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. 22-464-CFC-JLH (consolidated)
MYLAN LABORATORIES LIMITED, VIATRIS INC., and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Pending before the Court are the parties' claim construction disputes regarding five sets of terms across seven patents. The seven patents are U.S. Patent Nos. 8,338,427 (the "'427 patent"), 8,399,469 (the "'469 patent"), 10,525,057 (the "'057 patent"), 10,980,803 (the "'803 patent"), 11,154,553 (the "'553 patent"), 11,344,547 (the "'547 patent"), and 11,400,087 (the "'087 patent"). I held a *Markman* hearing on August 16, 2023 ("Tr. __.") and announced my recommendations from the bench at the conclusion of the hearing. I recommend that the Court adopt the constructions set forth below.

The parties agreed on the construction of one claim term.[1] In accordance with the parties' agreement, I recommend that the term be construed as follows:

	Term	Court
1	"Hydrate A of aripiprazole characterized by one or more of the properties chosen from" ('469 patent, claim 1)	"Aripiprazole hydrate having: (1) an endothermic curve characterized by the appearance of a small peak at about 71°C. and a gradual endothermic peak around 60°C. to 120°C.; (2) a 1H-NMR spectrum (DMSO-d6, TMS) having characteristic peaks at [specified levels]; (3) a powder x-ray diffraction spectrum having characteristic peaks at [specified levels]; (4) clear infrared absorption bands at [specified levels] on the IR (KBr) spectrum; and (5) a mean particle size of 50 μm or less; all as specifically defined in the specification of the '469 patent at 8:63–9:20."

Further, as announced at the hearing on August 16, 2023, I recommend that the following disputed claim terms be construed as follows:

	Term	Court
1	"comprising water, a viscosity enhancing agent, a wetting agent and a tonicity agent" ('427 patent, claim 9)	"comprising four separate ingredients: (1) water; (2) a viscosity enhancing agent; (3) a wetting agent; and (4) a tonicity agent"
2	"A method of initiating systemic aripiprazole treatment in a patient" ('057 patent, claims 1, 9, and 15)	The preamble is limiting. "A method of starting a patient on a particular dosing or medication regime involving systemically delivering aripiprazole to a patient"
3	"A method of treating schizophrenia in a patient" ('803 patent, claims 1, 6, 9, and 14)	The preamble is limiting.
4	"A method of treating schizophrenia or bipolar I disorder in a patient" ('553 patent, claims 1, 10, and 25; '547 patent, claims 1, 7, and 16; '087 patent, claims 1, 10, and 25)	The preamble is limiting.

[1] (D.I. 137 at 6.)

5	"administering of the long-acting suspension is avoided when the patient is taking a CYP3A4 inducer" ('547 patent, claims 1, 7, and 10)	This is a limitation.

I. LEGAL STANDARDS

The purpose of the claim construction process is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). When the parties have an actual dispute regarding the proper scope of claim terms, their dispute must be resolved by the judge, not the jury. *Id.* at 979. The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

"[T]here is no magic formula or catechism for conducting claim construction." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). But there are guiding principles. *Id.*

"The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* at 1313. In some cases, the ordinary meaning of a claim term, as understood by a person of ordinary skill in the art, is readily apparent even to a lay person and requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. Where the meaning is not readily apparent, however, the court may look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history,

and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.*

"The claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive." *Id*. Considering other, unasserted, claims can also be helpful. *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.

In addition, the "claims must be read in view of the specification, of which they are a part." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification "is always highly relevant to the claim construction analysis." *Id.* (quoting *Vitronics*, 90 F.3d at 1582). The specification may contain a special definition given to a claim term by the patentee, in which case, the patentee's lexicography governs. *Id.* at 1316. The specification may also reveal an intentional disclaimer or disavowal of claim scope. *Id.* However, "even 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 marks omitted).

