IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* TO LIMIT THE TESTIMONY OF MICHAEL GLACKEN, SC.D.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

Statutes

Other Authorities

INTRODUCTION

The opinions of Defendants' expert witness, Dr. Michael Glacken, Sc.D., are notable in that they fail to address the central scientific propositions on which Janssen's infringement and validity cases are based. Instead, Dr. Glacken relies primarily on legal arguments, many of which are incorrect as a matter of law, and on legal instructions that are also incorrect. The upshot is that most of Dr. Glacken's disagreements with Janssen's expert witnesses are not true factual controversies but rather disputes over legal principles, which should be resolved by the Court, not the jury. Dr. Glacken should not be allowed to confuse the jury with testimony that is based on erroneous legal premises.

Janssen's challenges to the admissibility of Dr. Glacken's opinions rely on three basic principles, two from the Federal Rules of Evidence and the third from the patent law. First, to be admissible expert testimony must, among other things, "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Therefore, expert testimony "must have 'a valid . . . connection to the pertinent inquiry.'" *Cipollone v. Yale Indus. Prods.*, 202 F.3d 376, 380 (1st Cir. 2000) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 (1993) (alteration in original)). Where proposed expert testimony relies on legally erroneous or irrelevant principles, it is properly excluded under Rule 702 because the opinions have no valid connection to any pertinent inquiry. *See Cavanagh v. Taranto*, 95 F. Supp. 3d 220, 231 (D. Mass. 2015) (excluding legally irrelevant testimony under Rule 702). In sum, "conclusions of an expert opinion grounded in an error of law are inadmissible." 4 *Weinstein's Federal Evidence* § 702.05(2)(a).

Second, testimony based on incorrect legal assumptions, aside from having no connection to the pertinent inquiry, also has the potential of "confusing the issues" or "misleading the jury." Fed. R. Evid. 403. As such, evidence offered that is legally irrelevant or based on a

misapprehension of the law is routinely excluded under Rule 403. *See, e.g., United States v. Pierre*, 599 F.3d 19, 23 (1st Cir. 2010) (excluding expert testimony offered to establish legally impermissible defense under Rule 403 due to its potential to confuse and mislead)

Third, caselaw from the Federal Circuit and federal district courts holds that several of the issues on which Dr. Glacken opines are issues for the Court, not the jury, to decide. As discussed below, these issues include Dr. Glacken's opinions that the doctrines of vitiation, ensnarement, or other purported legal limitations on the doctrine of equivalents defeat Janssen's infringement case, and his opinion that U.S. Patent No. 7,598,083 (the '083 patent) is invalid for indefiniteness. Even if Dr. Glacken's opinions on these issues were not legally flawed (which they are), they still would not be appropriate to present to the jury.

Based on these principles, Dr. Glacken should be prevented at the upcoming jury trial from:

- Testifying as to purported legal limitations on the doctrine of equivalents, such as vitiation, ensnarement, and the prohibition on seeking "equivalents of equivalents" (Part I);
- Incorrectly equating the legal standards for application of the doctrine of equivalents and for obviousness (Part II);
- Testifying that the asserted claims would have been obvious in the absence of a motivation to combine prior art elements and without considering differences between the concentration ranges in the prior art and in the patent (Part III); and
- Asserting that the claims of the '083 patent would be invalid as indefinite under 35 U.S.C. § 112 if infringement is found under the doctrine of equivalents (Part IV).

I. DR. GLACKEN SHOULD NOT BE ALLOWED TO TESTIFY BEFORE THE JURY AS TO PURPORTED LEGAL LIMITATIONS ON THE DOCTRINE OF EQUIVALENTS

It is undisputed that the Celltrion Media contain every single one of the 52 ingredients required by claim 1 of the '083 patent, as well as seven of the nine optional ingredients, and that for all but twelve (or in the case of one of the accused media, thirteen) of these ingredients, the

concentrations in the Celltrion Media fall literally within the ranges claimed by the patent. Janssen contends that these concentration differences are insubstantial and that the Celltrion Media therefore infringe claims 1 and 2 of the '083 patent under the doctrine of equivalents. *See, e.g. Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1346 (Fed. Cir. 2013) ("To find infringement under the doctrine of equivalents, any differences between the claimed invention and the accused product must be insubstantial.").

Remarkably, Defendants' non-infringement expert Dr. Glacken does not dispute that the differences between the Celltrion Media and the asserted claims are insubstantial as a matter of science. Indeed, he has formed no opinion as to whether the differences are substantial or not. Instead, Dr. Glacken's primary argument is that Janssen's evidence is flawed and that Janssen has therefore failed to meet its burden of proof. Janssen looks forward to refuting Dr. Glacken's criticisms of its evidence and proving its case at trial. Those criticisms, at least, join issue on a disputed question of fact.

More troubling, Dr. Glacken's non-infringement report is also rife with arguments to the effect that Janssen's doctrine of equivalents case is subject to legal limits separate and apart from the factual question whether the differences between the Celltrion Media and the asserted claims are insubstantial according to science. In particular, Dr. Glacken argues that (1) the specification of the '083 patent either precludes the doctrine of equivalents or limits the range of equivalents, Rebuttal Expert Report of Michael Glacken, Sc.D. Regarding Non-Infringement ("Glacken Non-Infringement Report") (Ex. A) ¶¶ 60–68; (2) Janssen's infringement theory eliminates (or vitiates) claim limitations, *id.* ¶¶ 69–81; (3) Janssen's reliance on the doctrine of equivalents theory makes it difficult for a person of skill in the art to predict whether a particular media

would infringe, *id.* ¶¶ 82–89, and (4) Janssen's doctrine of equivalents theory ensnares the prior art, *id.* ¶¶ 90–112. For the below reasons, none of these theories should be presented to the jury.

A. 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

As Janssen's expert witness Dr. Michael Butler will explain at trial, two scientific propositions underlie Janssen's contention that the twelve (or thirteen) concentration differences between the Celltrion Media and the asserted claims of the '083 patent are insubstantial. First, Dr. Butler analyzed the concentration differences of the twelve (or thirteen) particular ingredients in light of the scientific literature and his knowledge and experience working with cell culture media and concluded that they were not, in his scientific opinion, substantial; that is, he did not expect that cells would perform differently in the Celltrion Media than in otherwise identical media that met the literal concentration limitations of the '083 patent. Opening Infringement Expert Report of Professor Michael Butler, Ph.D. ("Butler Infringement Report") (Ex. B) ¶¶ 39–97. Second, Dr. Butler reviewed experiments performed by Dr. Florian Wurm and concluded that the results of these experiments confirmed his analysis. Cells grown in the Celltrion Media performed substantially the same as cells that were grown in altered versions of the media that met the limitations of the '083 patent.[1] *Id.* ¶¶ 102–25.

In response, Defendants' expert witness Dr. Glacken offered no opinion disputing that the differences between the accused Celltrion Media and the asserted claims of the '083 patent are insubstantial as a matter of science. Dr. Glacken confirmed this at his deposition:

[1] As Dr. Butler testified at his deposition, his infringement opinion is based on these two propositions operating together. Butler Tr. (Ex. C) at 101:12–102:6. As Janssen will explain in its opposition to Defendants' motion *in limine*, the fact that Dr. Butler relied on two modes of analysis to conclude that the specific concentration differences at issue here are insubstantial hardly means that his opinion vitiates the concentration limitations of the '083 patent, as Defendants argue.

