IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARRAY BIOPHARMA, INC., Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED and SANDOZ, INC., Defendants.	C. A. No. 22-cv-1277-GBW

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April 16, 2024
Wilmington, Delaware

MEMORANDUM OPINION

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Before the Court is Plaintiff Array BioPharma, Inc. ("Array") and Defendants Alembic Pharmaceutical Limited and Sandoz, Inc. ("Defendants,") joint request for construction of certain terms in United States Patent Nos. 9,314,464 (the "'464 patent"), 9,850,229 (the "'229 patent"), 10,005,761 (the "'761 patent"), 9,562,016 (the "'016 patent"), 9,598,376 (the "'376 patent"), and 9,980,944 (the "'944 patent").[1] *See* D.I. 72. The Court has reviewed the parties' briefing, *see id.*, heard oral argument, and construes the terms at issue as set forth below.

I. LEGAL STANDARDS

"'[T]he 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) (citation omitted); *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (same). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although "subsidiary factfinding is sometimes necessary." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015); *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) ("the construction of a patent . . . is exclusively within the province of the court.").

[1] The Court refers to the '464, '229, and '761 patents as the "Huang Patents" and the '016, '376, and '944 patents as the "Krell Patents."

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016) (similar). The "'only two exceptions to this general rule'" are (1) when a patentee defines a term or (2) disavowal of "'the full scope of a claim term either in the specification or during prosecution.'" *Thorner*, 669 F.3d at 1365 (citation omitted).

The Court "'first look[s] to, and primarily rel[ies] on, the intrinsic evidence,'" which includes the claims, written description, and prosecution history and "'is usually dispositive.'" *Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (citation omitted). "[T]he specification ' . . . is the single best guide to the meaning of a disputed term.'" *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (citation omitted). "'[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.' When the patentee acts as its own lexicographer, that definition governs." *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1316). However, "'[the Court] do[es] not read limitations from the embodiments in the specification into the claims.'" *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) (citation omitted)). The "written description . . . is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The 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), *aff'd*, 517 U.S. 370; *Cont'l Cirs.*, 915 F.3d at 796 (same). The prosecution history may "'demonstrat[e] how the

inventor understood the invention and whether the inventor limited the invention in the course of prosecution . . . ." *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1377 (Fed. Cir. 2021) (quoting *Phillips*, 415 F.3d at 1317).

The Court may "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; *Phillips*, 415 F.3d at 1317 (same). Extrinsic evidence may be useful, but it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Cont'l Cirs.*, 915 F.3d at 799 (internal quotation marks and citations omitted). However, "[p]atent documents are written for persons familiar with the relevant field . . . . Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (explaining that patents are addressed "to those skilled in the relevant art").

II. AGREED-UPON TERMS

The parties agree on the construction for the following seven terms.

Claim Term	Agreed-upon Construction	Court's Construction
"A method for treating a B-Raf protein kinase mediated cancer" '464 patent, claim 1	Preamble is limiting	Preamble is limiting
"A method of treating melanoma in a subject in need	Preamble is limiting	Preamble is limiting

Claim Term	Agreed-upon Construction	Court's Construction
thereof, the method comprising" '229 patent, claim 1		
"A method of treating cancer in a subject in need thereof, comprising" '761 patent, claim 1	Preamble is limiting	Preamble is limiting
"Non-fixed combination" '229 patent: claim 2; and '761 patent: claims 15, 21	The active ingredients are both administered to a patient as separate entities simultaneously, concurrently or sequentially with no specific time limits, wherein such administration provides therapeutically effective levels of the two compounds in the body of the patient.	The active ingredients are both administered to a patient as separate entities simultaneously, concurrently or sequentially with no specific time limits, wherein such administration provides therapeutically effective levels of the two compounds in the body of the patient.
"Sequentially" '464 patent: claim 8, 13, 15, 20, 22, 27; '229 patent: claim 3; and '761 patent: claims 16, 22	Plain meaning: forming or following in a logical order or sequence.	Plain meaning: forming or following in a logical order or sequence.
"A method of treating a cancer is selected from melanoma, pancreatic cancer, ovarian cancer, carcinoma of the fallopian tubes, peritoneal cancer, biliary cancer, colon cancer, or rectal cancer in a patient in need thereof, comprising"	Preamble is limiting	Preamble is limiting

