IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH,

Plaintiffs,

v.

INTELLIPHARMACEUTICS INTERNATIONAL INC., INTELLIPHARMACEUTICS CORPORATION, and INTELLIPHARMACEUTICS LTD., Civil Action No. 17-392-RGA

Defendants.

MEMORANDUM OPINION

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Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 9,060,976 ("the '976 patent"), 9,073,933 ("the '933 patent"), 9,522,919 ("the '919 patent"), 9,492,389 ("the '389 patent"), and 9,492,391 ("the '391 patent"). The Court has considered the parties' joint claim construction brief. (D.I. 85). The Court heard oral argument on June 22, 2018. (D.I. 128).

I. BACKGROUND

This suit arises from Defendants' filing a New Drug Application ("NDA"). Plaintiffs filed suit on April 7, 2017, alleging that the generic product that is the subject of the NDA would infringe six of Plaintiffs' patents. (D.I. 1). The patents-in-suit relate to OxyContin®, an extended-release pain medication. Plaintiffs have asserted the '976 and '933 patents in another action, No. 15-1152, in which I issued a *Markman* opinion. (Civ. Act. No. 15-1152, D.I. 120).

II. LEGAL STANDARD

"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). ""[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the 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." *Phillips*, 415 F.3d at 1315.

"[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. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *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).

III. PATENTS-IN-SUIT

The '976 patent is directed to an abuse deterrent dosage form of OxyContin®. The sole

claim of that patent reads as follows:

1. An extended release abuse deterrent dosage form comprising:

a. a core matrix comprising a blended mixture of:

(a) PEO having a molecular weight of from about 300,000 daltons

to about 5,000,000 daltons;

(b) magnesium stearate; and

(c) oxycodone or a pharmaceutically acceptable salt thereof; wherein the core matrix is heated to melt at least a portion of the PEO

included in the core matrix during preparation of the dosage form; and b. PEG applied onto the core matrix;

wherein the dosage form provides extended release of the drug.

('976 patent, claim 1) (disputed term italicized).¹

The '933 and '919 patents are directed to oxycodone formulations having low amounts of

14-hydroxycodeinone and 8a, respectively. Claim 1 of the '933 and claim 1 of the '919 patent

are representative. They read:

1. An *oxycodone hydrochloride* composition which comprises *at least* 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.

('933 patent, claim 1) (disputed terms italicized).

1. An *oxycodone HCl* composition comprising oxycodone HCl and 8α ,14dihydroxy-7,8-dihydrocodeinone, wherein *the ratio* of 8α ,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl *is 0.04% or less as measured by HPLC*.

('919 patent, claim 1) (disputed terms italicized).

¹ The '976 patent was the subject of an *inter partes* review. The PTAB invalidated the patent. There is an appeal pending in the Federal Circuit.

The '389 and '391 patents are directed to cured pharmaceutical dosage forms. Claim 1 of

the '389 patent and claim 20, which depends from claim 1, are representative. They read as

follows:

1. A cured shaped pharmaceutical tablet comprising:

(1) at least a first compression shaped and then air cured matrix, wherein *said* curing is without compression, by heated air having a temperature of at least about 62° C. for a duration of at least about 5 minutes, said matrix comprising an opioid or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and optionally further comprising at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000;

(2) optionally a second air cured matrix comprising an opioid or a pharmaceutically acceptable salt thereof in combination with at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000; and

(3) optionally a coating,

wherein, in said tablet:

said high molecular weight polyethylene oxide is at least 54% by weight of the total weight of said uncoated tablet;

low molecular weight polyethylene oxide, if present, is at least 10% by weight of the total weight of said uncoated tablet; and

said tablet provides a once-daily or twice-daily extended release of said opioid or pharmaceutically acceptable salt thereof from said tablet.

('389 patent, claim 1) (disputed term italicized).

20. A cured shaped tablet according to claim 1, wherein, after a plurality of at least 100 of *the same tablets* are stored at 40° C. and 75% relative humidity for at least 3 months, a set of at least ten of said stored tablets, on average, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37° C., in the absence of an added stabilizer, release an amount of said opioid or pharmaceutical salt thereof, after 1 hour, 4 hours, and 12 hours, that deviates from an initial dosage amount of said opioid or pharmaceutically acceptable salt thereof by no more than about 10% points.

