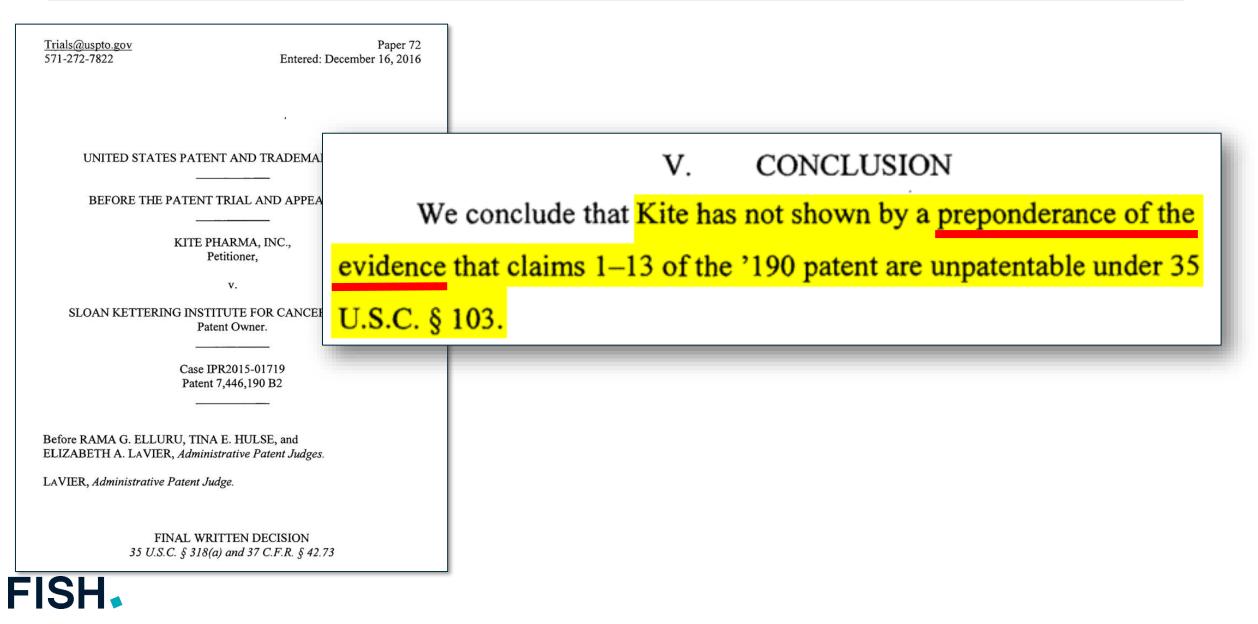




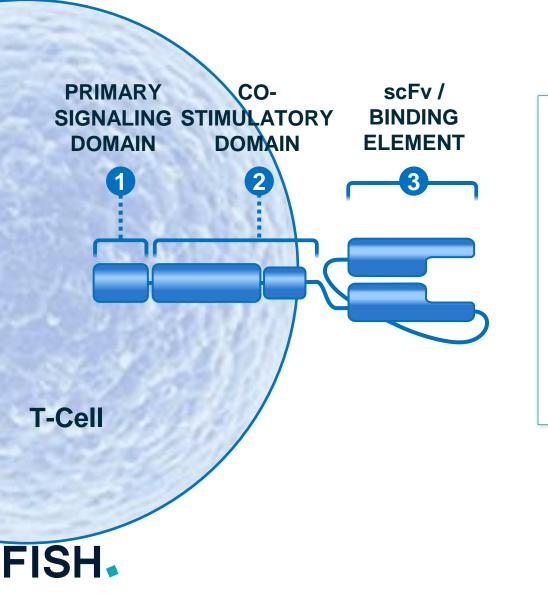


Memorial Sloan Kettering Cancer Center

Kite Tried to Kill the Patent, but Failed



- 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



The invention claimed is:

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 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

