IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Civil Action No. 1:15-cv-10698-MLW Civil Action No. 1:16-cv-11117-MLW **CONFIDENTIAL – FILED UNDER SEAL** [*Leave to File Overlength Brief Granted on 12/30/16*]

OPPOSITION TO JANSSEN'S MOTION *IN LIMINE*
TO LIMIT TESTIMONY OF MICHAEL GLACKEN, SC.D.

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I. Introduction

Janssen's motion focuses on preventing Defendants' cell culture media expert, Dr. Michael Glacken, from testifying about what the law is or should be. But as we have explained to Janssen's counsel, Dr. Glacken will offer no such testimony. Further, the parties have now agreed that issues of ensnarement and indefiniteness will be addressed in post-trial briefing and, if necessary and appropriate, a separate hearing—thus mooting Sections I.D. and IV. of Janssen's motion. Janssen's remaining arguments improperly seek to exclude scientific opinions tied directly to jury issues, and should therefore be rejected.

First, Janssen's suggestion that Dr. Glacken has offered no opinions on "central scientific propositions" (Dkt. 343 at 1) grossly mischaracterizes his testimony. Dr. Glacken submitted a 90-page non-infringement report detailing, among other flaws in Janssen's theory, that "the accused products contain multiple claimed ingredients that are more than double the maximum claimed concentrations or less than half the minimum claimed concentrations[,]" and further explaining why Janssen's testing "does not sufficiently address whether each individual missing ingredient performed substantially the same function, substantially the same way, for substantially the same result." *See* Ex. 1 (Glacken Rebuttal Report) ¶¶ 70, 177, 183, 195.[1] Dr. Glacken's scientific opinions as to non-infringement are all relevant and unchallenged under *Daubert*. Thus, they are admissible. In fact, Janssen makes no real effort to argue otherwise. Instead, it focuses on trying to limit Dr. Glacken's ability to speak about the law—which, again, is not Defendants' intent.

[1] References to "Ex." refer to the Exhibits attached to the Declaration of Melinda K. Lackey, submitted in support of Defendants' Opposition to Janssen's Motion *in limine* to Limit Testimony of Michael Glacken, Sc.D.

Second, Janssen hopes to hide from the jury that it has taken dramatically inconsistent positions on claim scope to support its theories of infringement and non-obviousness. For example, to support his infringement theory, Janssen's Dr. Butler opined that "the precise concentrations" claimed in the patent "are not critical." Ex. 2 (Butler Opening Report) ¶ 42. But he took the opposite position to avoid prior art that plainly renders the asserted claims obvious—emphasizing that each of these same claim limitations has "a clearly defined" and "tailored" "concentration range (described in the claim by upper and lower limits)" that is "important" to the claimed invention. Ex. 3 (Butler Rebuttal Report) ¶¶ 168, 175; Ex. 4 (Butler Dep.) at 60:18-61:10. Janssen cannot have it both ways. As Janssen readily concedes, "claims must be construed consistently both for validity and infringement." Dkt. 343 at 16-17 (citation omitted). Thus, unless Janssen is willing to abandon one of its theories as to claim scope, Defendants are well within their right to inform the jury how Janssen's theories contradict each other.

Finally, Janssen misconstrues the law when challenging Defendants' obviousness theories. According to Janssen, Dr. Glacken needed to point to a "***particular experiment*** that would supposedly result in the particular combination of ingredients and ranges claimed in the '083 patent or that would motivate a scientist to reach that result." Dkt. 343 at 22 (emphasis added). That is not the law. Under Supreme Court precedent, the jury may use several "flexible" and "common sense" approaches to analyzing whether the '083 patent is obvious, including whether the asserted claims are directed to "a combination which only unites old elements with no change in their respective functions." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415-16 (2007). And "the motivation to combine prior art references" is a "factual issue" for the jury. *See e.g., Commonwealth Sci. & Indus. Res. Organisation. v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1376-77 (Fed. Cir. 2008). This case is no exception. Nor can Janssen ignore precedent holding that "[w]here a

claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).

As discussed in greater depth below, Janssen's motion *in limine* to limit Dr. Glacken's testimony should be denied—in part as moot and in part on the merits.

II. Dr. Glacken should be allowed to present all of his scientific opinions relating to Janssen's theory of infringement under the doctrine of equivalents (aside from ensnarement).

Janssen argues that "Dr. Glacken should not be allowed to testify before the jury as to purported legal limitations on the doctrine of equivalents." Dkt. 343 at 2. But again, Dr. Glacken will not testify about the state of the law, and the parties will address the jury instructions and verdict form according to the Court's process. As detailed below, Dr. Glacken will offer many scientific opinions that debunk Janssen's unprecedented and otherwise untenable infringement theory. His scientific opinions are highly probative, unchallenged under *Daubert*, and admissible.

A. Janssen grossly mischaracterizes the scope of Dr. Glacken's opinions.

Janssen begins its argument by asserting: "Dr. Glacken has not opined that the differences between the Celltrion media and claim 1 of the '083 patent are substantial as a matter of science." Dkt. 343 at 4. Janssen's characterization is demonstrably false.

First, Janssen asserts that Dr. Glacken "did not opine in [his] expert report about insubstantiality of the differences" between the accused products and the asserted claims. *Id.* at 4-5 (quoting Glacken Dep. 201:19-202:03). As Janssen well knows, Dr. Glacken offered many such opinions in his non-infringement report. A single, out-of-context sound bite from Dr. Glacken's deposition does not change the fact that his 90-page non-infringement report offered numerous opinions challenging Janssen's application of both the insubstantial differences and function-way-result tests for equivalence. Indeed, in the same answer that Janssen cites, Dr. Glacken made it very clear that he thought Janssen's question concerned the burden of proof, and he "d[id] not believe" Janssen

satisfied its "burden of proving infringement by preponderance of the evidence." Ex. 5 (Glacken Dep.) 201:17-202:3). While Janssen would have the Court believe that Dr. Glacken somehow admitted equivalence, nothing could be further from the truth.