(Id. at claim 20) (disputed term italicized).

IV. CONSTRUCTION OF DISPUTED TERMS

1. "PEO having a molecular weight of from about 300,000 daltons to about 5,000,000 daltons"

- a. *Plaintiffs' proposed construction*: "one or a combination of polyethylene oxides having an overall weight average molecular weight of from about 300,000 daltons to about 5,000,000 daltons"
- b. *Defendants' proposed construction:* "a measurement of the weight of a molecule or an average weight of a composition of polymer molecules, including weight-average molecular weight, number average molecular weight, or viscosity-average molecular weight"
- c. *Court's tentative construction*: "one or a combination of polyethylene oxides having an average molecular weight of from about 300,000 daltons to about 5,000,000 daltons"

The parties primarily dispute whether, as Plaintiffs argue, the "molecular weight" of the recited polyethylene oxide ("PEO") is an "overall weight average molecular weight," or whether, as Defendants maintain, the "molecular weight" can include weight-average, number-average, or viscosity-average.

As support for their proposed construction, Plaintiffs point to my *Markman* opinion in Civil Action No. 15-1152, in which I construed a term similar to the PEO term here. (D.I. 85 at 21; *see* Civ. Act. No. 15-1152, D.I. 120 at 8–10). But, as Plaintiffs acknowledge, unlike the patent in which the term appeared in that case, the '976 patent does not define PEO as having a particular molecular weight by reference to a specific test performed on a specific instrument. Thus, I do not find my prior construction particularly helpful in this case.

Plaintiffs further argue the intrinsic evidence supports their construction because in characterizing PEO, the patent only ever refers to average molecular weight as weight-average. (*See* D.I. 85 at 23–24).

I agree with Plaintiffs that the intrinsic evidence suggests the inventors were referring to weight-average molecular weight. (See, e.g., '976 patent, 23:35–39 (referring to "weightaverage molecular weight" of PEO)). As Defendants pointed out in the briefing and at the Markman hearing, however, the application that resulted in the '976 patent originally included claims that referred to the "weight-average molecular weight of" PEO. (See, e.g., D.I. 86-6 at 27). After cancelling those claims, it seems the applicants drafted a new claim referring only to the "molecular weight" of PEO. (See id. at 12). At the hearing, Plaintiffs asserted, "[T]he amendment wasn't made to change scope in response to an office action.... What it had to do with was provoking an interference." (D.I. 128 at 10:24–11:2). To provoke the interference, Plaintiffs explained, the applicants copied a claim from the Kumar patent. (Id. at 11:4–6). Plaintiffs stated, "[A] settlement was reached . . . with the declaration of priority in Purdue's favor." (Id. at 33:6-8). As Defendants point out, however, the claim was later amended. (See D.I. 86-6 at 35). Those amendments added, among other things, language indicating that the unit of the recited molecular weights is "daltons." (See id.). The applicants did not amend the "molecular weight" term, however, or otherwise clarify that "molecular weight" refers specifically to "weight-average molecular weight."

Considering this prosecution history, I do not think it would make sense to construe "molecular weight" as "weight-average molecular weight." The applicants drafted a new claim without any reference to "weight-average molecular weight," albeit to provoke an interference, and then later amended the claim without limiting the scope of the "molecular weight" term. While the applicants could have clarified the meaning of the term, they chose not to. *Cf. In re Rambus Inc.*, 694 F.3d 42, 47 (Fed. Cir. 2012) ("To the extent [the patentee] wanted to limit [the scope of the claim], it could have expressly done so."). Indeed, the prosecution history indicates

that when the applicants wanted to limit "molecular weight" to "weight-average molecular weight," they knew how to do so. Thus, I decline to adopt Plaintiffs' proposed construction.

Though I agree with Defendants that "molecular weight" in the claim should not be limited to "weight-average molecular weight," I decline to include the additional language proposed by Defendants, that is, "including weight-average molecular weight, number average molecular weight, or viscosity-average molecular weight." In my opinion, that language improperly imports into the claims different ways of measuring molecular weight. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004) ("[I]t is improper to read a limitation from the specification into the claims."). Nor do I agree with Defendants that the patent contemplates measuring "the weight of a molecule" of PEO. Finally, I see no reason to exclude from the construction, as does Defendants' proposal, the molecular weights in the disputed term—"about 300,000 daltons to about 5,000,000 daltons."