> Q. . . .[N]owhere in your report did you opine that those differences were substantial differences, right?
>
> ***
>
> A. No, for these 14 components[2] in the HyClone media that are outside the range of the claim 1 of the `083 patent, my understanding was that plaintiffs bear the burden of proving infringement by preponderance of the evidence, which I do not believe they did and ***I consequently did not opine in my expert report about insubstantiality of the differences***.

Glacken Tr. (Ex. D) at 201:19–202:03 (emphasis added). Similarly, asked whether he had opined that the Wurm experiments revealed substantial differences, Dr. Glacken answered "No."

> Q. Okay. Again, in your report, you didn't express an opinion that Dr. Wurm's results revealed any substantial difference in performance in terms of cell growth and antibody production comparing the Celltrion media to the respective variants he created?
>
> ***
>
> A. ***No***. In my – in my expert report, ***I spent all my time explaining why I thought the experiment was not – not valid and not, you know – wasn't worth the time to talk about the results***.

Glacken Tr. at 187:17–188:5 (emphasis added).

Although Dr. Glacken's criticisms of the Wurm experiments are unpersuasive, Janssen does not object to Dr. Glacken's right to present them at trial. Janssen does object, however, to a series of incorrect legal theories that appear in Dr. Glacken's non-infringement report.

B. Dr. Glacken's Opinion That the Specification of the '083 Patent Precludes or Limits the Doctrine of Equivalents Is Improper

In his report, Dr. Glacken asserts that the concentrations in the Celltrion Media cannot be equivalent to the asserted claims because a person of skill in the art reading the '083 patent

[2] The reason Dr. Glacken refers to 14 differences is that the two accused media, collectively, have 14 separate literal differences from the claimed concentrations ranges. Neither of the accused media itself has 14 concentration differences.

would believe that the patent was intended to preclude (or limit) assertion of the doctrine of equivalents as to concentration – irrespective of whether the differences between the patent and any particular product are, as a matter of scientific fact, insubstantial. Glacken Non-Infringement Report ¶¶ 60–68. This opinion is improper and should not be presented to the jury.

Dr. Glacken's opinion that the concentration ranges in the '083 patent preclude application of the doctrine of equivalents is purportedly based on his interpretation of the specification of the patent. According to Dr. Glacken, the "'083 patent describes a single example and embodiment of the alleged invention, referred to as the MET 1.5 medium," and the concentration ranges recited in claim 1 are based on the formulation of that medium. Glacken Non-Infringement Report ¶¶ 61–62. Therefore, according to Dr. Glacken, a person of ordinary skill in the art ("POSA") "would read claim 1 already to cover and capture a range of equivalents." *Id.* ¶ 62. Dr. Glacken opines that as a result, the doctrine of equivalents is either "unavailable" with respect to the concentration ranges in the '083 patent, or must be "narrow." *Id.* ¶¶ 67–68.[3]

Dr. Glacken's opinion that the '083 patent limits equivalents by claiming concentration ranges is contrary to the law. The Federal Circuit has consistently and repeatedly held that the inclusion of numeric ranges in a patent claim does not rule out the possibility of infringement under the doctrine of equivalents. *See, e.g. Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1107–08 (Fed. Cir. 2002) ("The fact that a claim recites numeric ranges does not, by itself, preclude . . . [reliance] on the doctrine of equivalents."); *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1291–92 (Fed. Cir. 2010) (collecting cases applying the doctrine of equivalents

[3] At deposition, Dr. Glacken asserted for the first time that this "narrow" range of equivalents was equal to measurement error. That is, if the bottom end of a range was 10 mg, a scientist attempting to measure 10 mg of an ingredient might err by as much as 5% and actually measure 9.5 mg. Such an amount, Dr. Glacken asserted, might constitute an equivalent. *See* Glacken Tr. at 255:24–257:2.

to patent claims incorporating numeric ranges). The Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997), also found the doctrine of equivalents could be applied to a patent containing a claim with a numerical range. *Id.* at 32 (holding that a "lower limit of 6.0" did "not necessarily preclude the application of the doctrine of equivalents"). Indeed, the *Warner-Jenkinson* Court found that a pH of 5.0 to infringe a pH range of 6.0–9.0 under the doctrine of equivalents, a tenfold deviation from the lower endpoint of the claimed range (since the pH scale is logarithmic). *See id.* at 22 n.1.

Contrary to the legal instructions Dr. Glacken received, the possibility that claimed numeric ranges may relate to a preferred embodiment disclosed in the specification does not preclude or limit application of the doctrine of equivalents. Dr. Glacken appears to be relying on inapposite caselaw holding that where the language of a patent claim ***literally*** encompasses equivalents, it should not be broadened to encompass "equivalents of equivalents." But this caselaw is limited to patents whose claims contain words of approximation such as "about" and have been construed to literally include a range of equivalents around the endpoint of the range. In the leading case, *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008), the Federal Circuit held that the use of the word "about" in a claim including the limitation "greater than about 30 μm" should be construed to "encompass[] particle diameters that perform the same function, in the same way, with the same result as the 30 μm particles, as long as those diameters are within the range left open by the specific disclosures of the specification." *Id.* at 1372. Based on this claim language and claim construction, the court concluded that "the patentee has in this case already captured what would otherwise be equivalents within the literal scope of the claim" and therefore could not "rely on the doctrine of equivalents to encompass equivalents of equivalents." *Id.*

Notably, the *Cohesive Technologies* court rejected "the district court's argument[] that the breadth of Cohesive's claim – i.e., that it literally encompasses 'a substantial set of diameters' – somehow limits its ability to claim infringement by equivalents," holding that this was "wrong as a matter of law." *Id.* at 1371. Subsequently, the Federal Circuit held that the doctrine of equivalents was available for a claim requiring "substantially all" of an ingredient to be in a given layer, because unlike in *Cohesive Technologies*, the claim construction of this term ("at least 90%") did not expressly encompass equivalents. *Pozen, Inc. v. Par Pharm., Inc*., 696 F.3d 1151, 1170 (Fed. Cir. 2012). Thus, the "equivalents of equivalents" rule from *Cohesive Technologies* is a narrow one, applying only to claims that, as construed by the court, literally encompass the equivalents of a claimed element.

Here, there are no words of approximation in the claims of the '083 patent, much less language that has been construed to literally encompass equivalents of the claimed concentration ranges. The concentrations ranges are precise, and Dr. Glacken himself opines that "the inventors carefully chose the upper and lower concentration ranges for each of the recited ingredients." Glacken Non-Infringement Report ¶ 63. As such, *Cohesive Technologies* has no application here. Rather, the '083 patent falls well within the heartland of cases which hold that a patent containing numerical ranges is subject to the doctrine of equivalents – as *Cohesive Technologies* itself acknowledges is the general rule. *See Cohesive Techs.*, 543 F.3d at 1371 (noting that the Federal Circuit has "repeatedly held, 'the fact that a claim recites numeric ranges does not, by itself, preclude . . . [reliance] on the doctrine of equivalents'" (quoting *U.S. Philips Corp. v. Iwasaki Elec. Co. Ltd.*, 505 F.3d 1371, 1378 (Fed. Cir. 2007) (alterations in original)). Dr. Glacken's opinion that the doctrine of equivalents is "unavailable" here is legally incorrect and should not be presented to the jury. Glacken Non-Infringement Report ¶ 67.