For example, Dr. Glacken laid out the substantial differences between the accused products and the asserted claims in Tables 3–6 of his report, explaining that [redacted] Ex. 1 (Glacken Rebuttal Report) ¶ 70. And "it is well known to a POSA [i.e., a person of ordinary skill in the art] that various ingredients frequently included in cell culture media (and that are included in the accused products here) perform ***different functions*** at ***different concentrations***." Ex. 1 (Glacken Rebuttal Report) ¶ 176 (emphasis added). As Dr. Glacken put it at his deposition: [redacted] Ex. 5 (Glacken Dep. 254:20-255:5) (emphasis added). He also expressly testified that [redacted] *Id.* 252:2-9, 253:7-18, 253:19-254:5 (emphasis added). Indeed, Dr. Glacken repeatedly disputed in his report that the differences between the asserted claims and the accused products are insubstantial.[2]

[2] *See, e.g.*, Ex. 1 (Glacken Rebuttal Report) ¶ 52 (disputing that "accused products" are "insubstantially different from the '083 claims 1 and 2" given that [redacted] and thus "do not meet the stated goal of the claims"), ¶ 76 ("Prof. Butler does not provide any standard for how he evaluates an 'insubstantial' or 'close' difference" and "no testing to support his characterizations of 'insubstantial' or 'close' difference with respect to an ingredient's function or concentration."), ¶ 78 (Prof. Butler did not "articulate any scientific basis for evaluating whether the differences in the amounts of the ingredients are actually 'insubstantial' as he alleges."), ¶¶ 80-81 ("Prof. Butler adopts a broad functional test under which, in his opinion, [redacted] ¶¶ 135-36 (Prof. Wurm purported to test "'the substantiality (or lack

As Dr. Glacken's report further explains, these substantial differences are meaningful because, among other reasons, "the inventors could have tried to define their invention in functional terms (e.g., 'a sufficient amount present to fulfill the biological function of the element'), but they did not do that. Instead, they chose specific concentration ranges, which the PTO accepted with modification." Ex. 1 (Glacken Rebuttal Report) ¶ 73. While Janssen's Dr. Butler declared "the concentration limits of the asserted claims to be 'not critical,'" Dr. Glacken responded by saying "the way that I read Prof. Butler's report, he essentially is saying a POSA would ignore the claimed concentration ranges altogether. I disagree." *Id.* ¶ 74; *see also id.* ¶ 71. For example, [redacted] Dr. Glacken clearly said in his report that "***I disagree***" with Dr. Butler's conclusion that "[redacted]." *Id.* ¶ 75 (emphasis added) (internal quotations omitted).

Dr. Glacken further explained how Janssen's theory of "insubstantial differences" raises significant, practical problems for a skilled artisan assessing whether a competing product would infringe. Although Janssen's experts would have the jury believe that [redacted]

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thereof) of the literal differences between the [HyClone products] and claim 1,'" but he "did not run the same type of experiment as described in the '083 patent."), ¶¶ 171-72 (Prof. Wurm's testing and conclusion as to insubstantial differences "provides no information as to whether each claimed element that does not literally infringe the claims in the accused products, functions in substantially the same way to provide substantially the same results as the patented invention."), ¶ 177 ("In my opinion, merely looking at [redacted], like Prof. Wurm did, does not sufficiently address whether each individual missing ingredient performed substantially the same function, substantially the same way, for substantially the same result."), ¶ 183 ("[B]y merely looking at [redacted], Prof. Wurm did not sufficiently address whether the ingredients-at-issue at HyClone's concentrations performed substantially the same function, substantially the same way, for substantially the same result."), ¶ 195 ("[L]ike Prof. Wurm, Prof. Butler performed no testing or analysis to determine whether the ingredients-at-issue (i.e., those that are not literally satisfied in the accused media) perform the same function in substantially the same way to provide substantially the same result as those in claim 1.").

[redacted]

such contrived analysis ignores how a POSA would actually understand the patent. *See id.* ¶¶ 79, 80 (Prof. Butler provided [redacted]. As Dr. Glacken explained, under Janssen's theory, "a POSA considering whether to make a soluble composition that includes at least the 52 ingredients required by claim 1 (all of which were used to prepare cell culture media at the time) would have to conduct extensive and expensive testing to assess infringement—even if [redacted] and recited ingredients far beyond the scope of the claimed concentration ranges." *Id.* ¶ 86. Yet the patent discloses no testing protocol for such an analysis. *Id.* ¶ 41, 139.

According to Dr. Glacken, the many differences here are significant because "applying the doctrine of equivalents under the circumstances here would not give a skilled artisan fair notice that the accused products infringe the asserted claims of the '083 patent." *Id.* ¶ 89. Therefore, "a POSA reading claims 1 and 2—including the specific concentration limitations of claim 1—would ***not*** conclude that either of these claims could reasonably be expanded under the doctrine of equivalents to cover the accused products here." *Id.* (emphasis added).

Janssen also relies on deposition testimony from Dr. Glacken that it [redacted] of Dr. Wurm's testing, because [redacted] Dkt. 343 at 5. This offhand remark minimizing Dr. Wurm's testing results does not alter any opinions timely disclosed in Dr. Glacken's report. For example, although not the primary basis for his opinions, Dr. Glacken found that Dr. Butler's own analysis revealed [redacted] Ex. 1 (Glacken Rebuttal Report) ¶ 131 [redacted]

[redacted] *see also id.* ¶¶ 152-54; Ex. 5 (Glacken Dep.) at 187:17-188:5; 189:7-23. Notably, Janssen's brief ignores that Defendants submitted a separate expert report from a biostatistician, Dr. Rebecca Betensky, who offered more detailed testimony as to the [redacted] Ex. 6 (Betensky Report).

In short, Janssen has absolutely no basis to assert that Dr. Glacken "fail[ed] to address the central scientific propositions." Dkt. 343 at 1. Indeed, as discussed below, Dr. Glacken's scientific opinions applying the tests for assessing insubstantial differences are all both relevant and admissible—and, we submit, devastating to Janssen's infringement case.

B. Janssen has no basis to bar Dr. Glacken's opinion that a POSA would view the concentration limitations narrowly in view of the intrinsic record.

Janssen next argues that "Dr. Glacken should be limited to testifying about the relevant scientific evidence" and barred from testifying that "the concentration ranges in the '083 patent preclude application of the doctrine of equivalents." Dkt. 343 at 6, 10 (citing Glacken Rebuttal Report ¶¶ 61-62). Again, Dr. Glacken will not offer opinions as to what the law is, or what it should be. To the extent that covers Janssen's point, there is no dispute.