Courts should also consider the patent's prosecution history. *Phillips*, 415 F.3d at 1317. It may 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.* Statements made by a patentee or patent

owner during inter partes review may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

In appropriate cases, courts may also consider extrinsic evidence, which "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 example, dictionaries, especially technical dictionaries, can be helpful resources during claim construction by providing insight into commonly accepted meanings of a term to those of skill in the art. *Phillips*, 415 F.3d at 1318. Expert testimony can also 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.*; *see also Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331-32 (2015).

II. DISCUSSION

The Court's report and recommendation was announced from the bench on August 16, 2023, as follows:

> I'm prepared to issue a report and recommendation on the claim construction disputes argued today. I will not be issuing a separate written report and recommendation. I want to emphasize that while I am not issuing a separate written report and recommendation, we have followed a full and thorough process before making the recommendations I'm about to state. There was full briefing on each of the disputed terms. The parties submitted their briefing in accordance with my procedures, so each side had the opportunity to submit two briefs, and they were combined into one joint claim construction brief incorporating all arguments. The parties' briefing also included numerous exhibits with intrinsic and extrinsic evidence.
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> My oral recommendation will cite to the evidence cited by the parties that I conclude best supports my proposed constructions, but my failure to cite to other evidence provided by the parties does

not mean that I ignored or failed to consider it. I want to be clear. We have carefully considered all of the arguments and cases cited by both sides. With respect to the cases, there were a lot of cases cited. We looked at them, and the parties did a good job pointing out differences between this case and those cases, and I agree that many of the claims and patents described in the case law are different than this case for one reason or another. But just because a case is different for one reason or another does not mean that the case is materially distinguishable.

I am not going to read into the record my understanding of the general legal principles of claim construction. I set forth the relevant standards in my opinion in *3Shape v. Align*,[2] and I incorporate that articulation by reference.

The parties agreed on at least one claim term construction, set forth at page 6 of the Amended Joint Claim Construction Chart at D.I. 137. I ask that the parties put that agreed-upon construction into an order that Judge Connolly can sign.

["comprising water, a viscosity-enhancing agent, a wetting agent and a tonicity agent"]

The first term to be construed is "comprising water, a viscosity-enhancing agent, a wetting agent and a tonicity agent." The term appears in claim 9 of the '427 patent.[3]

Plaintiffs assert that the phrase should be construed in accordance with its plain and ordinary meaning, which Plaintiffs propose is "comprising water and excipients functioning collectively as viscosity-enhancing, wetting, and tonicity agents." Defendants propose "comprising four separate ingredients: (1) water; (2) a viscosity-enhancing agent; (3) a wetting agent; and (4) a tonicity agent." The real dispute here is whether one excipient in

[2] *3Shape A/S v. Align Tech., Inc.*, No. 18-886, 2020 WL 2188857, at *1–2 (D. Del. May 6, 2020).

[3] Claim 9 recites:

> 9. A composition comprising a suspension of at least about 10 mg of aripiprazole and an aqueous injection vehicle comprising water, a viscosity enhancing agent, a wetting agent and a tonicity agent wherein upon administration of the composition the aripiprazole release is for at least 7 days.

the accused product can satisfy more than one of the agent claim limitations. Under Plaintiffs' construction, for example, the same excipient could be both a viscosity-enhancing agent and a wetting agent.

I agree with Defendants that a single excipient in a particular formulation cannot satisfy more than one of the agent limitations in claim 9. The claim lists four separate elements of the injection vehicle: (1) water, (2) a viscosity-enhancing agent, (3) a wetting agent, and (4) a tonicity agent. The Federal Circuit has repeatedly explained that where, as here, "a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention."[4] And that's in the *Becton, Dickinson* case, for example.

Nothing else in claim 9 or any of the rest of the claims suggests that a single excipient can satisfy more than one of the agent terms. Neither does the specification. It lists a number of example viscosity-enhancing agents, wetting agents, and tonicity agents, and the exemplary items on the list do not overlap. I point to Column 2, line 62 to Column 3, line 11. Instead, the specification discusses each agent separately.