Both in his report and at his deposition, Dr. Glacken appeared to suggest that although he believed the doctrine of equivalents was "unavailable," his ultimate opinion was that the range of equivalents should be "narrow" (so as to embrace measurement error) such that the Celltrion Media cannot be equivalent to the claims of the '083 patent. *Id.* ¶ 68; *see* Glacken Tr. at 252:10–254:19. As Dr. Glacken acknowledged, this opinion was not based on the facts related to the Celltrion Media, but rather on his belief that the claims of the '083 patent limited the permissible range of equivalents as a matter of law. Glacken Tr. at 258:5–17. Dr. Glacken's opinion that the range of equivalents is "narrow" is based on the same misreading of the law as his opinion that the doctrine of equivalents is "unavailable." It should be excluded on the same basis.

Not only is Dr. Glacken's opinion about the doctrine of equivalents based on an improper legal instruction, but to the extent the law limits a plaintiff's ability to assert the doctrine of equivalents, that is an issue of law for the Court, not of fact for the jury. The caselaw "recognize[s] 'various legal limitations on the application of the doctrine of equivalents'" such as the doctrine of prosecution history estoppel (not asserted here) and the doctrine of ensnarement (discussed below). *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F. 3d 1314, 1323 (Fed. Cir. 2009) (quoting *Warner-Jenkinson*, 520 U.S. at 39 n.8) (emphasis and alteration in original). But these "'legal limitations . . . are to be determined ***by the court*** either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict'" – not by the jury. *Id*. (quoting *Warner-Jenkinson*, 520 U.S. at 39 n.8) (emphasis and alteration in original). Although less well established, the "equivalents of equivalents" doctrine, like those other limitations, has been treated as a question of law for the courts.[4] Furthermore, as noted above, Dr. Glacken's "equivalents of equivalents"

[4] *See, e.g., Cohesive Techs.*, 543 F.3d at 1372 (affirming grant of summary judgment); *Takeda Pharm. Co., Ltd. v. TWI Pharms., Inc.*, 87 F. Supp. 3d 1263, 1282 (N.D. Cal. 2015) (granting summary judgment

opinion here is based on his legally incorrect interpretation of the meaning and scope of the '083 patent's claims. The Federal Circuit has repeatedly held that "the meaning and scope of the patent claims" is a question that "the court, not the jury, must resolve." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co*., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quotation marks omitted); *accord Warsaw Orthopedic, Inc. v. NuVasive, Inc*., 824 F.3d 1344, 1350 (Fed. Cir. 2016).

There is no support in the law for allowing a jury to decide whether a patentee is somehow entitled to a range of equivalents as a matter of law. That is confusing, unduly prejudicial, and legally improper. The jury should be instructed to decide the proper factual question: whether Janssen has proved, on a limitation by limitation basis, whether any deviations from literal infringements are insubstantial. At trial, Dr. Glacken should be limited to testifying about the relevant scientific evidence and should not be permitted to confuse the jury by positing erroneous legal limitations on the doctrine of equivalents.

C. Dr. Glacken Should Not Be Allowed to Testify as to Vitiation

Next, Dr. Glacken argues that extending the concentration ranges claimed in the '083 patent to encompass the infringing product would render the ranges so broad as to essentially eliminate the limitations in the patent. Glacken Non-Infringement Report ¶¶ 69–81. Defendants are filing a concurrent motion *in limine* on this issue, commonly known as vitiation, and Janssen will respond in full to Defendants' legal vitiation case in opposition to that motion. It is clear, however, that Dr. Glacken should be foreclosed from presenting this legal argument to the jury.

Vitiation is a "legal determination" which requires the court to consider whether a "reasonable jury could find equivalence." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356

based on *Cohesive Technologies*); *cf. Regents of the Univ. of Minn. v. AGA Med. Corp*., No. 07-cv-4732, 2011 U.S. Dist. LEXIS 615, *39–41 (D. Minn. Jan. 4, 2011) (reasoning that *Cohesive Technologies* is an application of the vitiation doctrine, discussed below, and granting summary judgment on that basis).

(Fed. Cir. 2012). Unlike doctrines such as prosecution history estoppel and ensnarement, vitiation "is not an exception to the doctrine of equivalents" that can lead to a finding of non-infringement even where the literal differences in question are in fact insubstantial. *Id.* (correcting this "misperception"). But neither is vitiation a question of fact for the jury. Rather, it is "a legal determination that 'the evidence is such that no reasonable jury could determine two elements to be equivalent.'" *Id.* (quoting *Warner-Jenkinson*, 520 U.S. at 39 n.8).[5] Making this legal determination "is the role of the court." *Id.* 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.'" *Charles Mach. Works, Inc. v. Vermeer Mfg. Co.*, 723 F.3d 1376, 1380 (Fed. Cir. 2013) (quoting *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013)).

In their motion *in limine*, Defendants are asking the Court to conclude that Janssen's doctrine of equivalents theory fails as a matter of law because it supposedly vitiates claim elements. Based on the caselaw cited above, this is nothing more than a belated motion for summary judgment on non-infringement, which Defendants previously declined to bring but have apparently decided to pursue now that their other motions for summary judgment have been denied. As Janssen will demonstrate in its opposition papers, Defendants' vitiation argument fails. But in any event, Defendants should not be permitted to present their legal argument to the jury through the vehicle of Dr. Glacken's testimony.

[5] *Accord Cadence Pharms., Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015) ("A holding that the doctrine of equivalents cannot be applied to an accused device because it 'vitiates' a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency.") (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1018–19 (Fed. Cir. 2006) and collecting cases standing for same proposition).

D. Dr. Glacken Should Not Be Permitted to Testify that Janssen's Doctrine of Equivalents Theory Ensnares the Prior Art

Dr. Glacken's report also offers his opinion that the Janssen's doctrine of equivalents theory ensnares the prior art. Glacken Non-Infringement Report ¶¶ 90–112. Dr. Glacken's ensnarement opinion misapplies the law and in any event, like the theories discussed above, presents a legal issue that is not for the jury to consider.

Under the ensnarement doctrine, a patentee may not assert "a scope of equivalency that would encompass, or ensnare, the prior art." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009) (quotation marks omitted). To test whether an assertion of infringement ensnares the prior art, a hypothetical claim is constructed that literally covers the infringing instrument, and then the hypothetical claim is examined to determine whether it would be patentable over the prior art. *Id.* at 1324. Although ensnarement resembles an obviousness analysis, a successful ensnarement defense only establishes non-infringement; it "has no bearing on the validity of the actual claims." *Id.* at 1323.