Importantly, Janssen concedes that Dr. Glacken can testify "about the relevant scientific evidence." Dkt. 343 at 6. This includes, among other things, his scientific opinions as to how a POSA would understand the importance of the concentration limitations based on the intrinsic record as a whole. For example, Dr. Glacken can take the jury through the patent specification, including its sole embodiment (a composition known as MET 1.5), and explain how a POSA would understand the purpose and disclosures of the patent in view of the intrinsic record. *See e.g., SSL Services, LLC v. Citrix Sys., Inc*., 940 F. Supp. 2d 480, 492 (E.D. Tex. 2013) (expert testimony comparing the accused products to preferred embodiments of the patent was proper and "amounted

to nothing more than an effort to educate the jury about the teachings of the [] patent"), *aff'd,* 769 F.3d 1073 (Fed. Cir. 2014). And he may validly present his opinion that a POSA would understand the concentration limitations to be both important and narrowly construed. *See Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1356 (Fed. Cir. 2001) ("[Expert testimony] concerning the technological aspects of a patented invention may be of assistance to the court when dealing with complex technologies or those outside of the court's expertise."). This point goes directly to whether the differences between the asserted patent claims and accused products are substantial.

In particular, as Dr. Glacken's report explained, "the '083 patent sought to address an express need in the art for a chemically defined media composition that was optimal for the production of biopharmaceutical products" and "describes a single example and embodiment of the alleged invention, referred to as the MET 1.5 medium." Ex. 1 (Glacken Rebuttal Report) ¶ 61. Dr. Glacken further explained:

> As compared to the MET 1.5 medium (and corresponding unasserted claim 6), the soluble composition of [asserted] claim 1 (called generically the "MET" composition) contains the exact same ingredients. *Compare id*. at 6:5-7:6 *with* claim 1. The only difference is the ingredient concentrations, with claim 1 reciting concentration ***ranges*** for each named ingredient that encompass the specific concentrations found in the MET 1.5 composition."

Id. ¶ 62. Thus, "a POSA would read claim 1 already to cover and capture a range of equivalents for the concentration ranges of the specific ingredients, because claim 1 already incorporates broader concentration ranges than the sole MET 1.5 composition that the inventors made, disclosed, and tested in the '083 patent." *Id.* ¶ 62.

Dr. Glacken further emphasized how a POSA would find the claimed concentration ranges important: "The language of claim 1 itself confirms that the inventors carefully chose the upper and lower concentration ranges for each of the recited ingredients. Evidence of this is suggested by the tremendous variance in the relative breadth of concentration ranges specified by claim 1 of

the '083 patent." *Id.* ¶ 63. As he then explained: "Given the tremendous variety of these ratios of the maximum specified concentrations to the minimum specified concentrations, a POSA would conclude these concentrations are indeed meaningful, as clearly the inventors did not arbitrarily specify a uniform 2-fold, 5-fold, 10-fold, or 100-fold concentration span on either side of each of the MET 1.5 concentrations." *Id.* ¶ 64. Indeed, "[g]iven these unique maximum-to-minimum concentrations and ratios specified by claim 1 for nearly half of the ingredients, a POSA would reasonably conclude that these concentrations and ratios were deliberately established and supported as equivalents of MET 1.5." *Id.* Dr. Glacken's point is emphasized by "the advanced state of the prior art, " because the "soluble composition of the '083 patent is not a pioneering or first-of-its-kind invention." *Id.* ¶ 66. "Each of the claimed ingredients was commonly used in cell culture media in amounts that overlap with the claimed concentration ranges." *Id.*

Dr. Glacken's testimony explaining the intrinsic record will assist the jury in understanding the highly technical issues presented in this case, and should thus be allowed. *See Two Moms And A Toy, LLC v. Int'l Playthings, LLC*, No. 10-cv-02271, 2012 WL 5249459, at *4, 6 (D. Colo. Oct. 24, 2012) (denying motions to exclude expert testimony on "subject matter not within the knowledge of the average layperson" because "it will assist the trier of fact in understanding the technical issues presented in this case"). While Dr. Glacken will not offer opinions on legal standards, he should be allowed to explain his scientific view that any range of equivalents here must be narrow in view of the intrinsic record, and that the differences at issue here are all substantial.

C. Dr. Glacken's opinions related to claim vitiation are relevant and admissible.

Janssen next argues that "Defendants should not be permitted to present their legal argument [as to vitiation] to the jury through the vehicle of Dr. Glacken's testimony." Dkt. 343 at 11. As the Supreme Court made clear, application of the doctrine of equivalents requires "a special

vigilance against allowing the concept of equivalence to eliminate completely any such elements[.]" *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Defendants agree that the Court can—and should, as discussed in their pending *Daubert* motion—make the admittedly "legal determination" that Janssen's equivalence theory fails as a matter of law, because it would "vitiate" at least one "claim element." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (quotations omitted). If the Court were to allow Janssen's equivalence theory to proceed to trial, however, the jurors can and should consider whether Janssen's theory of "insubstantial differences" requires them to ignore claim limitations.

The concept of claim vitiation is inextricably tied to whether the admitted differences between the asserted claims and accused products are insubstantial—an issue Janssen concedes goes to the jury: "The underlying factual question for the jury to decide is whether there is an 'equivalent to the claim element in the accused device based on the well-established 'function-way-result' or 'insubstantial differences' tests.'" Dkt. 343 at 11 (quoting *Charles Mach. Works, Inc. v. Vermeer Mfg. Co.*, 723 F.3d 1376, 1380 (Fed. Cir. 2013)). Similarly, "vitiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result." *Brilliant Instruments, Inc. v. Guidetech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013).

Thus, as the Federal Circuit has held, "saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device based on the well-established 'function-way-result' or 'insubstantial differences' tests." *Id.* That is, the concept of claim vitiation simply provides the Court with a doctrine to reject a jury finding of equivalence as untenable and inconsistent with the patent laws. *See Deere & Co.*, 703 F.3d at 1356 ("It is the role

of the court . . . to ensure that the doctrine of equivalents is not permitted to overtake the statutory function of the claims in defining the scope of the patentee's exclusive rights.").