So, in short, the claims suggest that the elements have to be distinct components, and nothing else in the claims or the specification or any other evidence changes my mind about that.

I reject Plaintiffs' argument in support of their proposed construction. Plaintiffs point out that the "four separate ingredients" language in Defendants' proposal does not appear in the claims or the specification. That is true, but the plain language of the claims suggests four separate ingredients, and that interpretation is entirely consistent with the specification and Federal Circuit law.

Plaintiffs further argue (1) that each of the agent limitations is not limited to the exemplary excipients disclosed in the specification for that agent (*e.g.*, the "viscosity-enhancing agent" term is not limited to the disclosed agents carboxymethylcellulose and sodium carboxymethylcellulose and would cover any agent that enhances viscosity) and (2) that a person of ordinary skill in the art

[4] *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004) and *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1404–05 (Fed. Cir. 1996)).

would generally understand that a given excipient can serve multiple pharmaceutical functions. Defendants agree with both of those propositions, and I find that both of those propositions are correct. But that doesn't change the fact that the appropriate claim construction requires the claimed injection vehicle to have four components.

The real dispute here, again, is whether a single excipient can meet multiple of the claimed agent limitations. Plaintiffs cite the Federal Circuit's opinion in *Bracco Diagnostics* for the proposition that sometimes a single component of a pharmaceutical formulation can satisfy two claim limitations.[5] However, that case is distinguishable at least for the reason that the claims themselves in that case suggested that a particular category of components could meet multiple claim elements.[6]

Accordingly, I recommend that the term "comprising water, a viscosity-enhancing agent, a wetting agent and a tonicity agent" be construed as "comprising four separate ingredients: (1) water; (2) a viscosity-enhancing agent; (3) a wetting agent; and (4) a tonicity agent."

["A method of initiating systemic aripiprazole treatment in a patient"]

The second term to be construed is "[a] method of initiating systemic aripiprazole treatment in a patient." It appears in claims 1, 9, and 15 of the '057 patent.[7]

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[5] *Bracco Diagnostics Inc. v. Maia Pharms., Inc.*, 839 F. App'x. 479 (Fed. Cir. 2020).

[6] *Id.* at 485–87.

[7] For example, claim 1 recites:

> 1. A method of initiating systemic aripiprazole treatment in a patient, comprising initially intramuscularly administering to the patient 66% to 75% of a 300 or 400 mg weight equivalent dose of aripiprazole in the form of a long-acting drug-containing suspension which systemically releases aripiprazole, wherein the dose is released over a period of about one month, and wherein the patient is a CYP2D6 and CYP3A4 extensive metabolizer and is concomitantly administered a strong CYP2D6 inhibitor or a strong CYP3A4 inhibitor.

Plaintiffs assert that this preamble phrase is limiting and should be construed in accordance with its plain and ordinary meaning, which Plaintiffs say is "a method that has been identified as a method of initiating systemic aripiprazole treatment in a patient, that treatment being for schizophrenia or bipolar I disorder." Defendants contend that the preamble phrase is not limiting. Alternatively, if the preamble phrase is limiting, Defendants propose the term be construed as "a method of administering the claimed dose for the first time to a patient." The disputes include whether the preamble phrase is limiting and, if so, how the phrase should be construed.

"[W]hether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim and the invention as described in the specification and illuminated in the prosecution history."[8] As the Federal Circuit explained in detail in *Eli Lilly v. Teva*, claim format is particularly relevant in determining whether a preamble is limiting.[9] Although there is no bright line rule, "with regard to claims directed to apparatuses or compositions, . . . preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim."[10] That's because apparatus claims cover what a device is, not what a device does. But even with respect to apparatus and composition claims, preamble statements of intended purpose have been found to be limiting where "the preamble provided antecedent basis for the structural terms in the body of the claim."[11] The Federal Circuit further explained that "[i]n contrast to apparatus or composition claims, claims to methods of using such apparatuses or compositions are not directed to what the method 'is,' but rather they typically rely entirely on what the method 'does.' And what a

[8] *Artic Cat Inc. v. GEP Power Prods, Inc.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019) (quoting *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012)).

