IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 17-158-LPS
	:	Consolidated
MICRO LABS USA INC., et al.,	:	
	:	
Defendants.	:	
	:	

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MEMORANDUM OPINION

October 24, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Pfizer Inc., PF Prism C.V., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively, "Pfizer" or "Plaintiffs") have brought several patent infringement suits pursuant to the Hatch-Waxman Act in this District, each asserting infringement of U.S. Reissue Patent No. RE41,783 (the "'783 patent"). The '783 patent generally relates to pyrrolo[2,3-d]pyrimidine compounds, which are inhibitors of protein kinases and are useful therapy as immunosuppressive agents. (*See* '783 patent at 1:13-17) Plaintiffs' relevant brand name drug is called Xeljanz, whose active ingredient is tofacitinib. (*See* D.I. 68 at 2)

Presently before the Court is the issue of claim construction. Pfizer and Defendants Micro Labs USA, Inc., Micro Labs, Ltd., Sun Pharmaceutical Industries Limited, Sun Pharmaceuticals Industries, Inc., Prinston Pharmaceutical Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Limited (collectively, "Defendants") participated in claim construction briefing. The parties submitted one technology tutorial (*see* D.I. 66), objections to the technology tutorial (*see* D.I. 84), claim construction briefs (*see* D.I. 68, 70, 85, 87), and one expert declaration (*see* D.I. 69). The Court held a claim construction hearing on August 27, 2018, at which both sides presented oral argument. (*See* D.I. 95 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 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) (internal quotation marks omitted).

"[T]here is no magic formula or catechism for conducting 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 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 citations and 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. Conceptronic, 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 . . . [b]ecause claim terms are normally used consistently throughout the patent." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide. . . . 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 (internal citation omitted). 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., Ltd. 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) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (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), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [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.*

In some cases, "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*, 135 S. Ct. at

841. 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 meaning of a term to those of skill in the relevant art 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.* Furthermore, "statements made by a patent owner during an IPR [inter partes review] proceeding . . . can be considered for claim construction." *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017). 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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS[1]

R^5 Terms

There is really only one dispute here. In the footnotes and the attached order, the Court will include the specific chemistry underlying the dispute and the Court's resolution of it. But, fundamentally, the issue to address is the implication of the patentee's use in claim 1 of a semicolon where one might otherwise expect a comma.[2]

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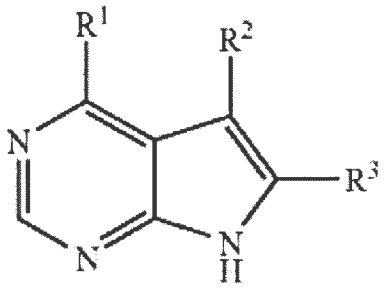
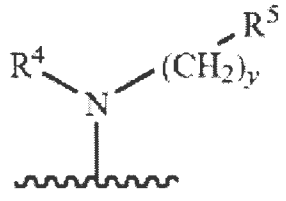
[1]In the attached order, the Court also adopts the parties' agreed-upon construction for another term.

[2]It is undisputed that claims 1 and 2 of the '783 patent claim genuses of compounds, as shown below:



Both claims 1 and 2 define R^1 the same way:



Both claims also define R^5 in parallel ways – as "a piperidinyl substituted by one to five [group of substituents separated by commas][;] or a group of the formula [compound figure shown]" –

In pertinent part, Claim 1 is of the following general format:

R^5 is a compound containing one to five A, B, C, D, E, F, G; or H.

Plaintiffs contend that H is part of the same disjunctive list of alternatives that may be contained in R^5 as are A through G. Therefore, R^5 could be, for example, a compound containing A, B, C, D, and H, or R^5 could be, as another example, a compound containing just H.[3] Defendants' view, by contrast, is that R^5 can ***either*** consist of one to five of A through G, ***or*** it can consist of H, ***but it cannot consist of a combination*** of any of A through G plus H. To Defendants, the "formula" for R^5 can be satisfied by what is before the semicolon or alternatively by what is after the semicolon. To Defendants, Plaintiffs are mistakenly treating the semicolon as if it were a comma.[4]

The Court agrees with Plaintiffs.