There is no legal or logical basis to bar the jury, when assessing whether the admitted differences are insubstantial, from considering whether a theory of equivalents would require re-writing the patent claims—as is the case here. The Federal Circuit has made it clear that claim vitiation is assessed "***based on the evidence presented and the theory of equivalence asserted***" at trial—indeed, the Federal Circuit has "repeatedly reaffirmed this proposition." *Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015) (emphasis added). Despite these repeated reaffirmations, Janssen is trying to prevent Defendants from presenting evidence that Janssen's asserted theory would essentially eliminate specific claim limitations. Janssen cites no case excluding expert opinions to this effect in the context of an *in limine* motion.

Importantly, Janssen does not seek to bar Dr. Glacken's scientific opinions that the differences between the asserted claims and the accused products are substantial, and that Janssen's experts failed to present evidence sufficient to show otherwise—including, among other opinions:

All of these opinions, among the other scientific observations and opinions stated in Dr. Glacken's reports and deposition, directly relate to issues the jury will be asked to consider, and are thus admissible. Again, Janssen does not (and cannot) suggest otherwise. *See, e.g.*, note 2, *supra*.

Dr. Glacken should be able to draw the logical conclusion from these opinions at trial—namely, "[a]pplying the doctrine of equivalents to differences of this magnitude would essentially eliminate the claim limitations that require particular ingredients within specified concentration ranges." Ex. 2 (Glacken Rebuttal Report) ¶ 71. The jury is certainly capable of making this assessment. After all, the Federal Circuit bar association expressly contemplates a jury instruction on this very point. *See* Ex. 7 at 25 ("If there is a question as to vitiation: You may not determine that an alternative aspect of a [product or process] is equivalent to an unmet requirement of a claim if a finding of infringement under the doctrine of equivalents would effectively eliminate that requirement. Specifically, the alleged equivalent cannot eliminate or ignore an element or requirement of the claim.") (alternation in original). Thus, Janssen's argument here should be rejected.

D. Janssen's ensnarement argument is moot.

By recent agreement of the parties, argument and testimony on ensnarement will not be presented to the jury. The parties agree that the Court can address the defense of ensnarement after trial, determining at that point the merit of the defense and whether an evidentiary hearing is necessary. This moots Janssen's ensnarement argument.

E. Dr. Glacken can explain to the jury that a POSA would have no practical way to assess infringement under Janssen's unprecedented theory.

Citing only paragraph 82 of Dr. Glacken's non-infringement report, Janssen seeks to bar Dr. Glacken from offering testimony about the practical implications to those skilled in the art if the differences at issue here were, in fact, deemed insubstantial. Dkt. 343 at 15. In that paragraph, Dr. Glacken cited his "understand[ing] that the language of the patent claims serves an important notice function—namely, to provide the public notice of the scope of the alleged invention." Ex. 1 (Glacken Rebuttal Report) ¶ 82. This "understand[ing]" of the law set forth in paragraph 82, however, does not purport to set out an opinion that Dr. Glacken intends to present at trial. *Id.* Once again, Dr. Glacken is not going to testify about what the law is, or what it should be.[3]

Janssen does not challenge any additional paragraphs of Dr. Glacken's report in this section. Thus, to the extent that Janssen is trying to exclude Dr. Glacken's application of the public-notice function of the patent laws, such an argument has not been properly raised and, in any event, would fail. For example, Dr. Glacken should be able to explain to the jury that Janssen's theory of infringement here would leave skilled artisans with no practical way to assess infringement. To illustrate this point, he offered the following observation and rhetorical questions:

> In evaluating claim 1 of the '083 patent where there is no literal infringement, the POSA's job is made very difficult by the fact that all of the ingredients in claim 1—every single one—are described in the public literature for use in serum-free cell culture medium. So when faced with claim 1 of the '083 patent, a POSA is given somewhat of a dilemma: how exactly does this '083 patent distinguish itself from

[3] Janssen argues that "purported lack of notice is not a defense to the doctrine of equivalents," citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). Although the Supreme Court contemplated some difficulty when determining "what is, or is not, an equivalent to a particular element of an invention," it did not say that the doctrine of equivalents eliminates entirely the notice function of the patent law. *Id.* On the contrary, the Court made it clear that the "patent laws" stemming from the Constitution "is a property right; and like any property right, its boundaries should be clear"—indeed, "[t]his clarity is essential to promote progress, because it enables efficient investment in innovation." *Id.* at 730-31. Janssen's view here that competitors need to spend more than a million dollars to conduct testing, without any guidance for such testing, is unprecedented and plainly turns the patent laws on their head.

> what is in the literature? How do I, as a POSA, know what I can use from the public literature and what I am prevented from using by the '083 patent?

Ex. 1 (Glacken Rebuttal Report) ¶ 84. These are all valid questions the jury should consider when addressing Janssen's unprecedented theory of infringement—where at least a dozen claim limitations are admittedly missing. Dr. Glacken explained how a POSA would answer these questions: "The most obvious answer is the claimed ingredients at the concentration ranges listed in claim 1. Because each and every ingredient in claim 1 of the '083 patent is in the public domain for a cell culture medium, the only limitation that would make sense to the POSA would be the concentration ranges specified in claim 1." *Id.* ¶ 85.

Dr. Glacken further pointed out that, "[a]ccording to Profs. Wurm and Butler, a POSA considering whether to make a soluble composition that includes at least the 52 ingredients required by claim 1 (all of which were used to prepare cell culture media at the time) would have to conduct extensive and expensive testing to assess infringement—[redacted] *Id.* ¶ 86 (note omitted). These opinions by Janssen's expert, Dr. Glacken explained, "would not give a skilled artisan fair notice that the accused products infringe the asserted claims of the '083 patent." *Id.* ¶ 89.

Janssen does not argue that these and similar scientific opinions from the perspective of a POSA are inadmissible. Nor does it cite any authority suggesting otherwise. Thus, any effort to exclude such opinions should be rejected.

III. Janssen reads the asserted claims differently to support infringement and oppose invalidity, and Dr. Glacken should be allowed to expose those inconsistencies.