For the reasons stated above, I will tentatively adopt the following construction for this term, which I note was not proposed by either Plaintiffs or Defendants: "one or a combination of polyethylene oxides having an average molecular weight of from about 300,000 daltons to about 5,000,000 daltons." The parties are invited to comment on this construction by letter submission to the Court.

2. "oxycodone hydrochloride" and "oxycodone HC1"

- a. *Plaintiffs' proposed construction*: No construction necessary, but, if construed, the plain and ordinary meaning: "hydrochloride salt of oxycodone"
- b. *Defendants' proposed construction*: Plain and ordinary meaning: "a specific salt (hydrochloride salt) of oxycodone as shown in Figure 1"
- c. Court's construction: "hydrochloride salt of oxycodone"

The parties seem to agree that "oxycodone hydrochloride" or "oxycodone HCl" means "hydrochloride salt of oxycodone." They dispute whether these terms should be limited to the specific salt of oxycodone in Figure 1 of the patents. Defendants argue they should be so limited (D.I. 85 at 56) while Plaintiffs argue they should not (*id.* at 58).

I agree with Plaintiffs.

As a general matter, it is improper to import limitations from the specification into the claims. *Liebel-Flarsheim Co.*, 358 F.3d at 904. Here, I see no support for Defendants' attempt to limit these terms to the specific salt in Figure 1. Other than arguing that Figure 1 is the only form of oxycodone hydrochloride depicted in the patents (D.I. 85 at 59–60), Defendants cite no intrinsic evidence suggesting the patentee intended Figure 1 to limit the claims.

Since the parties generally seem to agree that the plain meaning of "oxycodone hydrochloride" or "oxycodone HCl" is "hydrochloride salt of oxycodone," I will adopt that construction.

3. "at least 95%"

- a. *Plaintiff's proposed construction*: "95% or more of the weight of the material"
- b. *Defendant's proposed construction*: "95% or more calculated by the w/w, w/v, or HPLC peak area ratio method"
- c. Court's construction: "95% or more of the weight of the material"

The parties agree the "at least 95% oxycodone hydrochloride" can be measured by weight/weight and weight/volume. (*See* D.I. 85 at 61, 62). They dispute whether it can also be measured by HPLC peak area ratio method. Plaintiffs argue the "at least 95%" "refers to the purity of oxycodone HCl on a weight basis" (*id.* at 62) while Defendants maintain the claim language "is broader" than weight percentage (*id.* at 63).

I agree with Plaintiffs.

While the claim language does not explicitly limit this term to weight measurement, it seems to me that when read in the context of the surrounding claim language, "at least 95%" refers to the weight of the oxycodone hydrochloride relative to the claimed composition. The claim in which the disputed term appears reads: "An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride . . . and less than 25 ppm of 14-hydroxycodeinone." ('933 patent, claim 1). The only measurement referenced in the claim is parts-per-million ("ppm"), which, without dispute, is a weight-based measurement. In my opinion, when "at least 95%" is read together with the surrounding language, namely, "less than 25 ppm of 14-hydroxycodeinone," it seems clear to me that "at least 95%" refers to the weight of the material. I think that in attempting to construe this term to include measurement by HPLC peak area ratio, Defendants ignore the context in which the term appears. Further, while, as Plaintiffs acknowledge, the specification discloses "HPLC-based methods for measuring the purity of oxycodone hydrochloride . . . in Examples 4 and 6" (D.I. 85 at 61), I do not think those examples require that this term be construed to include measurement by HPLC peak area ratio.

For the reasons stated above, I will construe this term to mean, "95% or more of the weight of the material."

4. "the ratio . . . is 0.04% or less as measured by HPLC"

- a. *Plaintiff's proposed construction*: "0.04% or less, as calculated using HPLC peak area"
- b. *Defendants' proposed construction*: "0.04% or less, calculated by the w/w ratio or peak area ratio following an HPLC measurement"
- c. *Court's construction*: "0.04% or less, as calculated using HPLC peak area"

The parties dispute whether, as Plaintiffs argue, "0.04% or less" refers to the amount of the impurity 8 α calculated using HPLC peak area ratio, or whether, as Defendants argue, it refers to the amount of 8 α calculated by HPLC peak area or weight/weight ratio following an HPLC measurement.