Claim Term	Agreed-upon Construction	Court's Construction
'376 patent, claim 1		
"A pharmaceutical composition comprising" '016 patent, claims 3, 11	Preamble is limiting	Preamble is limiting
"A method of treating melanoma in a patient in need thereof, the method comprising" '944 patent, claim 1	Preamble is limiting	Preamble is limiting

III. DISPUTED TERMS

The following five terms are in dispute, require construction, and are construed as set forth below for the following reasons:

1. "ARRY-438162"

Term No.	Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
1	ARRY-438162 '464 patent: claims 11-13, 18-20, and 25–27; '229 patent: claims 5, 6, 11, 12, 16, 17, 19, 20; and '761 patent: claims 12, 13, 15–17, 21, 22	6-(4-bromo-2-fluorophenylamino)-7- fluoro-3-methyl-3H- benzoimidazole-5- carboxylic acid (2-hydroxyethyoxy)-amide or 5-[(4-bromo-2-fluorophenyl)amino]-4- fluoro-N-(2-hydroxyethoxy)- 1-methyl-1H-benzimidazole-6-carboxamide	Indefinite	Indefinite

The Huang Patents claim the compound "ARRY-438162" ("ARRY"). Prior to filing the applications that would later issue as the Huang Patents, ARRY was Array's internal name for the compound that is now known as "binimetinib." D.I. 72 at 15-17. However, prior to the priority date of the Huang Patents (August 28, 2009, *see* Tr. at 6), the only publicly-available documents that disclosed ARRY or binimetinib were: (1) a clinical study that identified ARRY as a MEK inhibitor and indicated that the molecule was currently undergoing clinical testing; (2) a scientific paper that discussed various MEK inhibitors and identified ARRY as a MEK inhibitor owned by Array BioPharma; (3) a patent application (U.S. Patent Application No. 10/387,879) that identified the chemical structure of binimetinib as "compound 29111;" and (4) a publication that identified a chemical structure for ARRY that does not match the chemical structure of binimetinib. *Id.* Array conceded at oral argument that those documents were not sufficient to teach a person of ordinary skill in the art that ARRY referred to the specific compound that is binimetinib as of the Huang Patents' priority date. Tr. 14:21-15:14.

Defendants argue that ARRY is indefinite because a person of ordinary skill in the art had no way of knowing what MEK inhibitor the Huang Patents' claimed as of the priority date of those patents. *See* D.I. 72 at 15. Array disagrees, and argues that the term is not indefinite because a person of ordinary skill in the art would have known that ARRY was an MEK inhibitor. *See* D.I. 72 at 13. Array contends that the Huang Patents are directed to the use of MEK inhibitors instead of those molecules' structures. *See* Tr. at 15:15-16-19. As a result, Array argues that the Huang Patents needed only teach a person of ordinary skill in the art how to use those MEK inhibitor in the context of the claimed invention for ARRY to be a definite term. *Id.*

The Court agrees with Defendants that ARRY is indefinite. The purpose of the definiteness requirement is to give notice to the public of what an inventor has claimed so that the public can

determine whether or not they infringe. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). For example, claim 6 of the '464 patent recites a method for treating a cancer by using ARRY. Accordingly, the patent must teach a person of ordinary skill in the art how to identify ARRY. Otherwise, the public would not be able to determine whether a specific treatment that uses an MEK inhibitor infringes that claim because the public would not be capable of determining if the MEK inhibitor used in that treatment is ARRY. As Array's counsel conceded, the Huang Patents do not teach a person of ordinary skill in the art how to identify ARRY. Tr. 14:21-15:14. As such, the term is indefinite.

HZNP Medicines LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 688-691 (Fed. Cir. 2019), supports the Court's conclusion. In that case, the Federal Circuit affirmed a district court's ruling that a chemical compound ("Impurity A") was indefinite when the specification did not (1) recite the chemical structure of Impurity A, and (2) did not include information sufficient for a person of ordinary skill in the art to identify Impurity A. *Id.* Similarly, in the instant case, the Court finds that ARRY is indefinite because the Huang Patents do not teach a person of ordinary skill in the art how to identify ARRY.

