

Horizon Pharma v. Reddy's Labs.

United States Court of Appeals for the Federal Circuit

January 6, 2021, Decided

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

Reporter

2021 U.S. App. LEXIS 296 *

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 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 2 HORIZON PHARMA, INC. v. DR. REDDY'S LABORATORIES INC.

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Core Terms

target, dose, district court, indefinite, patent, esomeprazole, specification, pharmaceutically, administered, naproxen, grant of summary judgment, invalid, skill, words

Opinion

[*1] 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.

Decided: January 6, 2021

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.

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 [*3] 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 (AUC_{0-10,am}) is 1216 hr*ng/mL ($\pm 20\%$),

b) for the PM dose of esomeprazole, the mean area [*4] under the plasma concentration-time curve from when the PM dose is administered to 14 hours ($\pm 20\%$) after the PM dose is administered (AUC_{0-14,pm}) is 919 hr*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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($\pm 20\%$) after the AM dose is administered (AUC₀₋₂₄) is 2000 hr*ng/mL ($\pm 20\%$); 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 [*5] 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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only pieces of intrinsic evidence Appellants cited were a "specification passage in which the treatment method is described as *producing* certain PD and PK profiles, as well as one in which the treatment method is said 'to *target* a specific PD profile." *Id.* at *4 (emphasis added). The [*6] court found that the specification's use of both words (target and produce) does not mean that the words are interchangeable or that one necessarily means the other. *Id.* Addressing Appellants' expert testimony in support of its proposed construction, the district court found it to be "the kind of conclusory, unsupported assertion that, under *Phillips*, is not useful in claim construction." *Id.* (citing [Phillips v. AWHCorp.](#), *415 F.3d 1314, 1318 (Fed. Cir. 2005)* (en banc)).

Appellees then moved for summary judgment of invalidity on the ground of indefiniteness. The district court first held that the target clauses are claim limitations, based primarily on Appellants' reliance on the target clauses to distinguish the claimed invention from the prior art during patent prosecution. 1 [HorizonPharma, Inc. v. Dr. Reddy's Labs., Inc.](#), *2018 WL 6040265 at *4 (D.N.J. 2018)* (*Summary Judgment Opinion*). The court then held that the patent claims were indefinite because, while the goal itself was clearly defined, the "act of targeting that goal" was not. *Id.* The court found that "pills cannot be said to set goals," and even if the claims were understood to say that it is a treating physician who sets the goals, the claims would require a treating physician to "avoid having a subjective intent to achieve the defined outcomes." *Id.* at *4-5. The district [*7] emphasized that even if "[t]he claim language delineating the target [were] clear as day . . . 'target' would still be indefinite." *Id.* at *7.

Finally, Appellants argued that the disagreement of the parties' experts was a factual dispute that precluded a

grant of summary judgment. *Id.* at *8. However, the

1 This holding is not challenged on appeal.

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district court found that Appellants' expert's opinion was "not a factual assertion, but a legal conclusion" and that the court "need not credit conclusory statements by experts and need not find such statements sufficient to raise material factual disputes." *Id.* Accordingly, finding no dispute as to any genuine issue of material fact, the district court granted summary judgment, holding the asserted claims of the '698 patent and the '208 patent invalid due to indefiniteness. *Id.* at *8-9.

II

The "ultimate construction" of a patent claim is an issue of law which we review de novo, and we review the "factual findings that underlie a district court's claim construction" for clear error. [Teva Pharms. USA, Inc. v. Sandoz, Inc.](#), *574 U.S. 318, 332-33 (2015)*. Indefiniteness is a question of law which we review de novo. [Teva Pharms. USA, Inc. v. Sandoz Inc.](#), *789 F.3d 1335, 1341 (Fed. Cir. 2015)*. We review the grant of summary judgment under the law of the regional circuit. [BSG Tech LLC v. Buyseasons, Inc.](#), *899 F.3d 1281, 1285 (Fed. Cir. 2018)*. [*8] The Third Circuit reviews the grant or denial of summary judgment

de novo. [Cranbury Brick Yard, LLC v. United States](#), *943 F.3d 701, 708 (3d Cir. 2019)*.

