

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTSUKA PHARMACEUTICAL CO., LTD.	:	
and H. LUNDBECK A/S,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 19-1938-LPS
	:	(consolidated)
ZENARA PHARMA PRIVATE LTD., et al.,	:	
	:	
Defendants.	:	

Steven J. Balick and Andrew C. Mayo, ASHBY & GEDDES, Wilmington, Delaware
James B. Monroe, Denise Main, Erin M. Sommers, C. Collette Corser, and Tyler B. Latcham,
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP, Washington, DC
Attorneys for Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, Delaware
Timothy H. Kratz and George J. Barry III, KRATZ & BARRY LLP, Atlanta, Georgia
Attorneys for Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, Delaware
Dmitry V. Shelhoff, Kenneth S. Canfield, and Edward D. Pergament, PERGAMENT &
CEPEDA LLP, Florham Park, New Jersey
Attorneys for Defendants Zenara Pharma Private Ltd. and Biophore India
Pharmaceuticals Private Ltd.

John M. Seaman and April M. Kirby, ABRAMS & BAYLISS LLP, Wilmington, Delaware
A. Neal Seth, Teresa M. Summers, and Alexander B. Owczarczak, WILEY, Washington, DC
Attorneys for Defendants Accord Healthcare Inc., MSN Laboratories Pvt. Ltd., and MSN
Pharmaceuticals Inc.

John C. Phillips, Jr. and David A. Bilson, PHILLIPS MCLAUGHLIN & HALL, P.A.,
Wilmington, Delaware
William R. Zimmerman, Andrea L. Cheek, and Aryeh N. Feinstein, KNOBBE, MARTENS,
OLSON & BEAR, LLP, Washington, DC
Carol Pitzel Cruz, KNOBBE, MARTENS, OLSON & BEAR, LLP, Seattle, Washington
Attorneys for Defendants Lupin Limited and Lupin Pharmaceuticals, Inc.

Anne Shea Gaza and Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR, LLP,
Wilmington, Delaware

Kent M. Walker and Mary E. LaFleur, CROWELL & MORING LLP, Chicago, Illinois
Attorneys for Defendants Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals
Company GmbH, and Raks Pharma Pvt. Ltd.

Dominick T. Gattuso and Elizabeth A. DeFelice, HEYMAN ENERIO GATTUSO & HIRZEL
LLP, Wilmington, Delaware

William A. Rakoczy, Amy D. Brody, and Lauren M. Lesko, RAKOCZY MOLINO MAZZOCHI
SIWIK LLP, Chicago, Illinois
Attorneys for Defendant Alkem Laboratories Ltd.

Anne Shea Gaza and Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR, LLP,
Wilmington, Delaware

Mark H. Remus, Laura A. Lydigsen, and Alexis S. White, CROWELL & MORING LLP,
Chicago, Illinois
Attorneys for Defendant Sandoz Inc.

Pilar G. Kraman and Beth A. Swadley, YOUNG CONAWAY STARGATT & TAYLOR, LLP,
Wilmington, Delaware

Michael J. Gaertner, Myoka Kim Goodin, and Wasim K. Bleibel, LOCKE LORD LLP, Chicago,
Illinois
Zhibin Li, LOCKE LORD LLP, New York, New York
Attorneys for Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare
Limited

Kelly E. Farnan and Renée Mosley Delcollo, RICHARDS, LAYTON & FINGER, P.A.,
Wilmington, Delaware

B. Jefferson Boggs, MERCHANT & GOULD PC, Alexandria, Virginia
Christopher J. Sorenson and Karen L. Beckman, MERCHANT & GOULD PC, Minneapolis,
Minnesota

Andrew O. Larsen, MERCHANT & GOULD PC, New York, New York
Attorneys for Defendant Unichem Laboratories Limited

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, Delaware

Dmitry V. Shelhoff, Kenneth S. Canfield, and Edward D. Pergament, PERGAMENT &
CEPEDA LLP, Florham Park, New Jersey
Attorneys for Defendants Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd., Unit-
V, Hetero Labs, Ltd., and Honour Lab Ltd.

Kenneth L. Dorsney, MORRIS JAMES LLP, Wilmington, Delaware
Devan V. Padmanabhan and Sri K. Sankaran, PADMANABHAN & DAWSON, P.L.L.C.,
Minneapolis, Minnesota
Attorneys for Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA,
Inc.

Stamatios Stamoulis, STAMOULIS & WEINBLATT LLC, Wilmington, Delaware
Ronald M. Daignault and Richard Juang, DAIGNAULT IYER, Mclean, Virginia
Attorneys for Defendants Ajanta Pharma Ltd. and Optimus Pharma Pvt. Ltd.

Stamatios Stamoulis, STAMOULIS & WEINBLATT LLC, Wilmington, Delaware
Shashank Upadhye, Yixin Tang, and Brent Batzer, UPADHYE TANG LLP, Chicago, Illinois
Attorneys for Defendant Princeton Pharmaceutical Inc.