Janssen next argues that Dr. Glacken "conflates the legal tests for obviousness and infringement under the doctrine of equivalents." Dkt. 343 at 16-19 (citing Glacken Opening Report ¶¶ 220, 248 n.37, 259 n.39; Glacken Reply Report ¶¶ 5-12, 50, 77, 161). Not so. To be sure, these legal

tests are different. Defendants do not contend, and Dr. Glacken will not testify, that "the principles of obviousness and equivalence [are] identical." *Id.* at 18. Instead, Dr. Glacken will explain how Janssen offers inconsistent positions as to ***claim scope***. "As [the Federal Circuit] has repeatedly instructed in the past, '[i]t is axiomatic that claims are construed the same way for both invalidity and infringement.'" *Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009) (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). Defendants should be allowed to present argument, and Dr. Glacken should be allowed to offer testimony, consistent with this axiom.

Janssen readily concedes that "claims must be construed consistently both for validity and infringement." Dkt. 343 at 16-17 (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.* 239 F.3d 1343, 1351 (Fed. Cir. 2001). Yet its experts read the patent very differently depending on whether they are asserting infringement or opposing obviousness. Below is a chart summarizing some of these inconsistent positions, as explained in Dr. Glacken's reply expert report:

Janssen's Claim Scope Position For Infringement	Janssen's Inconsistent Claim Scope Position For Obviousness
[redacted]	[redacted]

[4] All emphases in table quotations added unless otherwise indicated.

Janssen's Claim Scope Position For Infringement	Janssen's Inconsistent Claim Scope Position For Obviousness
[redacted]	[redacted]
[redacted]	[redacted]

See Ex. 11 (Glacken Reply Report) ¶¶ 5-12, 16, 20, 28, 73, 75-77, 119, 121, 161-164.

Janssen cannot have it both ways. To prove that the accused GE HyClone products infringe, Janssen has construed the asserted claims as ***not*** limited to the "clearly defined" "upper and lower [concentration] limits," or the expressly recited ingredients. *Compare* Ex. 2 (Butler Opening Report) ¶ 42; *with* Ex. 3 (Butler Rebuttal Report) ¶¶ 168, 175. Indeed, the parties disputed whether the asserted claims exclude [redacted], and the Court declined to so limit the claims—at Janssen's urging. Dkt. 226 at 5-6. This and the other Janssen positions discussed above all purport to "measure the invention," and thus "the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." *Amazon.com*, 239 F.3d at 1351; *see also C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1363 (Fed. Cir. 1998) ("Claims must be interpreted the same way for determining infringement as was done to sustain their validity.").

The law provides ample authority for Defendants to argue, and Dr. Glacken to inform the jury, that Janssen reads the claims very differently depending on whether the issue involves alleged infringement or obviousness. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); *Beachcombers, Int'l, Inc. v. WildeWood Creative Prods., Inc.*, 31 F.3d 1154, 1163 (Fed. Cir. 1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."). And, of course, underlying scientific principles (such as what happens to a salt when it is dissolves) do not turn on the particular legal standard being applied. *Compare e.g.*, Ex. 2 (Butler Opening Report) ¶ 59, Ex. 4 (Butler Dep.) 95:11-24, 111:20-112:2 *and* Ex. 12 (Excerpts of Transcript of deposition of Florian M. Wurm, Dr. rer. nat., December 7, 2016 ("Wurm

Dep.")) 218:5-12 [redacted], *with* Ex. 3 (Butler Rebuttal Report) ¶ 55 [redacted].

If the jury is confused by Janssen's inconsistent readings of the patent, Janssen has only itself to blame. It certainly cannot find justification for its contradictory approaches to claim scope in *Siemens Med Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269 (Fed. Cir. 2011). There, the Federal Circuit rejected the argument that, "where the purported equivalent is claimed in a separately issued United States patent[,] proof of infringement by equivalence requires clear and convincing evidence." *Id*. at 1279-80. That holding has no relevance here, where the burden of proof is not disputed. Indeed, the panel "d[id] not express an opinion" on whether "equivalence [is] relevant to obviousness." *Id.* at 1282. Here, the claim scope and scientific positions taken by Janssen as to the alleged infringement ***are*** relevant to obviousness, and Dr. Glacken should be allowed to expose Janssen's inconsistent positions.

IV. Dr. Glacken should be allowed to testify that the asserted claims are obvious.

Next, Jansen offers two legal arguments challenging Defendants' obviousness theory. First, according to Janssen, Dr. Glacken needed to cite a "particular experiment that would supposedly result in the particular combination of ingredients and ranges claimed in the '083 patent or that would motivate a scientist to reach that result." Dkt. 343 at 22. Second, Janssen argues that Dr. Glacken "improperly assumed that overlapping, non-identical concentration ranges are obvious." Dkt. 343 at 23-28. Both arguments misconstrue the law and Dr. Glacken's related opinions.

Dr. Glacken has offered admissible opinions that raise a triable issue of fact as to obviousness. As Dr. Glacken explained in his reports, "the asserted claims are invalid" as obvious "regardless of whether they are construed narrowly or broadly." Ex. 11 (Glacken Reply Report) ¶ 12.

This is because, among other reasons, "the asserted claims represent no more than combining well-known prior art ingredients in well-known concentration ranges to yield predictable results and products." Ex. 13 (Glacken Opening Report) ¶ 22; *see also* Ex. 11 (Glacken Reply Report) ¶¶ 20-152 (addressing obviousness in view of prior art).

Janssen does not dispute that Dr. Glacken's challenged opinion comes directly from the seminal Supreme Court case, *KSR*, which held: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. Nor does Janssen dispute, as the Supreme Court further explained, that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (citation omitted). And, critically, Janssen has never disputed that ***all*** ingredients and ***all*** concentration ranges for those ingredients recited in the asserted claims were known in the art and were combined with other ingredients in similar ways for the claimed purpose of culturing cells. Yet, resorting to hyperbole, Janssen argues that Dr. Glacken's obviousness opinions—in particular, a POSA's motivation to combine prior art elements to render the claimed invention obvious—"flies in the face of binding precedent." Dkt. 343 at 22 (citing *KSR*, 550 U.S. at 398). This argument fails for four independent reasons.

