

NOTE: This disposition is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**HORIZON PHARMA, INC., HORIZON PHARMA  
USA, INC.,**  
*Plaintiffs*

**HORIZON MEDICINES LLC, NUVO  
PHARMACEUTICAL (IRELAND) DESIGNATED  
ACTIVITY COMPANY,**  
*Plaintiffs-Appellants*

v.

**DR. REDDY'S LABORATORIES INC., DR. REDDY'S  
LABORATORIES, LTD.,**  
*Defendants-Appellees*

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**HORIZON PHARMA, INC., HORIZON PHARMA  
USA, INC.,**  
*Plaintiffs*

**HORIZON MEDICINES LLC, NUVO  
PHARMACEUTICAL (IRELAND) DESIGNATED  
ACTIVITY COMPANY,**  
*Plaintiffs-Appellants*

v.

**LUPIN LTD., LUPIN PHARMACEUTICALS INC.,**  
*Defendants*

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2019-1607, 2019-1609, 2019-1611, 2019-1612, 2019-1614

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Appeals from the United States District Court for the District of New Jersey in Nos. 2:15-cv-03324-SRC-CLW, 2:15-cv-03326-SRC-CLW, 2:15-cv-03327-SRC-CLW, 2:16-cv-04918-SRC-CLW, 2:16-cv-04920-SRC-CLW, 2:16-cv-04921-SRC-CLW, 2:16-cv-09035-SRC-CLW, Judge Stanley R. Chesler.

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Decided: January 6, 2021

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JAMES B. MONROE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, for plaintiff-appellant Horizon Medicines LLC. Also represented by CHARLES COLLINS-CHASE.

MICHAEL HAWES, Baker Botts, LLP, Houston, TX, for plaintiff-appellant Nuvo Pharmaceutical (Ireland) Designated Activity Company. Also represented by JEFFREY SEAN GRITTON, STEPHEN M. HASH, Austin, TX.

ALAN HENRY POLLACK, Windels Marx Lane and Mitten-dorf LLP, Madison, NJ, for defendants-appellees. Also represented by WILLIAM H. BURGESS, JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC.

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Before MOORE, O'MALLEY, and HUGHES, *Circuit Judges*.  
HUGHES, *Circuit Judge*.

Appellants Horizon Medicines LLC and Nuvo Pharmaceutical (Ireland) Designated Activity Company appeal the United States District Court for the District of New

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Jersey's grant of summary judgment that the claims of U.S. Patent Nos. 9,220,698 and 9,393,208 are invalid for indefiniteness. The parties' primary dispute on appeal is the district court's construction of the claim term "target." Because we agree with the district court's construction of the term "target" to mean "set as a goal," we affirm.

## I

Millions of Americans take non-steroidal anti-inflammatory drugs (NSAIDs) each day as a treatment for pain or inflammation, but many of these NSAIDs are associated with gastrointestinal complications, often caused by the presence of acid in the stomach and the upper small intestines. In recent years, attempts have been made to decrease these gastrointestinal complications by administering agents, such as proton pump inhibitors (PPIs), that inhibit stomach acid secretion. U.S. Patent Nos. 9,220,698 (the '698 patent) and 9,393,208 (the '208 patent) are directed to methods of delivering a pharmaceutical composition comprising the NSAID naproxen and the PPI esomeprazole to a patient.

The parties agree that claim 1 of the '698 patent is representative of the asserted claims of both the '698 patent and the '208 patent. Claim 1 reads:

1. A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours ( $\pm 20\%$ ) later, a PM unit dose form, wherein:

the AM and PM unit dose forms each comprises:

naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and

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esomeprazole or a pharmaceutically acceptable salt thereof in an amount to provide 20 mg of esomeprazole;

said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,

the AM and PM unit dose forms *target*:

i) a pharmacokinetic (pk) profile for naproxen where:

a) for the AM dose of naproxen, the mean  $C_{\max}$  is 86.2  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{\max}$  is 3.0 hours ( $\pm 20\%$ ); and

b) for the PM dose of naproxen, the mean  $C_{\max}$  is 76.8  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{\max}$  is 10 hours ( $\pm 20\%$ ); and

ii) a pharmacokinetic (pk) profile for esomeprazole where:

a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours ( $\pm 20\%$ ) after the AM dose is administered ( $\text{AUC}_{0-10,\text{am}}$ ) is 1216  $\text{hr}\cdot\text{ng/mL}$  ( $\pm 20\%$ ),

b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours ( $\pm 20\%$ ) after the PM dose is administered ( $\text{AUC}_{0-14,\text{pm}}$ ) is 919  $\text{hr}\cdot\text{ng/mL}$  ( $\pm 20\%$ ), and

c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours

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(±20%) after the AM dose is administered (AUC<sub>0-24</sub>) is 2000 hr\*ng/mL (±20%); and

the AM and PM unit dose forms further *target* a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%

'698 Patent 52:26–67 (emphasis added).

Appellants Horizon and Nuvo sued Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories, Ltd., and several other defendants who are not part of this appeal, for patent infringement in multiple lawsuits in the United States District Court for the District of New Jersey. The actions were consolidated for pretrial purposes, and the issues in this appeal were resolved in proceedings and orders common to all the district court cases.

The district court held a Markman hearing and issued a Markman order for several terms in the patent claims, but only the construction of the term “target” is contested in this appeal. See *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Inc.*, 2017 WL 5451748 (D.N.J. 2017) (*Markman Order*). At the Markman hearing, Appellants contended that “target” has its ordinary meaning, which is “produce.” *Id.* at \*4. Appellees contended that “target” is indefinite, but in the alternative, that it has its ordinary meaning, which is “with the goal of obtaining.” *Id.* at \*5.

The district court declined to find “target” indefinite at claim construction, but agreed with Appellees' proposed construction, slightly adjusted for grammatical fit. *Id.* at \*5. The district court found that construing “target” to mean “set as a goal” fit with the court's understanding of what “target” ordinarily means, with several dictionary definitions, and with claim 1 and the patent as a whole. *Id.*

The district court found Appellants' arguments for their proposed construction unpersuasive, noting that the

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