According to Plaintiffs, "unambiguous language" in the patent "makes clear that the ratio as measured by HPLC is the ratio of peak areas, i.e., the peak area of 8α to the peak area of oxycodone HCl." (D.I. 85 at 67). They point to example 3 in the '919 patent, which discusses analysis by HPLC peak area ratio of "8,14-dihydroxy-7,8,-dihydrocodeinone." (*Id.* at 66–67).

Defendants respond that their "construction accounts for both types of calculations . . . disclosed in the '919 patent specification, whereas Plaintiffs' argument is [] improperly based on the disclosure in examples without any 'words or expressions of manifest exclusion or restriction." (*Id.* at 67 (citation omitted)). They point to a declaration submitted to the U.S. Patent Office by one of the inventors, in which, according to Defendants, the inventor demonstrated "intent to equate 'ppm' numbers with '%' numbers when discussing the 8 α impurity . . . including the '0.290%' and '0.040%' values presented in [the] data table." (*Id.* at 68 (citation omitted)).

As an initial matter, I agree with Plaintiffs that the plain language of the disputed term supports their construction. The term refers to "the ratio" of 8 α "as measured by HPLC." Nowhere does the claim refer to measurement by weight/weight ratio. I think example 3 further supports their construction. Example 3 provides, "Analysis by HPLC showed that the ratio of the area of the 8,14-dihydroxy-7,8-dihydrocodeinone peak to that of oxycodone was reduced from 0.29% to 0.04% during this time." ('919 patent, 26:47–50). Although, as the parties point out, the patent defines "8,14-dihydroxy-7,8-dihydrocodeinone" as including 8 α , 8 β , or a mixture

of the compounds, I think example 3 is relevant to the extent it sheds light on the context in which the patentee was referring to the measurement of 8α in the claims. Further, contrary to Defendants' contentions, I do not think the inventor's referring to "0.290% of 8α " as a "ppm" value makes clear this term includes measuring the amount of 8α by weight/weight ratio. It seems clear to me, and Defendants do not seem to dispute, that the table to which the inventor refers in the declaration cited by Defendants "shows the amounts of" 8α as measured by HPLC peak area ratio. (*See* D.I. 86-6 at 118).

I will construe this term to mean, "0.04% or less, as calculated using HPLC peak area."

5. Conditions for "curing"

- a. *Plaintiffs' proposed construction*: "the curing is carried out without simultaneously shaping the tablet by compression, using heated air having a temperature of about 62° C or higher, for a duration of about 5 minutes or longer"
- b. Defendants' proposed construction: "A process step element in a product-by-process claim: the curing is carried out without simultaneously shaping the tablet by compression, using heated air having a temperature of about 62° C or higher, for a duration of about 5 minutes or longer, whereas the method of measuring temperature and curing time may include, but is not limited to, methods 1, 2, 3, and 4, as described in the specification"
- c. *Court's construction*: no construction necessary; plain and ordinary meaning; "without compression" means "without simultaneously shaping the tablet by compression"

The parties' dispute regarding this term is twofold. First, they dispute whether to include language identifying the term as a "process step." Second, they dispute whether to include the language proposed by Defendants, "whereas the method of measuring temperature and curing time may include, but is not limited to, methods 1, 2, 3, and 4, as described in the specification."

As to the first dispute, Plaintiffs agreed at the *Markman* hearing that this term is a process step. (D.I. 128 at 45:8–9; *see also id.* at 44:17–45:3). Thus, I understand the first dispute to have

been resolved and see no reason to include Defendants' proposed language in the construction for this term.²

As to the second dispute, Plaintiffs argue that including Defendants' proposed language would be "unnecessary and improper." (D.I. 85 at 72). They maintain, "Stating that one 'may use . . . but is not limited to' the referenced methods of measuring temperature and time renders those methods as merely optional and not actual limitations." (*Id.*).

Defendants respond that Plaintiffs' proposal "do[es] not add clarity and would render the claims indefinite." (*Id.* at 73). According to Defendants, "After defining 'curing time,' the McKenna patents set forth multiple alternative ways for setting and measuring the curing temperature and determining when the curing time starts." (*Id.* at 74). Defendants criticize Plaintiffs' proposal for merely "regurgitati[ng] [] the words in the claims themselves." (*Id.*).