CELL RECEPTORS Secret marine granulocyte macephage colosy-stimulating factor immunity from the sector specific and sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 833-834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser Theory, 1997, pp. 834, sequencing anti-mare immunity in CTL 2 eachs Caser and 2 eachy case Theory, 1993, pp. 535, 554, 554, 55	12) United States Patent Sadelain et al.	(10) Patent No.: US 7,446,190 B2 (45) Date of Patent: Nov. 4, 2008	
 Threators: Michel Sadelain, New York, NY (US): Renier Breetings, Maplexoco, NJ, VS (US): John Maher, Surry (GB) John Maher, Surry (GB) John Maher, Surry (GB) John Maher, Surry (GB) John Maher, Surry (GB) Soliget to any disclinance, the term of this pasteria is extended or adjusted under 35 U.S.C. 154(b) by 458 days. Zito any disclinance, the term of this pasteria is extended or adjusted under 35 U.S.C. 154(b) by 458 days. Zito any disclinance the term of this pasteria is extended or adjusted under 35 U.S.C. 154(b) by 458 days. Zito any disclinance the term of this Sito 3748, vol. 4, No. 6. Lexin, Graes TV, 1990, pp. 810, Philolizer Oxford Ulaversity Pre- Paster 1, No. 6. Lexin, Graes TV, 1990, pp. 810, Philolizer Oxford Ulaversity Pre- Paster 4, Nurth A., 2004 Related US. Application Data US 20040043401 A1 Mar. 4, 2004 Related US. Application Data Sto 2004, 2005, 01 US 20040043401 A1 Mar. 4, 2004 Related US. Application Data Sto 2014; 556 Related US. Application Data Sto 2002, 2002. Sito 234; 556(23.4; Sto 234; 556(23.4; Sto 234; 556(23.4; Sto 234; 556(23.4; Sto 297, 2002, 2002. Sto 2014; 556(23.4; Sto 2014; 557, 567, 576(23.4; Sto 2014; 557, 577, 577, 578, 578, 578, 578, 578,		Feldhaus et al., A CD2/CD28 chimeric receptor triggers the CD28 signaling pathway in CTLL.2 cells, Gene Therapy, 1997, pp. 833-	
 (3) Assignate: Shoan-Kettering Institute for Cancer Research, New York, NY (US) (*) Notice: Subject to any disclaimer, the term of this patient is extended or adjanted under 35 US.C. 154(4) by 45 days. (21) Appl. No: 10/448,256 (22) Filed: May 28, 2003 (3) Prior Publication Data US 20040043401 A1 Mar 4, 2004 (3) Related US. Application Data US 20040043401 A1 Mar 4, 2004 (4) Related US. Application Data US 20040043401 A1 Mar 4, 2004 (5) Prior Publication Data US 20040043401 A1 Mar 4, 2004 (5) Prior Publication Data US 20040043401 A1 Mar 4, 2004 (7) Provisional application No. 60/383.872, filed on May 28, 2002. (7) Int. C1. C2071 2104 (2006.01) (2006.01) US 2004.0043401 A2 Mar 4, 2004 (7) Martin and Science 1998, pp. 240-248, vol. 290. Path 20040043401 A1 Mar 4, 2004 (7) Int. C1. C2071 2104 (2006.01) (2006.01) US 20. References Cited US Application Science 1998, pp. 240-248, vol. 290. Path 20040043401 A2 Mar 4, 2004 Martin Mark 1989, pp. 240-248, vol. 290. Path 20040043401 A2 Mark 1980, pp. 240-248, vol. 290. Path 20040043401 A2 Mark 1980, pp. 240-248, vol. 290. Path 2004004401 Path 2004 Path 20040044004 Path 20040044004 Path 20040044004 Path 20040044004004 (2006.01) US 20040044004 Path 20040044004400400400000000000000000000	Renier Brentjens, Maplewood, NJ (US);		
 (1) Provise and application Data (21) Appl. No: 10448,256 (22) Filed: May 28, 2003 (23) Filed: May 28, 2003 (24) Filed: May 28, 2003 (25) Prior Publication Data (25) USAC 1544(b) by 458 days. (26) Prior Publication Data (27) Filed: May 28, 2003 (28) Prior Publication Data (29) Provisional application No. 60/383.872, filed on May (29) Provisional application No. 60/383.872, filed on May (20) References Cited U.S. PATENT DOCUMENTS (26) References Cited U.S. PATENT DOCUMENTS (26) Artistication Samma et al. (27) APP Reisfield et al. (28) 2003/27223, vol. 7. (28) TARENT DOCUMENTS (29) WOY 2004241, Al. 91989 (20) WOY 20042421, Al. 91999 (20) WOY 20042421, Al. 91999 (27) ARSTRACT (27) ARSTRACT (27) ARSTRACT 		Karpoff et al., Prevention of Hepstic Tumor Metastases in Rats with Herpes Viral Vaccines and y-Interferon, J. Clin. Invest., 1997, pp.	
 Filed: May 28, 2003 Filed: May 28, 2003 Prior Publication Data US 2004/0043401 A1 Mar. 4, 2004 Related US. Application Data US 2004/0043401 A1 Mar. 4, 2004 Related US. Application Data Related US. Application Data Provisional application No. 60/383.872, filed on May Ze 2002. Int Cl. COTI 2004 Liss, CL	patent is extended or adjusted under 35	Kutubuddin et al., Eradication of preexisting murine tumor using herpes amplicon vectors, Cancer Gene Therapy, 1997, pp. 826	