First, Janssen has mischaracterized the law. According to Janssen, "evidence of motivation" can be found "only where there are a 'finite number of identified, predictable solutions.'" Dkt. 343 at 23 (citing *KSR*, 550 U.S. at 421). This is dead wrong. The Supreme Court in *KSR* itself rejected such rigid application of the prior "'teaching, suggestion, or motivation' test (TSM test)" for obviousness. *KSR*, 550 U.S. at 399, 419-21; *see also Arrow Int'l., Inc. v. Spire Biomedical, Inc.*, 635 F. Supp. 2d 46, 70 n.24 (D. Mass. 2009) (recognizing Supreme Court criticism of

Federal Circuit's "teaching, suggestion, or motivation" test). Indeed, right after the passage block-quoted by Janssen on pages 20-21 of its brief, the Supreme Court explained why Janssen's narrow view of the law is inconsistent with precedent: "As our precedents make clear . . . , ***the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim***, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 415, 419 (emphasis added).

Of course, the existence of specific motivations to combine prior art references ***can*** support obviousness, but the Court rejected a "rigid approach" that would so limit the obviousness test in favor of a more "expansive and flexible approach." *KSR*, 550 U.S. at 415, 419 (holding that "the TSM test is incompatible with our precedents"). Under this framework, a jury may use several "flexible" rationales and "common sense" approaches to analyzing whether a patent is obvious, including whether a claim is directed to "a combination which only unites old elements with no change in their respective functions." *KSR*, 550 U.S. at 415-418.

This "flexible" standard applies here, because there were multiple known and obvious options available to a skilled artisan when preparing cell culture media compositions, some of which fall within the scope of the asserted claims—thus rendering them obvious. As Dr. Glacken explained, and Janssen's experts have not disputed, "[i]t was certainly within the skill of a POSA to formulate, with a reasonable expectation of success, soluble cell culture media compositions with these well-known ingredients in their well-known concentrations." Ex. 11 (Glacken Reply Report) ¶ 16.

Based on the prior art, "a POSA as of the priority date would have looked to known cell culture media and would have combined the desired ingredients and determined their concentrations through routine experimentation." *Id.* ¶ 17. Several prior art compositions were very close

to those in the asserted claims—for example, one prior art reference is missing only three claim elements, two ingredients and one concentration—even when the asserted claims are construed literally. *See id.* ¶ 122. Thus, "[t]he only required step by a POSA was to utilize routine skill and commonplace techniques of combining known ingredients with known concentrations together to create the claimed soluble composition. This task was well within the ability of a POSA as of 2004, as the prior art references discussed herein, including the specific combinations discussed below, clearly demonstrate." *Id.* ¶ 19.

The law does not require more, much less a "particular" motivation to choose one of many obvious compositions. *See KSR*, 550 U.S. at 417 ("[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.") (quoting *Sakraida*, 425 U.S. at 282); *see also In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("our case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.").

Second, the Federal Circuit has made it very clear that application of the *KSR* test raises a classic triable issue of fact—repeatedly vacating judgments of non-obviousness for this very reason. *See, e.g., Commonwealth Scientific*, 542 F.3d at 1376 (finding "a factual issue as to the motivation to combine prior art references that requires that we vacate the district court's order of summary judgment with respect to obviousness").[5] While Janssen may disagree with Dr.

[5] *See also Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322 (Fed. Cir. 2005) (reversing district court's grant of summary judgment, noting: "We conclude that a genuine issue of material fact exists with respect to motivation to combine."); *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1304 (Fed. Cir. 2005) ("Motivation to combine is a question of fact."); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) ("[T]he presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.").

Glacken's scientific conclusions as to motivations, its criticisms (invalid as they are) go to the ***weight*** of his testimony on obviousness, not to its ***admissibility***. *See, e.g.*, *Ferring Pharm., Inc. v. Braintree Labs., Inc.*, No. 13-12553, 2016 WL 5402738, at *3 (D. Mass. Sept. 26, 2016) (denying motion to exclude testimony because "[a]ny issues with the lack of a control group go to the weight, not the admissibility, of [the expert's] testimony"); *Bado-Santana v. Ford Motor Co.*, 364 F. Supp. 2d 79, 101 (D.P.R. 2005) (denying motion *in limine* where "any shortcomings in the expert's opinion goes to the weight of the testimony and not to its admissibility"). For this reason alone, the Court should reject Janssen's motion.

Third, Dr. Glacken properly applied the Supreme Court standard. *See* Ex. 13 (Glacken Opening Report) ¶¶ 31, 60 (citing legal standards he applied)). Consistent with *KSR*'s "flexible approach" to obviousness, Dr. Glacken set forth in detail the different approaches he took to examining the obviousness of the '083 patent, including whether the claims are merely a "combination of familiar elements according to known methods" to "yield predictable results." *KSR*, 550 U.S. at 416 ("This is a principal reason for declining to allow patents for what is obvious."); Ex. 13 (Glacken Opening Report) ¶¶ 28, 61; *see also* Ex. 7 (FCBA Jury Instructions) at 49. And "[b]ased on [his] review of all factual information and these criteria," he concluded that the "claimed invention as a whole would have been obvious as of 2003" to a skilled artisan. Ex. 13 (Glacken Opening Report) ¶ 62. Thus, there can be no question that Dr. Glacken engaged in a proper obviousness analysis, and he should be allowed to testify as to that analysis.[6]

[6] One of these approaches is the "obvious to try" rationale. While acknowledging that "obvious to try" is one of the ways a patent may be rendered invalid, Janssen also appears to argue that Dr. Glacken did not meet his burden in this particular approach. But this too raises a jury question. *See* Ex. 11 (Glacken Reply Report) ¶ 98.

Finally, Dr. Glacken did not "ignore[]" issues of motivation. Dkt. 343 at 20, 22. As more fully set forth in his reports, Dr. Glacken opined that "the ***motivation*** to combine prior art references with reasonable expectation of success is supported by ***a wealth of literature*** pertaining to cell culture media." Ex. 13 (Glacken Opening Report) ¶ 22 (emphasis added). Here, the supposed invention simply combines familiar prior art elements according to their well-known functions. Dr. Glacken thus explained—over 75-plus pages—the history of more than 60 years of cell culture media development and the known ingredients. This history details the existence of "several well-tested, publicly-known basal media" and the reasons and motivations why a skilled artisan would combine, adjust, and substitute those ingredients and their concentrations to arrive at the appropriate cell culture media for their needs, cell line, and purpose. *Id.* ¶¶ 25-207.