In *Intendis GmbH v. Glenmark Pharmaceuticals*, 822 F.3d 1355 (Fed. Cir. 2016), the Federal Circuit rejected the defendant's argument that the hypothetical claim should be broadened further than is necessary to cover the accused product in order to "match [the plaintiff's] theory of infringement." *Id.* at 1364. In *Intendis*, the claim required a "triacylglyceride" and "lecithin." *Id.* at 1359. The accused device "substituted isopropyl myristate for the claimed triglyceride and lecithin" so infringement was asserted under the doctrine of equivalents. *Id.* In appealing the district court's rejection of its ensnarement defense, the defendant argued that the proper hypothetical claim should have included any "penetration enhancer," not just the specific penetration enhancers in the accused product, because plaintiff's "theory of infringement" supposedly implied that any penetration enhancer would be equivalent

to the claimed elements. *Id.* at 1364. The Federal Circuit rejected this argument, holding that the district court "correctly rejected as too broad [defendants'] proposed hypothetical claim" and that a properly constructed hypothetical claim only "extend[s] the actual claim to literally recite the accused product." *Id.*

Dr. Glacken's hypothetical claim does exactly what the Federal Circuit rejected in *Intendis*. As Dr. Butler explains in his reply report, for certain elements where the Celltrion Media contain two particular sources of the same active ingredient, Dr. Glacken defines his hypothetical claim to encompass ***any*** source of this active ingredient, not just the specific sources that are present in the Celltrion Media. *See* Reply Infringement Expert Report of Professor Michael Butler, Ph.D. ("Butler Reply Report") (Ex. E) ¶¶ 35–37; Glacken Non-Infringement Report ¶ 93. Dr. Glacken compounds this error by asserting repeatedly that the "same reasoning" Janssen's experts apply in their doctrine of equivalents analysis would imply that the claims of the '083 patent are obvious over the prior art. *E.g.* Glacken Non-Infringement Report ¶¶ 99, 104, 111. This argument not only misapplies the law of obviousness, *see* Part II below, it misapplies the law of ensnarement by wrongly assuming that the analysis must "match [plaintiffs] theory of infringement" rather than the accused product. *Intendis*, 822 F.3d at 1364.

Defendants appear to rely on language in *Streamfeeder, LLC v. Sure-Feed Systems*, 175 F.3d 974 (Fed. Cir. 1999), which states that a litigant cannot "cut and trim, expanding here and narrowing there, to arrive at a claim that encompasses an accused device, but avoids the prior art." *Id.* at 983. But that case stands only for the proposition that the plaintiff cannot rely on a hypothetical claim that is both expanded to encompass an accused device and also ***narrowed*** for the purposes of avoiding the prior art. *See id.* (rejecting hypothetical claim that "impermissibly narrowed the gate member limitation"); *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204

F.3d 1360, 1365 (Fed. Cir. 2000) (noting that patentee may not "expand[] some limitations in order to read on an accused process or device while narrowing other limitations to avoid prior art"). Here, the proper hypothetical claim identified by Janssen's expert witness Dr. Butler involves no narrowing; it simply expands the relevant limitations to encompass the Celltrion Media. *See* Butler Reply ¶ 37. By expanding his hypothetical claim further than is necessary to encompass the Celltrion Media, Dr. Glacken's ensnarement analysis misapplies the law.

In any event, "ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents to be decided by the court, not a jury." *DePuy Spine*, 567 F.3d at 1323. This is true even though the legal determination of ensnarement may "be subject to underlying facts," because "the resolution of factual issues underlying a legal question may properly be decided by the court." *Id.* at 1324 (quotation marks omitted). Following *DePuy Spine*, numerous district courts have held that ensnarement is a question of law for the court, and that evidence of ensnarement should therefore not be presented to the jury. *See, e.g.*, *Everyscape, Inc. v. Adobe Sys.*, 31 F. Supp. 3d 322, 325 (D. Mass. 2014) ("Ensnarement is an issue of law for the court."); *Finjan, Inc. v. Blue Coat Sys.*, No. 13-cv-03999, 2015 U.S. Dist. LEXIS 88760, at *10 (N.D. Cal. July 8, 2015) ("Plaintiff next seeks to exclude from the jury's consideration evidence and argument concerning prosecution history estoppel and ensnarement. . . . These issues are questions of law reserved for the Court and Defendant agrees that they should not be presented to a jury."); *Tyco Healthcare Group LP v. E-Z-EM, Inc.*, No. 2:07-cv-2622010, 2010 U.S. Dist. LEXIS 57653, at *6 (E.D. Tex. June 8, 2010) ("Defendants are . . . forbidden from introducing evidence or argument relating to the ensnarement defense in front of the jury."). Dr. Glacken's ensnarement opinions should be excluded for the same reason.

E. Dr. Glacken Should Not Be Allowed to Testify that the Doctrine of Equivalents Provides Inadequate Notice to Potential Infringers

Dr. Glacken further contends that Janssen's claim of infringement under the doctrine of equivalents is impermissible because a competitor would not have sufficient notice of what is and is not infringing, based on his "understand[ing] that . . . competitors[] are entitled to clear and specific notice of what the inventor claims." Glacken Non-Infringement Report ¶ 82. On this basis, Dr. Glacken complains about the potential range of equivalents and the cost and uncertainty associated with determining whether a particular cell culture medium is, or is not, an equivalent to what is claimed in the '083 patent.

Contrary to Dr. Glacken's legal instructions, however, purported lack of notice is not a defense to the doctrine of equivalents as distinct from the scientific question whether the differences in question are substantial. As the Supreme Court has acknowledged, a certain lack of predictability is inherent to the doctrine of equivalents, as it "may be difficult to determine what is, or is not, an equivalent to a particular element of an invention" such that "competitors cannot be certain about a patent's extent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). But, the Court went on to reject the argument that these concerns about predictability defeated the doctrine of equivalents: "These concerns with the doctrine of equivalents . . . are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule." *Id*. Whether a potential competitor would or would not be certain about the precise bounds of equivalence is not a component of the test for infringement under the doctrine of equivalents.

Dr. Glacken should not be permitted to testify that the inclusion of concentration ranges in the '083 patent or an alleged lack of notice to competitors forecloses infringement under the

doctrine of equivalents. His proposed testimony, as set forth in his expert report, would confuse the jury as to the applicable legal standard, conflict with the jury instructions regarding the doctrine of equivalents, and would not relate to any issue that is legitimately part of the case.

II. DR. GLACKEN SHOULD BE PRECLUDED FROM INCORRECTLY EQUATING THE TEST FOR OBVIOUSNESS WITH THE TEST FOR INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

In Dr. Glacken's reports on the purported invalidity of the '083 patent, he conflates the legal tests for obviousness and infringement under the doctrine of equivalents. In addition to being legally incorrect, this testimony is particularly likely to mislead and confuse the jury as to proper legal standards to apply on infringement and validity. Dr. Glacken should be precluded from presenting testimony that conflates the two tests.

Dr. Glacken begins his reply invalidity report by asserting that Janssen's expert witnesses have somehow "taken contradictory positions with regard to the scope of the asserted claims of the '083 patent" by opining that the claims are both infringed under the doctrine of equivalents and not obvious over the prior art. Reply Expert Report of Michael Glacken, Sc.D. Regarding Invalidity ("Glacken Reply Invalidity Report") (Ex. F) ¶¶ 5–12. The concept that there is somehow a contradiction between Janssen's infringement theories and its non-obviousness theories permeates Dr. Glacken's reports. A sentence from his reply puts it best: "Janssen's experts are arguing for a double standard: one for infringement, and an entirely different one for validity." *Id*. ¶ 161.