Thomas J. Francella, Jr., COZEN O'CONNOR, Wilmington, Delaware
W. Blake Coblentz, Barry P. Golob, Aaron S. Lukas, and Kerry B. McTigue, COZEN
O'CONNOR, Washington, DC
Attorneys for Defendants Apotex Inc., Apotex Corp., Apotex Pharmachem Inc., and
Signa S.A. de C.V.

John W. Shaw, Karen E. Keller, and Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington,
Delaware
Elizabeth J. Holland, Naomi L. Birbach, and James P. Breen, GOODWIN PROCTER LLP, New
York, New York
Srikanth K. Reddy and Emily L. Rapalino, GOODWIN PROCTER LLP, Boston, Massachusetts
Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

David E. Moore, Bindu A. Palapura, and Stephanie E. O'Byrne, POTTER ANDERSON &
CORROON LLP, Wilmington, Delaware
Dennies Varughese, Pharm.D. and Robert W. Stout, STERNE, KESSLER, GOLDSTEIN &
FOX P.L.L.C., Washington, DC
Attorneys for Defendants Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals,
Inc.

MEMORANDUM OPINION

July 27, 2021
Wilmington, Delaware



STARK, U.S. District Judge:

In this consolidated action arising under the Hatch-Waxman Act, Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S (collectively, “Plaintiffs”) allege infringement of five patents against 18 pharmaceutical manufacturers seeking to market generic versions of Plaintiffs’ REXULTI® tablets before the patents expire. (D.I. 71; D.I. 92 at 1)¹ REXULTI® is an antipsychotic drug approved for the treatment of major depressive disorder and schizophrenia. (D.I. 71 ¶ 34) The five asserted patents are directed to brexpiprazole, the active ingredient in REXULTI®, and to pharmaceutical compositions and methods of use. (D.I. 92 at 1)

The parties have just one claim construction dispute from one of the five patents-in-suit, U.S. Patent No. 10,307,419 (the “’419 patent”). The parties submitted a joint claim construction brief (D.I. 92) and exhibits (D.I. 93-1), including competing expert declarations (*id.* Exs. 13, 18, 23). The Court held a claim construction hearing on June 28, 2021, at which both sides presented oral argument. (D.I. 102) (“Tr.”)

I. LEGAL STANDARDS

A. Claim Construction

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (citing *Markman v. Westview Instruments, Inc.* (“*Markman IP*”), 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting

¹ Unless otherwise indicated, all references to the docket index (D.I.) are to the lead action, C.A. No. 19-1938.

claim construction.” *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art [“(POSA”)”] in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent “specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment” because “claim terms are normally used consistently throughout the patent.” *Id.*

It is likewise true that “[d]ifferences among claims can also be a useful guide.” *Id.* “For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15. This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible 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. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

Sometimes, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. “Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the ordinary and customary meaning of a term because such dictionaries “endeavor to collect the accepted

meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted).

B. Indefiniteness

A patent claim is indefinite if, “viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir.

2015). But “[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique.” *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015). The facts underlying an indefiniteness determination must be proved by clear and convincing evidence. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

II. CONSTRUCTION OF DISPUTED TERM²

A. “coating substantially does not contain polyethylene glycol”³

<p>Plaintiffs The phrase “coating substantially does not contain polyethylene glycol” has its plain and ordinary meaning under <i>Phillips</i>, which means “polyethylene glycol is substantially not contained in the coating.” Not indefinite.</p>
<p>Defendants⁴ Indefinite.</p>
<p>Court The Court will decide indefiniteness in connection with trial.</p>

Defendants argue that this claim term is indefinite because the ’419 patent’s intrinsic evidence fails to provide any objective guideposts for determining whether any coating “substantially does not contain polyethylene glycol” (also referred to as PEG). (*See* D.I. 92 at

² Defendants also proposed a construction for the term “hydroxypropyl cellulose,” which they contend means “a derivative of cellulose including hydroxypropoxyl groups by about 50 to 85%.” (D.I. 92 at 1) Plaintiffs did not object to this construction; indeed, they agreed it is “consistent with [the term’s] plain and ordinary meaning.” (*Id.*) The Court will adopt this construction.

³ This term appears in claims 1-7 of the ’419 patent.

⁴ The following Defendants take no position on claim construction: Alembic Pharmaceuticals Ltd., Alembic Pharmaceuticals Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Company GmbH, Raks Pharma Pvt. Ltd., and Teva Pharmaceuticals USA, Inc. (*See* D.I. 92 at 4 n.3)

19) Plaintiffs counter that the term is not indefinite and also urge the Court to consider deferring ruling on indefiniteness. (*See, e.g.*, Tr. at 30)

Indefiniteness, like claim construction, is a question of law. *See Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 2015 WL 7737308, at *5 (D. Del. Dec. 1, 2015) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999)). The indefiniteness inquiry may, however, involve underlying factual disputes. *See, e.g., Bombardier Recreational Prods. Inc. v. Arctic Cat Inc.*, 785 F. App'x 858, 867 (Fed. Cir. 2019) (“[I]ndefiniteness ‘is amenable to resolution by the jury where the issues are factual in nature.’”) (quoting *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003)). For example, a “question about the state of the knowledge of a skilled artisan is a question of fact.” *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1225 (Fed. Cir. 2015) (Moore, J., concurring).

