

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Merck Sharp & Dohme LLC, MSD International GmbH, MSD International Business GmbH, and AIC246 AG & Co. KG v. DUS Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited

Civil Action No. 24-10820 (KMW-SAK) · No. Civil Action No. 24-10820 (KMW-SAK) · Decided December 29, 2025

SUMMARY

The United States District Court for the District of New Jersey construes disputed terms in U.S. Reissued Patent No. RE 46,791, relating to letermovir and antiviral treatment of cytomegalovirus. The court adopts Plaintiffs’ proposed constructions for terms concerning stereoisomeric forms, methods for treating, antivirally effective amounts, and enantiomeric excess, rejecting Defendants’ indefiniteness and racemic-mixture arguments. The court reserves any remaining indefiniteness arguments concerning the amount of an antivirally effective compound for summary judgment or trial.

CASE DETAILS

COURT	United States District Court for the District of New Jersey
WRITING FOR THE COURT	Karen M. Williams
JURISDICTION	United States District Court for the District of New Jersey
DECIDED	December 29, 2025
DOCKET	Civil Action No. 24-10820 (KMW-SAK)
DISPOSITION	other
PROCEDURAL POSTURE	The parties jointly sought construction of six disputed terms in the claims of U.S. Reissued Patent No. RE 46,791 pursuant to Local Patent Rule 4.5. The court conducted a Markman hearing and issued constructions of the disputed terms.
STANDARD OF REVIEW	Claim construction is a question of law for the court to decide.
PRECEDENTIAL VALUE	published district court memorandum opinion; persuasive authority

TOPICS

- patent infringement
- patent law
- intellectual property
- commercial litigation
- civil procedure

PRACTICE AREAS

QUESTIONS PRESENTED

1. Whether claim 1 is limited to racemic compounds or encompasses compounds existing in a stereoisomeric form or a mixture of stereoisomeric forms.
2. Whether claims 29 and 30 are limited to racemic compounds or encompass compounds existing in a stereoisomeric form or a mixture of stereoisomeric forms.
3. Whether claims 21, 26, 27, and 32 are limited to racemic compounds.
4. Whether the term "method for treating" in claims 18 and 21 includes prophylactic as well as curative treatment.
5. Whether the term "an antivirally effective amount" in claims 18 and 21 is indefinite and how it should be construed.
6. Whether the term "having an enantiomeric excess of more than 90%" in claims 41 and 42 is indefinite and how it should be construed.

HOLDINGS

1. Claim 1 is not limited to racemic compounds; it encompasses a compound existing in a stereoisomeric form or a mixture of stereoisomeric forms, consistent with the claim's plain and ordinary meaning.
2. Claims 29 and 30 encompass a compound existing in a stereoisomeric form or a mixture of stereoisomeric forms and are not limited to racemic mixtures.
3. Claims 21, 26, 27, and 32 are not limited to racemic compounds and have their plain and ordinary meaning encompassing stereoisomeric forms or mixtures of stereoisomeric forms.
4. The term "method for treating" includes both prophylactic or preventative treatment and curative treatment; it is not limited to treatment of an existing disease or injury.
5. The term "an antivirally effective amount" is not indefinite at the claim-construction stage and means an amount that provides an antiviral effect or activity. Any remaining dispute concerning the amount effective under particular circumstances is reserved for summary judgment or trial.
6. The term is not indefinite and means, within the limits of detection, having more than 95% of one enantiomer and less than 5% of the second enantiomer, such that the enantiomeric excess is greater than 90%.

KEY QUOTATIONS

"The claims of a patent define the invention to which the patentee is entitled the right to exclude." (at 4)

"the Court finds that a POSA would understand the term "method for treating" in Claims 18 and 21 to mean its plain and ordinary meaning—preventative and curative treatment" (at 10)

"The Court adopts Plaintiffs' proposed construction of each disputed claim term as the articulation of the respective term's plain meaning." (at 16)

FACTUAL BACKGROUND

The case concerns a reissued patent directed to substituted dihydroquinazolines and their use as antiviral agents against cytomegalovirus. Letemovir, the active ingredient in PREVYMIS and the defendants' proposed generic product, is within the claimed class of compounds. The disputed constructions concerned stereoisomeric forms and mixtures, the meaning of treating, an antivirally effective amount, and enantiomeric excess.

PROCEDURAL HISTORY

Merck and related plaintiffs filed a patent infringement action against DUS Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited. The parties submitted a joint claim-construction statement, opening and responsive briefs, and presented oral argument at a December 4, 2025 Markman hearing. The district court construed each disputed term in accordance with the plaintiffs' proposed construction and indicated that an appropriate order would follow.

DISPOSITION

other

CASES CITED

- Amgen Inc. v. Amneal Pharmaceuticals LLC, 945 F.3d 1368, 1375 (Fed. Cir. 2020)
- Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996)
- Bayer Healthcare LLC v. Baxalta Inc., 989 F.3d 964, 977 (Fed. Cir. 2021)
- Phillips v. AWH Corp., 415 F.3d 1303, 1312-23 (Fed. Cir. 2005) (en banc)
- Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)
- Allergan Sales, LLC v. Sandoz, Inc., 935 F.3d 1370, 1373 & nn.6-7 (Fed. Cir. 2019)
- Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-79, 986 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)
- Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)
- C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004)
- Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004)
- SynQor, Inc. v. Artesyn Technologies, Inc., 709 F.3d 1365, 1378-79 (Fed. Cir. 2013)
- Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003)
- Immunomedics, Inc. v. Roger Williams Medical Center, No. 15-4526, 2017 WL 788122, at *6 (D.N.J. Feb. 28, 2017)
- Wyeth v. Abbott Laboratories, No. 09-4850, 2011 WL 5873373, at *8 (D.N.J. Nov. 22, 2011)
- Sonix Technology Co. v. Publications International, Ltd., 844 F.3d 1370, 1377 (Fed. Cir. 2017)
- Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1382 (Fed. Cir. 2015)

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