This statement is based on a fundamental misunderstanding of the applicable law. There can be no double standard in contending that a patent is both infringed under the doctrine of equivalents and valid in light of the prior art. The tests for infringement and validity are completely different under the law. While it is true that claims must be construed consistently both for validity and infringement, *see, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239

F.3d 1343, 1351 (Fed. Cir. 2001), there is no issue of claim construction here. Application of the doctrine of equivalents is not a question of claim construction; it is a question of factual proof whether a particular difference is substantial. *See, e.g., Intendis*, 822 F.3d at 1360 ("Infringement under the doctrine of equivalents is a question of fact . . . ."). More important, there are entirely different, and well developed, standards for infringement under the doctrine of equivalents and invalidity due to obviousness, and there is no basis for Dr. Glacken to treat the questions as identical. The question for obviousness is whether "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious," 35 U.S.C. § 103, applying the four factors identified by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), none of which has anything to do with the accused product. Meanwhile, the test for infringement under the doctrine of equivalents focuses on the accused product and asks whether there is "'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson*, 520 U.S. at 21. Each question involves entirely different underlying analyses and relies upon an entirely different body of caselaw.

The Federal Circuit made this point abundantly clear in *Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269 (Fed. Cir. 2011). There, the accused product (asserted to be an equivalent of the patent at issue) was separately patented and the patent at issue was prior art to the defendant's later-issued patent. *Id.* at 1276, 1283. The defendant argued that there should be a higher burden of proof for equivalence under the doctrine of equivalents because a finding of infringement would constructively invalidate its separate, later-issued patent on the accused product. *Id.* at 1278. The defendant's logic was that if the accused product is equivalent to the patent at issue, then the accused product is necessarily

an obvious variation of the patent at issue and, since the patent office found the accused product to be separately patentable over the prior art (which included the patent at issue), a finding of equivalence is tantamount to a finding of obviousness of the separate patent. *Id.* at 1279. Since patents cannot be invalidated except by clear and convincing evidence, then, defendants argued, equivalence must also be proven by clear and convincing evidence. *Id.*

The Federal Circuit rejected this argument, explaining that it rested on the faulty premise that the principles of obviousness and equivalence were identical. Instead, it held that obviousness and equivalence "require different analytical frameworks." *Id.* at 1282. The doctrine of equivalents, on the one hand, "typically involves application of the insubstantial differences test." *Id.* "Obviousness, by contrast, requires analysis under the four *Graham* factors." *Id.* Obviousness considers factors beyond those relevant to an equivalence analysis, such as "objective evidence of commercial success" or the "level of predictability in the art." *Id.* Not only are the relevant modes of analysis different, but the relevant timeframes differ as well. Under the doctrine of equivalents, the proper time frame for evaluating equivalency "is at the time of infringement, not at the time the patent was issued." *Id.* (quotation marks omitted). In contrast, "obviousness asks whether a claimed invention 'would have been obvious at the time the invention was made.'" *Id.* (quoting 35 U.S.C. § 103(a)).

To be sure, the law does recognize that it is inappropriate to allow a patentee to assert infringement under the doctrine of equivalents if a patent literally claiming the same subject matter would have been obvious. But that idea is fully captured by the doctrine of ensnarement, discussed above. As explained there, the Federal Circuit has rejected the argument that the hypothetical claim in the ensnarement analysis must "match [the plaintiff's] theory of infringement," as opposed to the accused product. *Intendis*, 822 F.3d at 1364. Even if the

hypothetical claim were constructed in that overbroad manner, moreover, the obviousness analysis applied to it would still differ from the doctrine of equivalents analysis, as the Federal Circuit explained in *Siemens*. In any event, as explained above, ensnarement is an issue for the Court rather than the jury. In short, the doctrine of equivalents and obviousness should not be confounded at trial, much less in the simplistic and legally incorrect way that Dr. Glacken confounds them in his reports.

Numerous opinions in Dr. Glacken's reports are based on the legally false premise that the analysis for infringement is (or should be) the same as the analysis for validity. For example, in comparing the '083 patent to one of the prior art references, Dr. Glacken opines that the variance between the concentration ranges in the '083 patent and the prior art is less than that between the '083 patent and the Celltrion Media and, therefore, "to the extent that HyClone's media are deemed to infringe . . . the prior art ingredients that have concentrations outside the specific range should also be viewed to disclose the concentrations of claim 1." Opening Expert Report of Michael Glacken, Ph.D. [sic] Regarding Invalidity ("Glacken Opening Invalidity Report") (Ex. G) ¶ 220. Dr. Glacken goes on to make arguments of this kind throughout his opening and reply invalidity reports. *See*, *e.g. id.* ¶¶ 248 n.37, 259 n.39; Glacken Reply Invalidity Report ¶¶ 50, 77, 161. He repeatedly argues that the '083 patent should be deemed obvious using Janssen's experts' "application of the doctrine of equivalents." Glacken Reply Invalidity Report ¶ 77.

Given the propensity of Dr. Glacken's testimony to mislead the jury on key questions of patent law, which are already likely to be difficult for the jury to understand, he should not be permitted to testify that the same test applies to Janssen's application of the doctrine of equivalents and to the determination of whether the '083 patent is invalid for obviousness.

III. DR. GLACKEN SHOULD BE PRECLUDED FROM TESTIFYING THAT THE ASSERTED CLAIMS ARE OBVIOUS

A. Dr. Glacken Improperly Provided No Reason or Motivation to Combine Prior Art Elements to Create the Invention of the '083 Patent

Throughout his invalidity reports, Dr. Glacken argues that the '083 patent would have been obvious in view of combinations or modifications of the prior art that a person of ordinary skill in the art would have made as a matter of routine experimentation. *E.g.*, Glacken Reply Invalidity Report ¶¶ 17, 53, 78, 122. He purports to apply this legal instruction: "[A] claim would have been obvious if it is merely a combination of familiar elements according to known methods when it does no more than yield predictable results." Glacken Opening Invalidity Report ¶ 28. The circumstances here do not justify application of that rule and Dr. Glacken should be precluded from testifying on this point to avoid misleading or confusing the jury.

Dr. Glacken's analysis seems to derive from a misapplication of the standards enunciated in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). In *KSR*, the Court invalidated as obvious a patent that made a single change from the prior art, placing an electronic brake sensor in one location rather than another. It held that where "there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions" a person of ordinary skill has good reason to pursue those known options. *Id.* at 421. Where pursuit of those known options leads to the anticipated success, the invention is obvious because it is "the product not of innovation but of ordinary skill and common sense." *Id.* But the Court distinguished that simple situation from the situation where the number of choices is not finite:

> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the

> effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

Id. at 417–18.