[9] *Eli Lilly & Co. v. Teva Pharms. Int'l. GmbH*, 8 F.4th 1331, 1340 (Fed. Cir. 2021).

[10] *Id.* at 1340–41 (cleaned up) (quoting *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006)).

[11] *Id.* at 1341 (citing *Bicon*, 441 F.3d at 952–53.)

method does is usually recited in its preamble."[12] The Court went on to explain that its "claim construction analysis of statements of intended purpose in methods of using apparatuses or compositions has tended to result in a conclusion that such preamble language is limiting."[13]

Applying the Federal Circuit's guidance, I agree with Plaintiffs that the preamble phrase is limiting. The structure of these claims is a method of using a composition for an intended purpose. The preambles' references to "a patient" also provides antecedent basis to the claims' later references to "the patient." Although I think this can be resolved on claim language alone, I also note that treating the preamble as limiting is consistent with the specification, which evidences that the initiation of systemic aripiprazole treatment in a patient is central to the invention. The Abstract, Background, Summary of the Invention, and Detailed Description of the Invention all focus on the initiation of systemic aripiprazole treatment in certain patients.

Given my determination that the preamble is limiting, the next question is how or whether the preamble phrase should be construed. Plaintiffs' briefs proposed a construction that included the phrase "that has been identified." They have now withdrawn that proposed phrase, and I agree that that language is inappropriate.[14]

Plaintiffs still want to include the phrase "that treatment being for schizophrenia or bipolar I disorder." But I agree with Defendants that limiting the treatment to those disorders is inconsistent with both the claims and the specification of the '057 patent. The claims do not mention schizophrenia or bipolar disorders, and the specification says that "Aripiprazole can be administered to treat schizophrenia, bipolar mania (e.g., bipolar I disorder), depression, irritability associated with autistic disorder, agitation associated with schizophrenia or bipolar I disorder, and other psychological disorders." And that's at Column 1, lines 7 to 11. The specification thus expressly contemplates using aripiprazole to treat conditions other than schizophrenia and bipolar

[12] *Id.*

[13] *Id.*

[14] (Tr. 37:1–38:4.)

I disorder. For these reasons, I reject Plaintiffs' proposal to limit the claim to schizophrenia and bipolar I.

On the other hand, Defendants' proposal to construe the claimed "method of initiating . . . treatment" to mean "method of administering the claimed dose" is also not appropriate. I also disagree with Defendants' proposal to include the phrase "for the first time to a patient."

In light of what I just said, I proposed to the parties a construction that is consistent with the definition of "initiating aripiprazole treatment" in the specification at Column 2, lines 38 to 43, which says "'Initiating aripiprazole treatment' includes starting a patient on a particular dosing or medication regime involving systemically delivering aripiprazole to a patient. At the time of initiating aripiprazole treatment, the patient may have been previously treated with another drug, or by aripiprazole under a different dosing regime." I proposed a construction consistent with the first sentence of that at the hearing, and there were no disputes with it beyond those I've already addressed.[15]

Accordingly, I recommend that the term "[a] method of initiating systemic aripiprazole treatment in a patient" should be construed as limiting and that it be construed as "a method of starting a patient on a particular dosing or medication regime involving systemically delivering aripiprazole to a patient."

["A method of treating schizophrenia in a patient"]

The third term to be construed is "[a] method of treating schizophrenia in a patient." The term appears in claims 1, 6, 9, and 14 of the '803 patent.[16] The '803 patent is a continuation of the '057 patent and shares the same specification.

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[15] (Tr. 38:5–39:17, 51:22–52:12.)