As just one example, Dr. Glacken explained that although early cell culture media used "serum" as an ingredient, researchers had a "strong motivation" to "replace serum" with chemically defined ingredients to "promote propagation of cells to relatively high cell concentrations" and "to reduce manufacturing costs and to eliminate the presence of contaminating serum proteins that complicated the purification of the product of interest." *Id.* ¶¶ 81, 89, 203-204. Specifically, he opined that because serum is an animal-derived component that contains "transferrin," a skilled artisan would have known to replace transferrin in any serum-containing media with known iron sources in cell culture media, such as "ferric ammonium citrate." *Id.* ¶ 225. Indeed, Dr. Glacken opined time and again that there was ample "***motivation to combine*** [these] prior art references" because, among other reasons, "the types and quantities of ingredients beneficial to growing eukaryotic cells and propagating eukaryotic cell lines, was well developed and well understood as of

October 2003." *Id.* ¶¶ 205-206.[7] There is no basis for Janssen's effort to exclude this testimony, which plainly raises a triable issue of fact.

Tellingly, Janssen's main case, *KSR*, did not arise on a motion *in limine*. Indeed, Janssen has cited ***no cases*** where an indisputably qualified expert's obviousness opinion was precluded from trial—based not on scientific error, but because his proposed testimony offered supposedly insufficient reason or motivation to combine the prior art.[8] In the end, this issue—i.e., whether there was sufficient motivation to combine prior art references to arrive at the claimed invention—is squarely within the confines of the jury. *See, e.g.*, *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1351 (Fed. Cir. 2010) (explaining that jury was free to either credit or disbelieve expert testimony about "the differences between the prior art and the invention claimed").

[7] Dr. Glacken's report is full of specific explanations of reasons or motivation to combine the prior art to arrive at the claimed invention. For example, he opined that "As eRDF comprises DMEM/F12 and it was well known to often be supplemented with ITES, as instructed by at least Jayme 1997 and Murakami 1987, which included ethanolamine, a person of ordinary skill in the art would be ***motivated to combine that supplement with eRDF or DMEM/F12 to improve the nutritive nature of the cell media***." Ex. 13 (Glacken Opening Report) ¶ 213 (emphasis added). He also stated: "[I]n my opinion, the '704 patent not only discloses every trace element claimed in the '083 asserted claims but also clearly would have ***motivated a person of ordinary skill in the art to include these trace elements*** in media in which protein (or serum) was not being included, such as eRDF." *Id.* at ¶ 217 (emphasis added); *see also id.* at ¶ 225 ("disclosing a motivation to replace transferrin, a protein, with inorganic iron supplements because they were less expensive and resulted in easier antibody purification from the hybridoma's growth media").

[8] None of Janssen's cases supports excluding Dr. Glacken's opinion. *Veracode, Inc. v. Appthority, Inc.*, 137 F. Supp. 3d 17, 36 (D. Mass. 2015), was a ruling on a post-trial motion on "invalidity defenses" after the testimony was "submitted to the jury." Both *KSR*, and *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F. 3d 1353 (Fed. Cir. 2008), involved obviousness analysis in the context of a summary judgment motion. *In re Kubin*, 561 F. 3d 1351 (Fed. Cir. 2009), and *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), were appeals from the USPTO rejecting the claims of their patent applications as obvious.

A. Dr. Glacken properly applied the law as to prior art with overlapping, non-identical concentration ranges.

Next, Janssen challenges the legal standard applied by Dr. Glacken as to prior art with overlapping, non-identical concentration ranges. Dkt. 343 at 23-28. According to Janssen, "Dr. Glacken opined that when a prior art reference contains concentration ranges that overlap with, but are not identical to, ranges in the '083 patent, there is no need to analyze the differences because they are all obvious as a matter of law." *Id.* at 23. This mischaracterizes Dr. Glacken's disclosed opinions. Dr. Glacken not only applied the correct legal standard, but also properly analyzed the differences between the prior art concentration ranges and claimed concentration ranges.

First, Janssen's view of the law is wrong. It is well established that "[w]here a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) (holding claim disclosing range of 2 to 20 days obvious over prior art disclosing 14 to 21 days).[9]

Citing *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011), Janssen says its case is not a "typical" one where such a presumption should apply. Janssen is wrong. For one, *Genetics Institute*—a patent interference case before the Patent

[9] *See also Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1331 (Fed. Cir. 2008) (holding that a claim disclosing 5 m/s to 28 m/s was obvious over prior art disclosing 2.4 to 5.6 m/s); *In re Harris*, 409 F.3d 1339, 1343 (Fed. Cir. 2005) (concluding that a claimed invention was rendered prima facie obvious by a prior art reference whose disclosed range (5.0-14.0 % chromium) overlapped the claimed range (4.3-5.3% chromium)); *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (acknowledging that a claimed invention was rendered prima facie obvious by a prior art reference whose disclosed range (100-600 Angstroms) overlapped the claimed range (50-100 Angstroms)); *In re Woodruff*, 919 F.2d 1575, 1576-78 (Fed. Cir. 1990) (concluding that a claimed invention was rendered obvious by a prior art reference whose disclosed range ("about 1–5%" carbon monoxide) abutted the claimed range ("more than 5% to about 25%" carbon monoxide); *Application of Malagari*, 499 F.2d 1297, 1298-99, 1303 (C.C.P.A. 1974) (concluding that a claimed invention was rendered prima facie obvious by a prior art reference whose disclosed range (0.020–0.035% carbon) overlapped the claimed range (0.030–0.070%).

Office, determining priority of invention—addresses an entirely distinct procedural posture, and is inapposite for this reason alone. Moreover, the Federal Circuit there merely held that the "typical" rule that prima facie obviousness is established by partially overlapping claim ranges did "not apply to the facts of" *Genetics Institute* due to highly specific findings: the prior art encompassed 68,000 protein variants, there was "no motivation to optimize" the prior art, the prior art differed substantially "in terms of the size of the permitted amino acid deletions, the location of those deletions, and the degree of allowable amino acid substitutions," and the prior art taught away from the "larger recombinant proteins" of the patented claim. *Id.* at 1304-06. This holding has no application here.