 (22) Field: May 28, 2003 (55) Prior Publication Data (56) Prior Publication Data (57) Related US. Application Data (58) For Publication Data (59) Provisional application No. 60/383,872, filed on May 28, 2002. (50) Provisional application No. 60/383,872, filed on May 28, 2002. (51) Int. C1. (2006,01) (52) US. C1	 Appl. No.: 10/448,256 	Lewin, Genes IV, 1990, pp. 810, Publisher: Oxford University Press.	
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5:485,090 A 4'1995 Binke et al. 5:585,096 A 12'1996 Minuxa et al. 5:686,096 A 12'1996 Minuxa et al. 5:686,096 A 10'097 Roberts 5:7283,735 A 10'090 Form-Marina Larson & Associate 5:686,096 A 10'097 Roberts LLC 6:051,428 A 42000 Former et al. (57) ABSTRACT 2005/007249 A1' 42033 Roberts (57) ABSTRACT WO W096/29421 A1 9'1996 in a single chimeric species, the intracellular doesnin of CD WO W09750085 A1 1'197 Chimeric T cell receptors (TCR) are provided that combin in a single chimeric species, the intracellular doesnin of CD WO W09750085 11'97 Streamine et al. Streamine et al. OTHER PUBLICATIONS When expressed, for example in T-lym phocytes from the individual to be treated for a condition supportein sus condition via the individual to be treated for a condition supportein sus as the species from the individual to be treated for a condition supportein sus as the species of thim the individual to be treate	4.859,587 A 8/1989 Roizman 4.946,778 A 8/1990 Ladaer et al. 5.302,570 A 4/1994 Neumeier et al. 5.328,688 A 7/1994 Roizman	Vieweg et al., Considerations for the use of cytokine-secreting tumor cell preparations for cancer treatment, Cancer Investigation, 1995, pp. 193-201, vol. 13, No. 2.	
5.586,096 A. 121996 Mutuza et al. Primary Examine	5.359:046 A 10/1994 Capon et al. 5.405:090 A 4/1995 Burke et al.		
6.344.45 BI 22003 Boristall et al. (57) ABSTRACT 2003.0007249 A1* 4/2003 Bethiagos et al. 424.93.2 (57) ABSTRACT WO W094/23421 A1 9/1996 in a single chimeric species, the intracellular domain of CD ç-chain, a signaling region from a costimulatory protein suc as CD28, and a binding element that specifically intervent with a selected target. When expressed, for example in T-by phocytes from the individual to be treated for a condition associated with the selected target. Teel immunor reports	5,585,096 A 12/1996 Martuza et al. 5,686,281 A 11/1997 Roberts 5,728,379 A 3/1998 Martuza et al.	(74) Attorney, Agent, or Firm-Marina Larson & Associates,	
WO W096/29421 A1 91996 Chinseric T cell receptors (TCR) are provided that combin in a single chinner's projects, the intracedlut of domin of CD 2-chain, a signaling region from a costimulatory protein suc suc WO W072700885 A1 11997 OTHER PUBLICATIONS with selected target. When expressed, for example in T-lyn phacytes from the individual to be treated for a condition associated with the selected target, and with a selected target.	6,344,445 B1 2/2002 Boursnell et al.	(57) ABSTRACT	
W0 W09623921 A1 91996 in a single chimeric species, the intracellular domain of CD W0 W097034634 A1 91997 C-chain, a signaling region from acostimulatory protein ac W0 W097134634 A1 91997 CCD28, and a binding element that specifically interest OTHER PUBLICATIONS with a selected target, When expressed, for example in T-by phocytes from the individual to be treated for a conditionation accounted with the selected target, a T cell immune responses	FOREIGN PATENT DOCUMENTS		
Kroczek et al., 2005, J. Allergy Clin. Immunel, 116: 906-909.* Chakson et al., 2005, Transpharation, 89: 555-563.*	WO W097/00085 AI 1/1997 WO W097/34634 AI 9/1997	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	
Maker et al., 2002, Nature Biotechnology, 20: 70-75.* TCR's are able to provide both the activation and the or Alvarez-Vallina et al., Artigen-specific targeting of CD28-mediated stimulation signals from a single molecule to more effectivel	Kroczek et al., 2005, J. Allergy Clin. Immunol, 116: 906-909.* Zhrkoro et al., 2005, Transpharation, 89: 555-563.* Maler et al., 2005, Molecular Cell, 19: 707-716.* Maler et al., 2002, Nature Biotechnology, 20: 70-75.* Wratez-Vallian et al., Artigen-specific targeting of CD28-mediated re cell co-stimulation using chimeric inglechnia antibody variable	phocytes 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-Jympocyte cytotoxicity against the selected target	