Plaintiffs argue that conjunctions, such as "and" or "or," are commonly placed before the last item on a list and indicate that all items before the conjunction as well as the one item after the conjunction are all part of the same list. (*See* D.I. 68 at 13) The Court agrees with Plaintiffs

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except that claim 1 has a semicolon where indicated and claim 2 instead has a comma. ('783 patent, cls. 1-2)

[3]Specifically, Plaintiffs' position is that the placement of the word "or" after the list of substituents separated by only commas indicates that what the parties have agreed to refer to as the "formula II group" ("H" in the Court's simplified example) is included with the previously-listed group of substituents from which one to five substituents may be substituted. (*See* D.I. 68 at 13)

[4]That is, Defendants' position is that if formula II is a substituent, none of the other listed substituents are permitted under the claim, because the use of a semicolon and the word "or" after a list separated by commas indicates that there are two groups of disjunctive substituents (i.e., one group of all the possible substituents separated by commas, and a second formula II group). (*See* D.I. 70 at 6-8)

that this is a well-established grammatical structure for use of conjunctions. It would be known to a person having ordinary skill in the art ("POSA").

Additionally, as Plaintiffs assert and Defendants do not deny, under Defendants' construction, "12 of the 25 Examples . . . would not be covered by ***any*** of the claims of the RE'783 patent." (*Id.* at 14) (emphasis added) "[W]here claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary." *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008). Defendants have not presented any intrinsic evidence, including in the prosecution history, supporting their position that 12 of the 25 Examples in the specification should be excluded from all claims of the patent. Similarly, Defendants' construction would exclude tofacitinib, the active ingredient in Xeljanz, thereby reading out of the patent the brand name drug. (*See* D.I. 68 at 11) Again, Defendants cite no support for why the patentee would have done this.

With respect to claim 1, the best (and perhaps only) point in Defendants' favor is the semicolon where a non-POSA would ordinarily expect a comma. But then Defendants seek the same construction for claim 2 – even though claim 2 ***does*** have a comma, just as one would expect, and not a semicolon. In the Court's view, this undermines whatever weight might otherwise be given to the semicolon in claim 1.

In the end, it seems most likely that the semicolon in claim 1 was due to error.[5] The

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[5]The Court is not entirely persuaded by Plaintiffs' view that claim 1's semicolon is intentional, to reflect that the last item in the list before the semicolon is itself a lengthy definitional phrase. That this might be correct certainly supports Plaintiffs' proposed construction, but the Court also finds it is quite possible the semicolon is a mistake.

record does not provide any other persuasive explanation. Even accepting that the reason for the semicolon is unclear, that lack of clarity supports Plaintiffs' proposed construction, as there is plainly no clear and unmistakable disavowal of claim scope.[6] At bottom, the Court finds that a POSA would read the claims in the manner Plaintiffs propose. Accordingly, the Court adopts Plaintiffs' proposed construction.

III. CONCLUSION

The Court construes the disputed and undisputed terms as explained above. An appropriate Order follows.

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[6]Defendants acknowledged at the hearing that the patent's uses of "or" are not consistent throughout. (*See* Tr. at 28) In this context, inconsistency and lack of clarity favors Plaintiffs' proposed construction.

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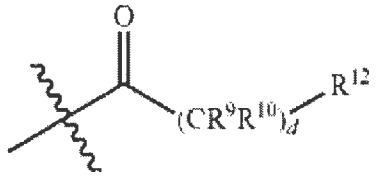
	:	Consolidated
MICRO LABS USA INC., et al.,	:	
	:	
Defendants.	:	
	:	

ORDER

At Wilmington, this **24th** day of **October, 2018**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the claim terms in this case are construed as follows:

Claim Term	**Court's Construction**
R^5 ('783 patent, cl. 1)	**Court** a piperidinyl that has 1 to 5 substituents selected from the group set forth in the claim which begins with "carboxy" and ends with "a group of the formula II," which group is further defined in the claim
R^5 ('783 patent, cl. 2)	a piperidinyl that has 1 to 5 substituents selected from the group set forth in the claim which begins with "carboxy" and ends with "a group of the formula  ," which group is further defined in the claim

3-{4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-r-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile ('783 patent, cl. 3)	3-{4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-r-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile free base

UNITED STATES DISTRICT JUDGE