In contrast to *Genetics Institute*, and as more fully detailed in Dr. Glacken's report, the prior art showed substantial (sometimes near identical) overlap in not only most of the ingredients but also the concentrations. The prior art also showed strong motivations and incentives to optimize for the different needs of the cell line and production, and further taught various routine experimentation to optimize both the ingredients and concentrations. And the prior art in no way taught away from the claimed invention. *See* Ex. 13 (Glacken Opening Report) ¶ 202-262; Ex. 11 (Glacken Reply Report) ¶¶ 15-159. While Janssen has its arguments and its own expert opinions, this is a classic battle of the experts to be resolved by the jury.

In arguing that overlapping ranges do not render claimed concentration presumptively obvious, Janssen also places undue reliance on *Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293 (Fed. Cir. 2015). Applying the settled rule that "where there is a range disclosed in the prior art, and the claimed invention falls within that range," "the burden of production falls upon the patentee to come forward with evidence" of non-obviousness, the court there found that the patentee "had produced ample evidence of teaching away and unexpected results." *Id.* at 1304-05.

Unlike in *Allergan*, when presented with overlapping ranges, Janssen has not come forward with any evidence—let alone met its burden of production—that the specifically claimed concentration ranges are patentably distinct from the prior art. Nor has Janssen asserted that there is any evidence of teaching away or unexpected results.[10]

Second, regardless of the legal standard, and contrary to Janssen's assertions, Dr. Glacken did not ignore the concentrations or make an assumption that "overlapping, non-identical ranges are obvious." Dkt. 343 at 28. Instead of ignoring the concentrations and their supposed "infinite number of possible combinations," Dr. Glacken took them head-on—explaining in detail the progression of ideas, experiments, and publications that taught skilled artisans to narrow the possibility of ingredients and concentrations by the claimed 2003-2004 priority date. Ex. 13 (Glacken Opening Report) ¶¶ 70-205. By the time of the claimed invention in 2003-2004, the supposed "infinite number" of combinations were not "infinite" at all. Instead, scientists were taking well-established "starting point" media and making routine optimization of ranges and other ingredients to arrive at their desired cell culture media for their desired purposes. Ex. 13 (Glacken Opening Report) ¶ 205; *see, e.g.*, *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. . . . [A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness.").

[10] Janssen also cites *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1106 (Fed. Cir. 2002), but this case is factually distinguishable. In *Abbott*, the defendant failed to present any prior art as to one of the claim limitations—free fatty acids—to support its ensnarement defense. *Id.* The absence of evidence was fatal to any finding of anticipation and further provided "no basis for concluding that [the] hypothetical claim would be obvious." *Id.* This failure of proof had nothing to do with the claimed concentration ranges, and everything to do with the failure to address a particular claim limitation.

At trial, Dr. Glacken will explain how a skilled artisan would have chosen a particular ingredient and at what concentrations. For example, as detailed in his reports, he will explain that certain ingredients were commonly understood to be necessary at certain concentrations based on decades of experience—starting from (1) Eagle's Basal Media in 1955 (21 ingredients); (2) progression to the "Minimal Essential Medium (MEM)" in 1959; (3) progression to a modified MEM called "DMEM" that increased the "concentrations four-fold over that in MEM," which "allowed the growth and accumulation of more cells"; (4) progression to the development of a combination DMEM and Ham's F12 medium (DMEM/F12), which actually "was the starting point for the development of [Janssen's asserted] '083 medium"; (5) to the dozens of variations to DMEM/F12 that were adopted to different cell lines, were published, and were patented prior to 2003-2004 time period. Ex. 13 (Glacken Opening Report) ¶¶ 70-205. As Dr. Glacken will explain, these experiences informed skilled artisans that certain ingredients were necessary, certain ingredients can be substituted, different concentrations were beneficial for different cell lines, and routine experimentation could be conducted to adjust these variables. *See e.g., id.*, at ¶¶ 103, 205.

With respect to concentrations specifically, Dr. Glacken further opined that, to the extent that there are any differences in concentrations, they are minor and can be determined with "routine experimentation." *Id.* at ¶¶ 103, 207; Ex. 11 (Glacken Reply Report) ¶ 17. For example, he explained that a chemically defined media must provide "essential amino acids," and that "it is well established that amino acids levels would have been routinely adjusted to suit the cell type before October 2003." Ex. 13 (Glacken Opening Report) ¶¶ 105, 221. Adjusting the individual amino acid levels to improve culture performance may be performed "empirically from statistically designed experiments as shown by Castro et. al., 1992," or by "the designed experiments using a

matrix-based experiment, an example of which is described in Lao and Schalla [1996]." Ex. 13 (Glacken Opening Report) ¶ 221; Ex. 11 (Glacken Reply Report) ¶ 17.

In short, Janssen's argument that Dr. Glacken ignored the differences in concentrations between the prior art and the claimed invention has no basis in either law or fact. Dkt. 343 at 27.

B. Dr. Glacken Should Not Be Precluded From Testifying About Obviousness.

Lastly, Janssen argues that because of the two supposed "errors in Dr. Glacken's obviousness opinion," he cannot "meet any standard of proof" and thus "should be barred from testifying about obviousness." Dkt. 243 at 28. Here too, however, Janssen's critiques go to the weight of Dr. Glacken's testimony, not its admissibility. As explained above, Dr. Glacken did not commit any errors warranting exclusion of his entire testimony as to obviousness, or misapply the law. Thus, this Court should deny Janssen's motion as to obviousness.

V. Janssen's indefiniteness argument is moot.

By recent agreement of the parties, testimony on indefiniteness will not be presented to the jury. The parties agree that the Court can address indefiniteness after trial, determining at that point the merit of the defense and whether an evidentiary hearing is necessary. This moots Janssen's indefiniteness argument.

VI. Conclusion

For the reasons stated above, Janssen's motion *in limine* to limit Dr. Glacken's testimony should be denied, in part as moot and in part on the merits.

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Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc.

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 13, 2017.

/s/Andrea L. Martin, Esq.
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