[16] For example, claim 1 recites:

> 1. A method of treating schizophrenia in a patient comprising:
>
> intramuscularly administering to the patient a long-acting suspension of an adjusted dose of aripiprazole of about 300 mg or of aripiprazole prodrug of about 441 mg,

Plaintiffs assert that the preamble phrase is limiting and should be construed in accordance with its plain and ordinary meaning, which Plaintiffs propose is "a method that has been identified as a method of treating schizophrenia in a patient who has schizophrenia." Defendants contend that the preamble phrase is not limiting. Alternatively, if the preamble is limiting, then Defendants propose the term be construed as "a method of administering the claimed dose to a patient with schizophrenia." The disputes, again, are whether the preamble phrase is limiting and, if so, how the phrase should be construed.

For the same reasons as the last term, I agree with Plaintiffs that this preamble phrase is limiting.

As for how and if it should be further construed, the parties' arguments somewhat overlap with their arguments on the last term.

I again disagree with Defendants that the "method of treating schizophrenia" should be replaced with "method of administering the claimed dose," and Plaintiffs have dropped their request to include the phrase "that has been identified."[17]

Accordingly, I recommend that the term "[a] method of treating schizophrenia in a patient" should be construed as limiting. The term should not be construed further.

["[a] method of treating schizophrenia or bipolar I disorder in a patient"]

The fourth term to be construed is "[a] method of treating schizophrenia or bipolar I disorder in a patient." The term appears in claims 1, 10, and 25 of the '553 patent; claims 1, 7, and 16 of the '547 patent; and claims 1, 10, and 25 of the '087 patent.[18]

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wherein the dose is systemically released over a period of about one month, and the patient is a CYP2D6 poor metabolizer.

[17] (Tr. 52:14–53:11.)

[18] For example, claim 1 of the '553 patent recites:

Plaintiffs assert that this preamble phrase is limiting and should be construed in accordance with its plain and ordinary meaning, which Plaintiffs propose is "a method that has been identified as a method of treating schizophrenia or bipolar I disorder in a patient who has schizophrenia or bipolar I disorder." Defendants contend that the preamble phrase is not limiting. Alternatively, if the preamble is limiting, then Defendants propose the term be construed as "a method of administering the claimed dose to a patient with schizophrenia or bipolar I disorder." The disputes are whether the preamble phrase is limiting and, if so, how the phrase should be construed.

These disputes are the same as the previous disputes, and they should be resolved in the same way for the same reasons.

Accordingly, I recommend that the term "[a] method of treating schizophrenia or bipolar I disorder in a patient" should be construed as limiting. The term need not be construed further.

["administering of the long-acting suspension is avoided when the patient is taking a CYP3A4 inducer"]

The fifth and final term to be construed is "administering of the long-acting suspension is avoided when the patient is taking a CYP3A4 inducer." It appears in claims 1, 7, and 10 of the '547 patent.[19]

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1. A method of treating schizophrenia or bipolar I disorder in a patient comprising:

intramuscularly administering to the patient a long-acting suspension of an adjusted dose of aripiprazole of 200 mg or 160 mg and co-administering to the patient an oral antipsychotic after a first administration of said adjusted dose of the long acting suspension,

wherein the dose is systemically released over a period of about one month, and the patient has concomitant use of the CYP2D6 and CYP3A4 inhibitors.

[19] For example, claim 1 recites:

1. A method of treating schizophrenia or bipolar I disorder in a patient comprising:

Plaintiffs assert that the term is "limiting" and that it should be construed in accordance with its plain and ordinary meaning, although Plaintiffs do not otherwise propose a construction. Defendants assert that the term is "nonlimiting" and also do not propose further construction.