That is the case here. The creation of a cell culture media, Dr. Glacken agrees, does not involve the substitution of "one known element for another" but rather the teachings of multiple patents and the background knowledge of a person having ordinary skill in the art. Glacken Reply Invalidity Report ¶¶ 52–53. The selection is from among hundreds of possible ingredients in an endless series of concentration ranges. Even the claimed invention, Dr. Glacken agrees, "encompass[es] a vast number of potential soluble compositions" in light of its many ingredients and different concentration ranges. Glacken Opening Invalidity Report ¶ 283. At his deposition, Dr. Glacken acknowledged that there were literally trillions of possible combinations in the prior art references that he relies upon. Glacken Tr. at 118:6–25. In such circumstances, as *KSR* holds, the obviousness analysis requires a determination of "whether there was an apparent reason to combine known elements in the fashion claimed by the patent at issue." 550 U.S. at 418.

Applying *KSR*, the Federal Circuit has consistently reaffirmed that mode of analysis. In order to demonstrate obviousness in such circumstances, a defendant must show that the "record before the time of invention would supply some reasons for narrowing the prior art universe to a 'finite number of identified, predictable solutions.'" *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (quoting *KSR*, 550 U.S. at 421). Otherwise, a person of skill would merely be "throw[ing] metaphorical darts at a board filled with combinatorial prior art possibilities" and, in such circumstances, "courts should not succumb to hindsight claims of obviousness." *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009).

Dr. Glacken's proposed method by which a skilled artisan would have identified the medium described in the '083 patent flies in the face of binding precedent. He outlines a series of step that amount to: (1) assembling a list of possible components (from among hundreds); (2) selecting ingredients from that list based on a variety of considerations "such as availability, purity, stability, cost, etc.," with no explanation of how to weigh or decide among those considerations; (3) designing experiments that vary the concentration of *every* selected ingredient to determine an optimal amount; and (4) executing those experiments. Glacken Reply Invalidity Report ¶ 17. After acknowledging that this method requires navigating through trillions of possible choices, *id.* ¶ 168 n.23, Dr. Glacken asserts that there are supposedly "matrix-based experiment[s]" that could allegedly narrow the range of choices. *Id.* ¶ 17. At no point does Dr. Glacken identify any 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. Nor does he explain why this supposed process of "optimization" would result in the invention of the '083 patent, rather than some other combination. Instead, he vaguely opines that, by following this process, a POSA was "quite capable" of "coming up with a media that works for them. And what works for them ***might be*** within the claims." Glacken Tr. at 149:12-17 (emphasis added). In the end, Dr. Glacken ignores both motivation to combine and the requirement of clear and convincing evidence. His obviousness analysis simply relies on his erroneous legal instruction – that because the possible ingredients in cell culture media were known, routine experiments might result in the claimed invention.

This is exactly what the law says is not the relevant test. It would not be obvious to "'vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result.'" *Kubin*, 561 F.3d at 1359 (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed.

Cir. 1988)); *see also Veracode, Inc. v. Appthority, Inc.*, 137 F. Supp. 3d 17, 40 (D. Mass 2015) (holding patent not obvious where "the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" (quotation omitted)). Dr. Glacken's approach, as described in his reports and testimony, amounts precisely to "throw[ing] metaphorical darts at a board filled with combinatorial prior art possibilities." *Kubin*, 561 F.3d at 1359. Accepting Dr. Glacken's premise would amount to completely reversing the Supreme Court's decision in *KSR*. Instead of foregoing evidence of motivation only where there are a "finite number of identified, predictable solutions," 550 U.S. at 421, it would allow claims to be found obvious where there is an *infinite* number of potential solutions and no particular reason to select any one. Dr. Glacken should not be permitted to testify that the '083 patent is obvious because it is a combination of known ingredients yielding a predictable result because this analysis is in direct contravention of Supreme Court precedent.

B. Dr. Glacken Improperly Assumed That Overlapping, Non-Identical Concentration Ranges Are Obvious As A Matter of Law

All of the prior art references on which Dr. Glacken relies for his obviousness opinions lack certain ingredients claimed in the '083 patent. In addition to this, Dr. Glacken's references all have different, generally overlapping, concentration ranges for the ingredients that they do share in common with the patent. Dr. Glacken ignores this problem in his obviousness analysis. Instead, in his reports on the purported invalidity of the '083 patent and at his deposition, 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.[6] This opinion represents an erroneous view of

[6] This erroneous view was represented by Celltrion in the slides presented at the December 21–22 hearing that reflected that there were "only" three, or six, differences between the '083 patent and two prior art references. Excerpts of Slides Accompanying Defendants' Motion for Partial Summary Judgment (Ex.

the test for obviousness as applied to this case. Dr. Glacken should be precluded from offering testimony that overlapping, non-identical ranges in the prior art render the corresponding concentration limitations of the '083 patent obvious as a matter of law.

In his reply report, Dr. Glacken states his understanding that "where there is a range disclosed in the prior art and the claimed invention lies within or overlaps that prior art range, the prior art shows that element of the claim to be obvious and known by a POSA." Glacken Reply Invalidity Report ¶ 127; *see also id.* ¶ 85. At his deposition, Dr. Glacken reiterated this view of the law, testifying that his "understanding was that an overlapping range would – between the prior art and the claim 1 of the '083 patent would signal to – would be obvious to a person skilled in the art." Glacken Tr. at 220:5-8. Dr. Glacken offered no further analysis of the differences. Rather, he indicated that he relied on this understanding of the law in reaching his conclusion that the '083 patent is obvious over certain prior art references. *Id.* at 226:2–12; 240:16–241:9.

Elsewhere in his reports, Dr. Glacken acknowledges the "vast number of potential soluble compositions" embraced within the '083 patent. Glacken Opening Invalidity Report ¶ 283. Indeed, Dr. Glacken "performed an exemplary calculation to illustrate how many species would be encompassed by the concentration ranges recited in claim 1" and determined, under conservative assumptions, that "approximately 10^{29} distinctive media" – or about 10 million trillion trillion media – "would fall within this claim." Glacken Reply Invalidity Report ¶ 168 n.23. At his deposition, Dr. Glacken admitted, as he had to, that the prior art references on which his obviousness opinion relies contain similarly enormous number of possible combinations. Glacken Tr. at 118:6–25.

H), at 7–8. That computation was performed by ignoring 20 and 26 differences, respectively, arising from non-identical but overlapping ranges in those two patents.

In light of the vast number of combinations claimed by the patent and disclosed by the prior art, the fact that some of the prior art's concentration ranges overlap with the claimed ranges does not make the ranges that were actually claimed obvious as a matter of law. There is simply no reason for a scientist to modify trillions of possible prior art concentrations to arrive at ones that happen to be within the ranges claimed by the '083 patent. Dr. Glacken appears to have received his instructions about overlapping ranges based on the Federal Circuit's decision in *In re Peterson*, 315 F. 3d 1325, 1329 (Fed. Cir. 2003), where the court noted that "[a] prima facie case of obviousness ***typically*** exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." (emphasis added).