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 CD3 ζ 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.

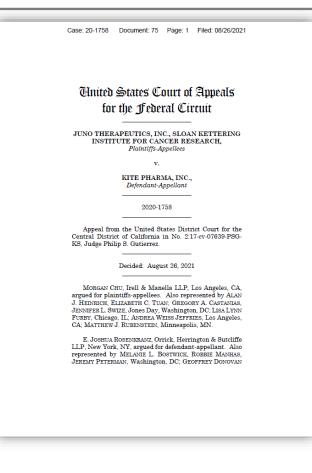
Kite arguments on appeal

- 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





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 CD19specific scFvs was vast and the number of known CD19specific 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)

· · · · ·	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	Dranoff et al., Vaccination with intadiated tumor cells engineered to secrete murine granulocyte-macrophage colony-stimulating factor stimulates potent, specific, and long-tasting anti-tumor immunity	
(75)	Inventors: Michel Sadelain, New York, NY (US) Renier Brentjens, Maplewood, NJ (U John Maher, Surrey (GB)	Proc. Natl. Acad. Sci. USA, 1993, pp. 3539-3543.	
(73)	Assignce: Sloan-Kettering Institute for Cancer Research, New York, NY (US)	Karpoff et al., Prevention of Hepatic Tumor Metastases in Rats with Herpes Viral Vaccines and y-Interferon, J. Clin. Invest., 1997, pp	
(*)	Notice: Subject to any disclaimer, the term of t patent is extended or adjusted under U.S.C. 154(b) by 458 days.		
(21)	Appl. No.: 10/448,256	Lewin, Genes IV, 1990, pp. 810, Publisher: Oxford University Press	
(22)	Filed: May 28, 2003	Panka et al., Variable region framework differences result in decreased or increased affinity of variant anti-digoxin antibodies	
(65)	Prior Publication Data	Proc. Natl. Acad. Sci. USA, 1988, pp. 3080-3084, vol. 85. Parijs, Homeostasis and Self-Tolerance in the Immune System: Turn	
	US 2004/0043401 A1 Mar. 4, 2004	ing Lymphocytes off, Science, 1998, pp. 243-248, vol. 280.	
	Related U.S. Application Data	Paul, Fundamental Immunology , 1993, pp. 553-554, Publisher Raven Press.	
(60)	Provisional application No. 60/383,872, filed on N 28, 2002.	fay Rudikoff et al., Single amino acid substitution altering antigen-bind ing specificity, Proc. Natl. Acad. Sci. USA, 1982, pp. 1979-1983, vol 79.	
	Int. Cl. C07H 21/04 (2006.01)	Sambrook, Molecular Cloning, a Laboratory Manual, 1989, pp. 16- & 16, 11, Publisher: Cold Spring Harbor Laboratory.	
(52) (58)	U.S. CL	ranger in a submit roomenou or interenting contenting runter even	
	See application file for complete search history.	by Herpes Simplex Virus-Mediated Gene Transfer: Implications fo Autologous Vaccine Production, Human Gene Therapy, 1996, pp 2217-2224, vol. 7.	
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	4,675,287 A 6/1987 Reisfeld et al. 4,769,331 A 9/1988 Roizman et al.	Stevenson FK., Turnor vaccines, FASEB J., 1991, pp. 2250-2257 vol. 5, No. 9.	
	4,859,587 A 8/1989 Roizman 4,946,778 A 8/1990 Ladaer et al. 5,302,370 A 4/1994 Neumeier et al.	Vieweg et al., Considerations for the use of cytokine-secreting turne cell preparations for cancer treatment, Cancer Investigation, 1995 pp. 193-201, vol. 13, No. 2.	
	5,328,688 A 7/1994 Roizman 5,359,046 A 10/1994 Capon et al.	* cited by examiner	
	5,405,990 A 4/1995 Burke et al. 5,585,096 A 12/1996 Martuza et al.	Primary Examiner-Ilia Ouspenski	
	5,686,281 A 11/1997 Roberts 5,728,379 A 3/1998 Martuza et al. 6,051,428 A 4/2000 Fong et al.	(74) Attorney, Agent, or Firm-Marina Larson & Associates LLC	
	6.344,445 B1 2/2002 Boursnell et al. 3/0077249 A1* 4/2003 Bebbington et al	3.2 (57) ABSTRACT	
	FOREIGN PATENT DOCUMENTS	Chinaria T and assesses (TOTR) and and it is in the	
wo	W096/29421 A1 9/1996	Chimeric T cell receptors (TCR) are provided that combine in a single chimeric species, the intracellular domain of CD.	
WO -	W097/00085 A1 1/1997	2-chain, a signaling region from a costimulatory protein such	