I agree with Plaintiffs. The additional language proposed by Defendants, that the "method of measuring temperature and curing time may include, but is not limited to" four methods disclosed in the specification, is wholly optional and thus in no way limits the "curing" process of the claim. Given that the language is optional, I do not see how, according to Defendants, the language is "useful to resolve the issue of how the curing temperature and curing duration in the claims is determined." (D.I. 128 at 45:16–18). Further, the specifications refer to measuring curing time by "any one of methods 1, 2, 3, or 4" where "curing takes place in a convection curing device." ('389 patent, 21:37–39; '391 patent, 21:36–38). To the extent incorporating Defendants' proposed language would import the "convection curing device" embodiment into the claims, doing so would be improper. *See Liebel-Flarsheim Co.*, 358 F.3d at

² I note that what seems to be in dispute between the parties, that is, whether the curing process of the claim causes a structural difference in the product, relates to patent validity, not claim construction, and thus will be an issue for trial.

904 ("[I]t is improper to read a limitation from the specification into the claims."). In any event, I see no reason to include the optional language proposed by Defendants.

The remaining language in the parties' proposed constructions for the most part reiterates conditions for "curing" expressly stated in the claims. More specifically, the parties include in their proposals, "using heated air having a temperature of about 62° C or higher, for a duration of about 5 minutes or longer." Because those conditions are stated in the claims, I see no reason to include them in the construction for this term. Those conditions for "curing" will be construed according to their plain and ordinary meaning. The only term the parties' proposals appear to construe is "without compression." As to that term, the parties seem to agree that "without compression," means, "without simultaneously shaping the tablet by compression."

6. "the same tablets"

- a. *Plaintiffs' proposed construction*: "tablets of claim 1 having the same formulation and manufactured by the same process as each other"
- b. *Defendants' proposed construction*: "tablets of claim 1 having the same formulation and manufactured by a process or processes that include the curing step according to claim 1, which may have been manufactured with processes that are different in other respects and/or stored under different conditions from each other"
- c. Court's construction: "tablets of claim 1"

The parties dispute the meaning of the phrase, "the same tablets." Plaintiffs argue a person of ordinary skill would understand "the same tablets" as "having the same formulation, and having been manufactured by the same process and subject to the same storage conditions." (D.I. 85 at 89). Plaintiffs cite, among other things, portions of the specification discussing the storing of tablets in "100 count bottles." (*See id.* at 90 (citation omitted)).

Defendants respond that their "proposed construction takes into account that all claim limitations of claim 1 are incorporated into claim 20 by claim dependency." (*Id.* at 91). They contend, "However, beyond that, there is no requirement that all aspects of the manufacturing of the tablets and the storage conditions of the tablets before the recited storage and testing must be exactly the same." (*Id.* (emphasis omitted)).

In my opinion, the plain language of the claims indicates that "at least 100 of the same tablets" refers to at least 100 tablets that meet the limitations of claim 1.

Claim 20 of the '389 patent provides, "A cured shaped tablet according to claim 1, wherein, after a plurality of at least 100 of the same tablets are stored" ('389 patent, 164:16–17). It seems clear to me that "the same tablets" refers to the antecedent "cured shaped tablet according to claim 1." Claim 20 of the '391 patent provides, "A method according to claim 1, wherein, after a plurality of at least 100 of the same tablets are stored" ('391 patent, 165:5–6). Claim 1 in that patent recites "[a] method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising" various limitations. (*Id.* at 163:35–36). As to the '391 patent, it seems clear to me that "the same tablets" refers to the antecedent "pharmaceutical tablet" in claim 1. Thus, when read in the context of the surrounding claim language, "the same tablets" are "cured shaped tablet[s] according to claim 1" in the '389 patent and "pharmaceutical tablet[s]" of claim 1 in the '391 patent.

I see nothing in the intrinsic record suggesting that "the same tablets" in the context of the claims are in fact tablets with "the same formulation and manufactured by the same process as each other." Nor do I see any reason to include the additional language proposed by

Defendants, that the tablets "may have been manufactured with processes that are different in other respects and/or stored under different conditions from each other."

For the reasons stated above, I will construe this term to mean, "tablets of claim 1."

V. CONCLUSION

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Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.