2. "Simultaneously" / "Concurrently"

Term No.	Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
2 / 3	Simultaneously '464 patent: claims 8, 15, 22 Concurrently '464 patent: claim 8, 15, 22; '229 patent: claim 9; and '761 patent: claim 17, 22	Plain meaning: at the same time Plain meaning: existing, happening, or done at the same time	Indefinite	Plain and ordinary meaning: at the same time

Defendants contend that these terms are indefinite because claims 8, 15, and 22 of the '464 patent recite a method of treatment wherein a therapeutic agent is administered "simultaneously, concurrently or sequentially" with another compound. D.I. 72 at 26. Defendants argue that the use of "simultaneously" in conjunction with "concurrently" in a disjunctive list implies that "simultaneously" means something other than "concurrently" because "[d]ifferent claim terms are presumed to have different meanings." *Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp.*, 533 F.3d 1362, 1371 (Fed. Cir. 2008)). Thus, since "simultaneously" and "concurrently" are synonyms, Defendants argue that a person of ordinary skill in the art would not be able to determine the meaning of those terms. *Id.* Array disagrees, and contends that a person of ordinary skill in the art would understand that those terms have their plain and ordinary meaning, namely "at the same time" for "simultaneously" and "existing, happening, or done at the same time" for "concurrently." *Id.*

The Court agrees with Array. "[N]o canon of construction is absolute in its application," *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998), and

"surplusage may exist in some claims." *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1312 n.6 (Fed. Cir. 2008). "Simultaneously" and "concurrently" are not terms of art. As a result, the Court finds that a person of ordinary skill in the art would be able to readily determine the meanings of those terms.

Moreover, the meaning of those terms is clear to a person of ordinary skill in the art because the claims cover simultaneous, concurrent, *and* sequential administration. *See, e.g.*, '464 patent, claim 8. A person of ordinary skill in the art would understand that the claims cover methods of treatments where the therapeutic agents are administered either (1) at the same time (i.e. "simultaneous" or "consecutive" administration), or (2) at different times (i.e. "sequential" administration). *See* '464 patent at 12:52-15:66 (comparing "fixed combination" dosages where the active ingredients are administered to a patient "simultaneously in the form of a single entity or dosage" with "non-fixed combination" dosages where the active ingredients are administered to a patient "as separate entities either simultaneously, concurrently or sequentially with no specific time limits wherein such administration provides therapeutically effective levels of the 2 compounds in the body of the patient.").

Accordingly, the Court finds that the terms "simultaneously" and "concurrently" are not indefinite, and construes those terms as having their plain and ordinary meaning. However, the Court does not see a substantive difference between "at the same time" and "existing, happening, or done at the same time" in the context of the Huang Patents. Thus, the Court construes both terms as "plain and ordinary meaning; at the same time."

3. "Crystallized" / "6-(4-bromo-2- fluorophenylamino)-7-fluoro-3-methyl-3H-benzoimidazole-5-carboxylic acid (2-hydroxyethyoxy)-amide"

Term No.	Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
4 / 5	Crystallized '016 patent, claims 3, 5-6, 8-9, and 11-14; '376 patent, claims 1-5 and 8-12; '944 patent, claims 1-12	Formed into crystals	Alembic: Indefinite Sandoz: In a crystalline form prior to inclusion in the pharmaceutical composition	Binimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol. The term is not indefinite.
	6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl- 3H-benzoimidazole-5-carboxylic acid (2-hydroxyethyoxy)-amide '016 patent, all asserted claims; '376 patent, all asserted claims; '944 patent, all asserted claims	Binimetinib	Binimetinib resulting from using a solvent mixture of ether and optionally an alcohol	

The parties proposed separate constructions for "crystallized" and "6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl-3H-benzoimidazole-5-carboxylic acid (2-hydroxyethyoxy)-amide."[2] At oral argument, the Court proposed construing those terms together because the terms always appear together in the claims of the Krell Patents. The parties had no objections and, accordingly, the Court will construe those terms together. For the reasons stated below, the Court finds that the term "crystallized binimetinib" is not indefinite, and construes that

[2] The Court refers to "6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl-3H-benzoimidazole-5-carboxylic acid (2-hydroxyethyoxy)-amide" as "binimetinib."

term as "binimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol."

A. Crystallized Binimetinib Refers To Binimetinib Crystallized According To The Process Described In The Claims And The Specification of the Krell Patents.