Clarkson et al., 2005, Transplantation, 80: 555-563.* Oki et al., 2005, Molecular Cell, 19: 207,716.* Maher et al., 2002, Nature Biotechnology, 20: 70-75.* Aburez-Vallina et al., Antigen-specific targeting of CD28-mediated T cell co-stimulation using chimeric single-chain antibody variable fragment-CD28 receptors, Eur. J. Immunol., 1996, pp. 2304-2309,

Amit et al., Three-Dimensional Structure of an Antigen-Antibody Complex at 2.8 Å Resolution, Science, 1986, pp. 747-753, vol. 233

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 costimulation 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.

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

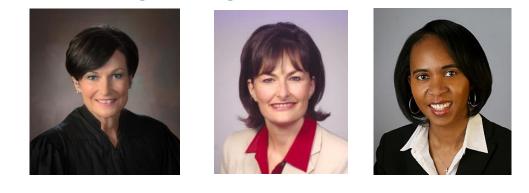
• Lourie, joined by Moore and Newman







 O'Malley, Stoll, and Cunningham did not participate



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













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."

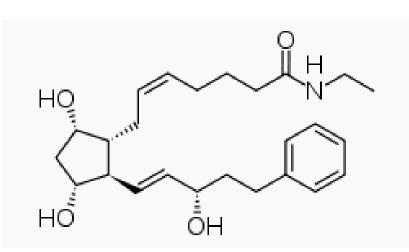
Four Errors by Panel Majority & DCT

- 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)





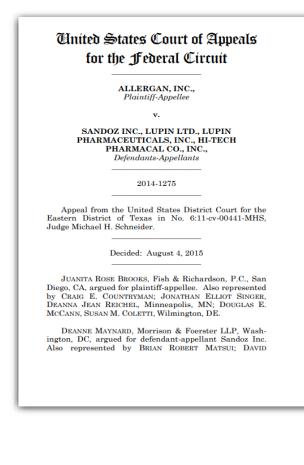


Allergan v. Sandoz (Fed. Cir. 2015)

United States Court of Appeals for the Federal Circuit 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)



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 IOPlowering 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)

United States Court of Appeals for the Federal Circuit 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

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)

- 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 <u>hepatic impairment</u>, the method comprising:

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

FISH

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 <u>hepatic impairment</u> an oral dosage unit having <u>hydrocodone</u> bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of <u>hydrocodone</u> bitartrate,

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

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

does not increase average <u>hydrocodone</u> AUC_0 . inf in subjects suffering from moderate <u>hepatic</u> <u>impairment</u> relative to subjects not suffering from <u>renal</u> or <u>hepatic impairment</u> in an amount of more than 30%.

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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 <u>'760</u> and <u>'499 patents</u> 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 <u>hepatic impairment</u>. They made that discovery after conducting a clinical <u>hepatic impairment</u> 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!

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