To support its argument that the term is "nonlimiting," Defendants rely on the so-called printed matter doctrine. That doctrine provides that "[c]laim limitations directed to printed matter are not entitled to patentable weight unless the printed matter is functionally related to the substrate on which the printed matter is applied," and that's the *Praxair* case.[20] The doctrine is somewhat of a misnomer [in] that the doctrine is not limited only to literal printed matter. Instead, the Federal Circuit has "held that a claim limitation is directed to printed matter 'if it claims the content of information.'"[21] "Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patentable subject matter under 35 U.S.C. § 101."[22]

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intramuscularly administering to a patient a long-acting suspension of an adjusted dose of aripiprazole of 200 mg or 300 mg,

wherein the dose is released over a period of about one month, the patient is concomitantly administered a strong CYP2D6 or CYP3A4 inhibitor, and

administering of the long-acting suspension is avoided when the patient is taking a CYP3A4 inducer.

[20] *Praxair Dist., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1031 (Fed. Cir. 2018) (citing *In re DiStefano*, 808 F.3d 845, 848 (Fed. Cir. 2015) and *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983)).

[21] *Id.* at 1032 (quoting *DiStefano*, 808 F.3d at 848).

[22] *Id.* "While the doctrine's underlying rationale is in subject matter eligibility, its application has been in analyzing other patentability requirements, including novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103." *Id.* (cleaned up) (citing *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) and *In re Huai-Hung Kao*, 639 F.3d 1057, 1072–74 (Fed. Cir. 2011)). "The printed matter doctrine thus raises an issue where the § 101 patent-eligibility inquiry and the § 102 and § 103 novelty and nonobviousness inquiries overlap." *Id.* at 1033.

In *Praxair*, the Federal Circuit said it is appropriate to "address[] the printed matter doctrine" during claim construction to the extent the Court's assessment only requires analyzing and interpreting the meaning of the claim language.[23] "The first step of the printed matter analysis is the determination that the limitation in question is in fact directed toward printed matter."[24] In other words, the first step is to see whether the limitation "claims the content of information."[25]

I disagree with Defendants that the disputed limitation "claims the content of information." The claim does not include merely the content of the information as to why patients taking a CYP3A4 inducer should not be given the claimed formulation. Instead, it directs that the long-acting suspension is not to be given to such patients as part of the claimed method. I therefore agree with Plaintiffs that the printed matter doctrine does not apply. The disputed phrase, although it implicitly relies on information—that patients taking a CYP3A4 inducer should avoid intramuscularly administered aripiprazole because such treatment is unlikely to be clinically effective for those patients—does not claim the content of that information. Instead, the term calls for taking a specific action as part of the claimed method—not administering something—in response to a certain trigger—a patient taking something else.

The limitations found to implicate the printed matter doctrine in the *Praxair* case are distinguishable because they either claimed the content of the information or merely required a medical provider to think about the information provided.[26]

To the extent the dispute is about the printed matter doctrine, I agree with Plaintiffs that it doesn't apply. That is all I need to say about these limitations at the claim construction phase of this case.

Defendants nevertheless cite to other portions of the *Praxair* opinion and the Federal Circuit's later opinion in *INO*

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[23] *Id.*

[24] *DiStefano*, 808 F.3d at 848.

[25] *Id.*

[26] *Praxair*, 890 F.3d at 1033–34.

> *Therapeutics*[27] to argue that the claims are invalid because they could be infringed by a physician who undertakes the mental analysis of determining whether a patient is taking a CYP3A4 inducer and then not doing anything. I agree with Defendants that there are some real questions here regarding the validity of these claims; however, my current referral of this case doesn't extend past claim construction disputes, and the parties have presented no further disputes regarding the meaning of the phrase "administering of the long-acting suspension is avoided when the patient is taking a CYP3A4 inducer."

And that concludes my report and recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which can be found on the Court's website.

Absent any objections, the parties shall file a Proposed Order consistent with this Report and Recommendation for the Court's approval.

Dated: September 12, 2023

The Honorable Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE

[27] *INO Therapeutics LLC v. Praxair Dist. Inc.*, 782 F. App'x. 1001 (Fed. Cir. 2019).