There are two problems – each fatal – with Dr. Glacken's reliance on *Peterson* as the basis for his obviousness analysis. First, *Peterson* involved an appeal arising from a U.S. Patent and Trademark Office proceeding. Such proceedings lack the presumption of validity that is afforded to issued patents in federal court litigation. *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 102 (2011). In *Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclopenzaprine Hydrochloride Extended Release Capsule Patent Litig.)*, 676 F.3d 1063, 1075–80 (Fed. Cir. 2012), the Federal Circuit held that in federal court litigation there is no such thing as "prima facie" obviousness that shifts the burden of proof to the patentee. The court noted that the Supreme Court "has never spoken in terms of a legally rebuttable presumption with respect to obviousness," nor has it provided any "indication that it believes the burden of persuasion should shift to the patentee at some point to prove nonobviousness." *Id.* at 1078, 1078 n.4. In the litigation context, "validity, rather than patentability, is the issue. The challenged patent enjoys a presumption of validity, and the challenger must convince a third-party decision maker of the patent's invalidity by clear and convincing evidence." *Id.* at 1080 n.7 (internal citations

omitted). Thus, the proper analysis of obviousness under *Graham* requires that "all evidence relevant to obviousness or nonobviousness be considered, and be considered collectively." *Id.* at 1078. Dr. Glacken cannot meet the clear and convincing burden of proof merely by observing that the prior art has ranges that overlap those of the '083 patent. Rather, a validity challenge requires assessing – clearly and convincingly – the differences of concentration along with all the other differences between the prior art and the patent claims.

Second, and equally fatal, the *Peterson* court made clear that overlapping ranges are prima facie obvious only in the "typical[]" case. The court pointedly noted, "we do not have here any assertion that the disclosed range is so broad as to encompass a very large number of possible distinct compositions" and therefore "do not need to decide whether a disclosed range of such breadth" would render overlapping ranges prima facie obvious. *Peterson*, 315 F.3d at 1330 n.1. Subsequently, the Federal Circuit held that overlapping ranges in the prior art do ***not*** render a claim prima facie obvious where, as here, the art encompasses large numbers of possible combinations.

In *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc*., 655 F.3d 1291, 1306 (Fed. Cir. 2011), the Federal Circuit held that the "facts here do not present the 'typical[]' case contemplated in *Peterson*" because "about 68,000 protein variants are encompassed by the claims of the '112 patent," which was "an important distinction" from *Peterson*. "The facts here present a case where the 'disclosed range is so broad as to encompass a very large number of possible distinct compositions' thus 'requir[ing] nonobvious invention,' not a case, as in *Peterson*, where prior art 'ranges that are not especially broad invite routine experimentation to discover optimum values.'" *Id.* (quoting *Peterson*, 315 F.3d at 1330 n.1). Put differently, where the choices are so very many, there must be proof that the choices made by the inventor were

obvious, *i.e.*, that there was a reason presented in the prior art to make those choices. Here, as Dr. Glacken himself acknowledges, the prior art here encompasses ***trillions*** more possible combinations than in *Genetics Institute*. Some would fall within the ranges of the '083 patent, but others would not. As such, overlapping ranges in the prior art do not render the corresponding concentration ranges in the '083 patent presumptively obvious. *See also Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015) (upholding finding of nonobviousness of overlapping ranges); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1106 (Fed. Cir. 2002) (holding that overlapping ranges do not create prima facie obviousness where "other limitations of the claim" are different).[7]

As Dr. Butler explained in his validity report and will testify at trial, a person of skill in the art starting from Dr. Glacken's prior art references would have to choose from effectively infinite numbers of possible combinations of ingredients and concentrations, with no particular reason to arrive at the ingredients and concentrations claimed in the '083 patent. Dr. Glacken could have disputed Dr. Butler's opinions in his reply report, but he did not. Instead, as to concentrations, he simply assumed the problem away based on an erroneous legal instruction that overlapping ranges are obvious, even where, as here, the number of possible combinations is essentially infinite. Because it is based on an error of law that will confuse and mislead the jury,

[7] Overlapping ranges are different in kind from ranges that are completely subsumed by prior art ranges. In that case, the prior art essentially invites experimentation within the range, which could result in discovery of an optimal range within what was claimed in the prior art. Even so, with respect to subsumed ranges, the burden of proof never changes, although the burden of production of evidence of non-obviousness does shift to the patent owner. *Galderma Labs., L.P. v. Tolmar, Inc.* 737 F.3d 731, 738 (Fed. Cir. 2013) ("[W]here 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. (emphasis added)). Even using that standard, the large number of ranges in the '083 patent and other differences between the patent and the prior art are sufficient to require Celltrion to come forward with clear and convincing evidence of obviousness.

Dr. Glacken should not be permitted to testify that overlapping, non-identical ranges are obvious as a matter of law.

C. Dr. Glacken Should Be Precluded From Testifying About Obviousness

The two errors in Dr. Glacken's obviousness opinion leave him with little left to testify about. The '083 patent is a combination of ingredients and concentration ranges. As to ingredients, Dr. Glacken opines that they are all known and so the combination of any particular ingredients is obvious, without identifying any reason or motivation to arrive at the claimed combination. As to ranges, Dr. Glacken opines that the prior art ranges overlap those claimed in the '083 patent and so the claimed ranges are obvious. This is just *ipse dixit* and does not meet any standard of proof. Dr. Glacken should be barred from testifying about obviousness.

IV. DR. GLACKEN SHOULD NOT BE PERMITTED TO TESTIFY BEFORE THE JURY ON INDEFINITENESS

Dr. Glacken's report also argues that the '083 patent is invalid for indefiniteness "to the extent that the accused products are found to infringe the asserted claims" under the doctrine of equivalents. Glacken Opening Invalidity Report ¶ 264. In other words, Dr. Glacken does not opine that the '083 patent as written is actually indefinite; he opines that it ***would be*** indefinite if Defendants are found to infringe under the doctrine of equivalents. This argument has no basis in law and should not be presented to the jury.

The patent statute requires patents to "conclude with one or more ***claims*** particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112(b) (emphasis added). Based on this statutory text, caselaw holds that a claim is invalid for indefiniteness "if its language, when read in light of the specification and the prosecution history, 'fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.'" *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F. 3d 1374,

1377 (Fed. Cir. 2015) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc*., 134 S. Ct. 2120, 2124 (2014)). Nobody could plausibly argue that the claims of the '083 patent, which identify specific chemical components in clearly delineated concentration ranges, are indefinite under this standard, and Dr. Glacken does not do so.

Rather than addressing the claims of the '083 patent, Dr. Glacken opines that Janssen's theory of infringement under the doctrine of equivalents is indefinite. *See, e.g.*, Glacken Opening Invalidity Report ¶ 264 ("If these media were nonetheless deemed to infringe . . . it is ambiguous how far the patent scope reaches"); Glacken Reply Invalidity Report ¶ 163 ("Janssen's [infringement] positions reveal the indefiniteness of the asserted claims."). But the definiteness of the range of equivalents has nothing to do with the definiteness of the patent claims under section 112. There is no basis in the law for assessing the definiteness of patent claims – the only proper inquiry under section 112 – in light of the range of equivalents. Rather, as noted above, the range of equivalents is necessarily always somewhat imprecise. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). And, as also noted above, if the range of equivalents is deemed excessive by the Court, the result is a judgment of non-infringement, not invalidity.