A

"[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips*, *415 F.3d* at 1312 (internal quotation marks and citations omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

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This is such a case. Here, the claim term "target" is a commonly understood word, and nothing Appellants

point to in the specification or the prosecution history suggests that it should be given anything other than its ordinary meaning. We agree with the district court that the use of both the terms "target" and "produce" at different points in the specification does not mean that these words have the same meaning. If anything, this suggests that the patent [*9] applicants were aware of their separate meanings and chose to use "target" in the patent claims instead of "pro-duce." We also find Appellants' expert testimony unper-suasive. Appellants' expert merely concluded that "[a] person of ordinary skill in the art would have understood that the claim term 'target' means 'produce'" and cited the same language from the specification that we find unper-suasive here. J.A. 2222-23, ¶¶ 28-29.

While it is true that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," [Phillips, 415 F.3d at 1316](#), the specification here does not. We therefore construe the claim term "target" to mean "set as a goal" as the district court did.

Appellants make much of this court's statements in other cases that "claims should be so construed, if possible, as to sustain their validity." [Phillips, 415 F.3d at 1327](#), (quoting [Rhine v. Casio, Inc., 183 F.3d 1342, 1345 \(Fed. Cir. 1999\)](#)). But this principle applies only where "the court concludes, after applying all the available tools of claim construction, that the claim is . . . ambiguous." [Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 \(Fed. Cir. 2004\)](#). Here, because the meaning of the claim term "tar-get" is not ambiguous, this principle does not apply.

B

Patent claims are indefinite if they do not "inform [*10] those skilled in the art about the scope of the invention with rea-sonably certainty." [Nautilus, Inc. v. Biosig Instruments](#),

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[Inc., 572 U.S. 898, 910 \(2014\)](#). One circumstance in which claims are indefinite is where the claims, as properly con-strued, are nonsensical. See [Trs. of Columbia Univ. v. Sy-mantec Corp., 811 F.3d 1359, 1366-67 \(Fed. Cir. 2016\)](#) (holding claims describing the extraction of machine code instructions from something that did not have machine code instructions indefinite as "nonsensical in the way a claim to extracting orange juice from apples would be"). We agree with the district

court that the "target" clauses of claim 1 render the claim indefinite because "[t]he fact that a goal is clearly defined does not mean that the act of tar-geting that goal is clearly defined, and this is the crux of the definiteness problem here." *Summary Judgment Opinion* at *4. As the district court explained, both clauses are incomprehensible. *Id.* Reading the claim literally, a dose form, which is an inanimate object, cannot set a goal. That the proper construction of the claims is nonsensical does not warrant judicial redrafting of the claims. [Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 n.6 \(Fed. Cir. 1990\)](#); see also [Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 \(Fed. Cir. 2004\)](#) ("Even a nonsensical re-sult does not require the court to redraft the claims of the [patent]." (internal quotation [*11] marks omitted)). Accord-ingly, we affirm the district court's holding that the claims of the '698 patent and the '208 patent are invalid for indef-iteness.

C

Appellants' final contention is that the district court improperly granted summary judgment because of a disa-greement between the parties' experts. As this court has previously stated, "a conclusory statement on the ultimate issue does not create a *genuine* issue of fact." [Imperial To-bacco Ltd. v. Philip Morris, Inc., 899 F.2d 1575, 1581 \(Fed. Cir. 1990\)](#) (emphasis in original) .

Here, Appellants' expert merely made conclusory statements about what a skilled artisan would understand

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about the meaning of the claim term "target" and quoted text from the patent's specification that did not support this conclusion. This type of cursory conclusion does not create a genuine dispute of material fact, and we therefore affirm the district court's grant of summary judgment.

III

We have considered Appellants' other arguments and find them unpersuasive. We agree with the district court's construction of the claim term "target" to mean "set as a goal," and we affirm the district court's grant of summary judgment holding the claims of the '698 patent and the '208 patent invalid for indefiniteness.

AFFIRMED

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