The claims recite methods of preparing crystallized binimetinib, methods of using crystallized binimetinib to treat cancer, and pharmaceutical compositions that include crystallized binimetinib. *See generally* '016 patent. The parties dispute whether the crystallized binimetinib that is claimed in the method of treatment and pharmaceutical composition claims must be binimetinib that has been crystallized according to the claimed method of preparing that compound.[3] Defendants contend that the patentee either (a) disclaimed other forms of binimetinib, or (b) lexicographically defined crystallized binimetinib as binimetinib that has been prepared according to the claimed method. Plaintiffs disagree, and contend that the claims cover any form of crystallized binimetinib, including naturally-crystalized binimetinib.

There are times when "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 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The standard for finding lexicography is "exacting." *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014).

The Court finds that the patentee acted as its own lexicographer and defined "crystallized binimetinib" as binimetinib that has been prepared according to the claimed method. The

[3] Claim 1 of the '016 patent recites a method of making binimetinib which includes, *inter alia*, "dissolving [binimetinib] in a solution comprising [] a solvent system comprising an ether and optionally an alcohol."

specification states that "[i]n the pharmaceutical compositions of the present invention, the crystallized [binimetinib] is in a crystal form produced by the crystallization process described above"—i.e. according to the claimed method. *See* '016 patent, claim 1; *id.* at 24:47-24:51 (describing the process for preparing binimetinib that is recited in claim 1.)

The specification uses the word "is" after the disputed term "crystallized [binimetinib]," which may "signify that a patentee is serving as its own lexicographer." *Abbott Lab'ys v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) ("The word 'is' may signify that a patentee is serving as its own lexicographer."). In the Krell Patents, this sentence is clearly lexicography and, as such, the patentee's lexicography governs. *Phillips*, 415 F.3d at 1316. Indeed, for each example of the invention provided in the section of the specification titled "Methods of Treating Proliferative Disease with Crystallized Compound A" the specification explains that "it is understood that crystallized Compound A is in crystalline form produced by the crystallization process described above." '016 patent, 28:1-28:10. The specification further explains that binimetinib crystallized according to the claimed method has an "improved purity profile" and "improved physical morphology" that is "advantageous in pharmaceutical drug development and manufacture." *Id.* at 16:32-16:37.

Accordingly, the Court finds that the patentee acted as its own lexicographer and defined crystallized binimetinib as "[binimetinib] [] in a crystal form produced by the crystallization process" described in the claims and the specification of the Krell Patents. That method, generally, involves the use of a solvent mixture of ether and optionally an alcohol. Thus, the Court construes "crystallized 6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl-3H-benzoimidazole-5-

carboxylic acid (2-hydroxyethyoxy)-amide" as "binimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol."[4]

B. "Crystalized Binimetinib" Is Not Indefinite.

Defendants also contend that the term "crystallized binimetinib" is indefinite because the specification explains that binimetinib prepared according to the claimed process "has an improved purity profile and an improved physical morphology" but fails to adequately teach a person of ordinary skill how to determine whether a specific crystalline binimetinib composition has those qualities. *See* D.I. 72 at 35.

The Court finds that "crystallized binimetinib" is not an indefinite term. Alembic's counsel conceded at oral argument that the method-of-making claims of the Krell patents, i.e., claims 1 and 16 of the '016 patent, recite specific process steps for making crystallized binimetinib. Tr. 43:9-43:23. The specification further explains how to crystallize binimetinib using the method described in the claims. *See generally* '016 patent. Thus, because the Court's construction of "crystallized binimetinib" is "binimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol," the Court finds that the term is not indefinite because a person of ordinary skill in the art would understand that they are in possession of "crystallized binimetinib" if that binimetinib was prepared according to the process described in the claims and

[4] The Court finds that its construction of crystallized binimetinib also resolves the parties' dispute regarding whether binimetinib must be crystallized prior to its inclusion in the claimed pharmaceutical compositions. *See* D.I. 72 at 38. The parties disputed whether binimetinib that naturally converts into a crystalline form is "crystallized binimetinib" for purposes of the Krell Patents' pharmaceutical-composition claims because amorphous binimetinib included in a pharmaceutical composition might naturally crystallize over time. Under the Court's construction, binimetinib that crystallizes naturally does not do so according to the claimed process and, as such, is not "crystallized binimetinib." Accordingly, that aspect of the parties' dispute regarding this term is moot.

the specification of the Krell Patents. Accordingly, the Court finds that Defendants have not shown that the term "crystallized binimetinib" is indefinite by clear and convincing evidence.

V. CONCLUSION

The Court will construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

Date: April 16, 2024