In many cases, it is possible to decide indefiniteness at the claim construction stage. *See, e.g., Huber Engineered Woods LLC v. Louisiana-Pacific Corp.*, 2020 WL 5132922, at *8-9 (D. Del. Aug. 31, 2020). The Court agrees with Defendants that, as a general matter, there is nothing inappropriate about deciding indefiniteness as part of claim construction. (*See generally* Tr. at 37) (“We’re not saying that Your Honor must or is required legally to decide [indefiniteness] now, but certainly it is appropriate to decide now.”) In some cases, however, resolution of indefiniteness as part of claim construction may be either impossible or inadvisable. Where, for example, there is a subsidiary factual issue, and the record reveals a genuine dispute of material fact, resolution may have to await further evidentiary development. *See, e.g., Waddington N. Am., Inc. v. Sabert Corp.*, 2010 WL 4363137, at *3 (D.N.J. Oct. 27, 2010) (noting that “practical

considerations [may] militate against determining indefiniteness prior to the end of fact or expert discovery”).

In the instant case, it is most appropriate – and likely even necessary – to defer ruling on the indefiniteness dispute presented by the parties.

Plaintiffs seek to have the Court construe this term as having its “plain and ordinary meaning,” but there is no agreement here as to what the “plain and ordinary meaning” is. Instead, the record contains conflicting expert opinions on this and related points. For instance, the parties’ experts disagree as to whether a POSA would understand the PEG limitation to relate to a specific *amount* of PEG – that is, the coating may contain only no PEG or just a miniscule amount of PEG, which is Defendants’ position (*see, e.g.*, D.I. 93-1 Ex. 13 at 1, 13, 18-19) – or, instead, to relate to *function* – that is, the coating may contain no PEG or any (potentially unlimited) amount of PEG, provided that the coating as a whole fulfills the patent’s function of tablets with “excellent disintegration ability, storage stability, and high photostability, so that [they] can be effectively used in the medical field” (’419 patent at 3:9-11), which is Plaintiffs’ position (*see, e.g.*, D.I. 93-1 Ex. 18 at 8).

More particularly, Plaintiffs contend that a POSA would understand the limitation to relate to the function of the coating and would have reasonable certainty as to whether any particular coating fulfills the claims’ function. (*See, e.g.*, Tr. at 15, 24) Plaintiffs’ expert, Dr. Williams, contends that a POSA would understand that the phrase “substantially does not contain polyethylene glycol,” when read in light of the specification, allows for the use of PEG in the coating layer of the tablet as long as the tablet maintains its photostability. (D.I. 93-1 Ex. 18 at 9-10, 14)

Defendants disagree. As they note, neither the specification nor the claims specifies how much PEG is necessary to yield reduced photostability and storage stability. (*See* D.I. 92 at 19-20) Nor, according to Defendants, would a POSA even understand which criteria must be met to determine whether storage stability is “excellent” or photostability is “high.” (*Id.* at 21-22)

In the Court’s view, there is a subsidiary factual dispute – a genuine dispute, on which both sides have provided evidence; and a material dispute, as it is germane to indefiniteness – as to whether the ’419 patent provides a POSA reasonable certainty as to the scope of the PEG limitation. The Court will benefit from a more robust evidentiary record on this issue – including, for example, transcripts of expert depositions (which had not been taken as of the claim construction hearing)⁵ and likely also live expert testimony at trial.

Moreover, the Court is not persuaded, at this stage, that a POSA would understand the prosecution history statements on which Defendants rely as constituting a clear and unmistakable disavowal of tablets with coatings with ~5.7% w/w or more of PEG. (*See id.* at 45-50) As Plaintiffs point out, the applicant did not assert that only the cited examples fell within the claim scope; nor did the applicant contend that the prior art references, like Yamashita, had “too much PEG.” (*Id.* at 48)

Notably, this matter (being an ANDA action) is scheduled for a bench trial. (*See* D.I. 34 at 22) There is no provision in the current schedule for summary judgment motions. (*See id.* at 20) Accordingly, the Court will not only be asked to decide the ultimate legal issue of indefiniteness but will also be the factfinder with respect to any subsidiary factual issues. Under the circumstances, the Court will benefit from making these decisions on a full evidentiary

⁵ Despite having the opportunity to depose Plaintiffs’ expert, Defendants “felt no need” to do so because they “didn’t feel [P]laintiffs’ expert said anything that was worth questioning him on.” (Tr. at 37)

record, after better understanding the technology and the merits of the parties' competing positions. Accordingly, the Court will defer deciding the indefiniteness issue until trial.

III. CONCLUSION

An appropriate Order follows.