In *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 680 (Fed. Cir. 1988), the Federal Circuit summarily rejected Dr. Glacken's argument. The district court had held that "***if*** the claims are 'understood to read on a pad that has a thin coating of cement over the foam core's bottom surface,' they would be invalid under § 112 for indefiniteness." *Id.* (emphasis in original). The Federal Circuit held that "it was improper for the court to redraft the claims [under the doctrine of equivalents] and then hold invalid the redrafted claims." Because the real issue was whether the doctrine of equivalents applies, "the error need not be belabored in the

context of § 112." *Id.*; *see also Warner-Jenkinson*, 520 U.S. at 26 n.3 (noting the Court has consistently rejected the argument that the doctrine of equivalents is inconsistent with the requirement of definiteness since 1854). As in *Diversitech*, the Court here should make short shrift of Defendants' indefiniteness defense.

In any event, "indefiniteness is a question of law." *LifeNet Health v. LifeCell Corp*., 837 F.3d 1316, 1327 (Fed. Cir. 2016). Although this determination may be based on factual findings, indefiniteness arguments should only be presented to the jury "where the issues are factual in nature." *BJ Servs. Co. v. Halliburton Energy Servs.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003). If the issues are not factual, the jury trial may be followed by a "non-jury indefiniteness proceeding." *Veracode, Inc. v. Appthority, Inc.* 137 F. Supp. 3d 17, 42 n.9 (D. Mass. 2015). Here, where Defendants improperly rely on Janssen's doctrine of equivalents case to argue indefiniteness, there are no separate facts related to indefiniteness for the jury to consider. All that Dr. Glacken's testimony would do is introduce a new legal argument that is incorrect as a matter of law. Defendants should not be permitted to distract and confuse the jury with Dr. Glacken's legally irrelevant testimony on indefiniteness.

CONCLUSION

For the above reasons, Dr. Glacken's testimony before the jury should be limited as required by law.

Dated: January 3, 2017

Of Counsel:

Dianne B. Elderkin (admitted *pro hac vice*)
delderkin@akingump.com
Barbara L. Mullin (admitted *pro hac vice*)
bmullin@akingump.com
Angela Verrecchio (admitted *pro hac vice*)
averrecchio@akingump.com
Jason Weil (admitted *pro hac vice*)
jweil@akingump.com
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
215-965-1200
FAX: 215-965-1210

Gregory L. Diskant (admitted *pro hac vice*)
gldiskant@pbwt.com
Irena Royzman (admitted *pro hac vice*)
iroyzman@pbwt.com
Aron Fischer (admitted *pro hac vice*)
afischer@pbwt.com
Andrew D. Cohen (admitted *pro hac vice*)
acohen@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212-336-2000
FAX: 212-336-2222

/s/ Heather B. Repicky

Heather B. Repicky (BBO # 663347)
hrepicky@nutter.com
Alison C. Casey (BBO # 688253)
acasey@nutter.com
NUTTER MCCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210
617-439-2000
FAX: 617-310-9192

Attorneys for Plaintiffs Janssen Biotech, Inc. and New York University

LIST OF EXHIBITS

Exhibit A – Rebuttal Expert Report of Michael Glacken, Sc.D. Regarding Non-Infringement

Exhibit B – Opening Infringement Expert Report of Professor Michael Butler, Ph.D.

Exhibit C – Excerpts of the Deposition of Professor Michael Butler, Ph.D.

Exhibit D – Excerpts of the Deposition of Michael Glacken, Sc.D.

Exhibit E – Reply Infringement Expert Report of Professor Michael Butler, Ph.D.

Exhibit F – Reply Expert Report of Michael Glacken, Sc.D. Regarding Invalidity

Exhibit G – Opening Expert Report of Michael Glacken, Ph.D. [sic] Regarding Invalidity

Exhibit H – Excerpts of Slides Accompanying Defendants' Motion for Partial Summary Judgment

CERTIFICATE OF SERVICE

I certify that on January 3, 2017, this document, filed through the Court's ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing.

/s/ *Heather B. Repicky*

3482251.1

EXHIBITS A-G

(Filed Under Seal)

EXHIBIT H

REDACTED COPY

Janssen Biotech v. Celltrion & Hospira

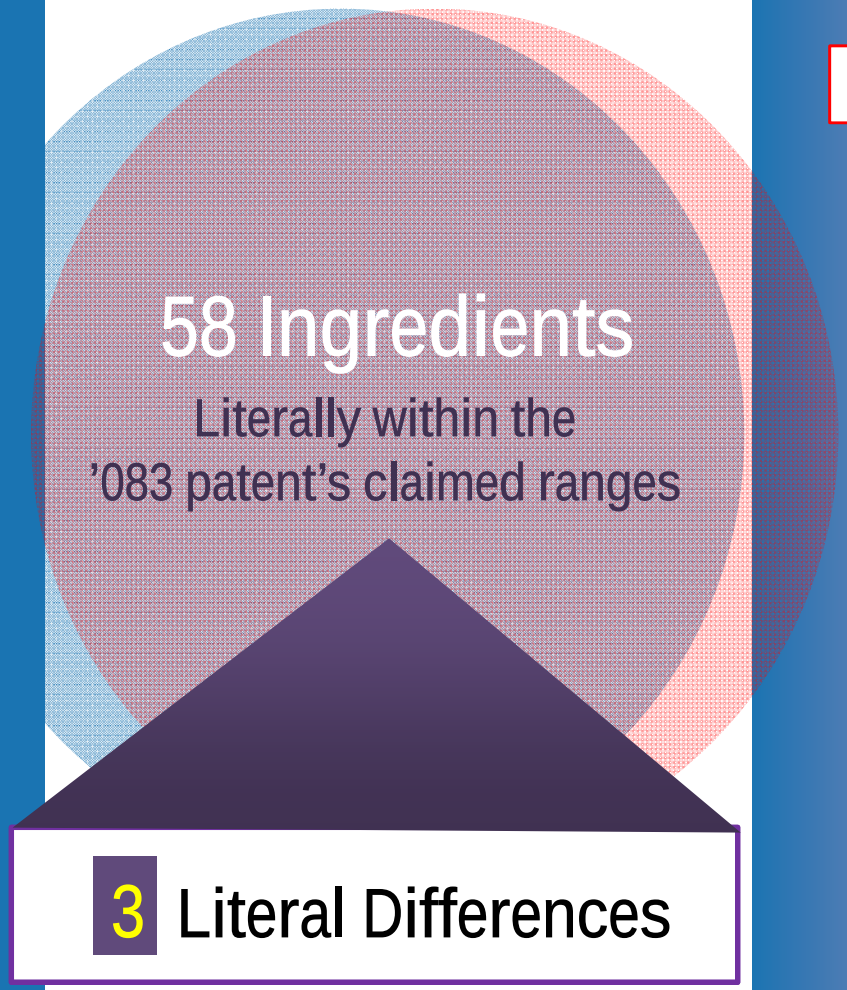
Motion for Partial Summary Judgment of Non-Infringement of U.S. Patent No. 7,598,083

December 21-22, 2016

Janssen's Patent Is Closer to the Prior Art than GE HyClone's Powders

'083 Patent

- ferric ammonium citrate, 0.04-200 mg/L
- NH_4VO_3, 0.0001-0.0025 mg/L
- L-histidine.HCl.H_2O, 100-500 mg/L



GSK Application

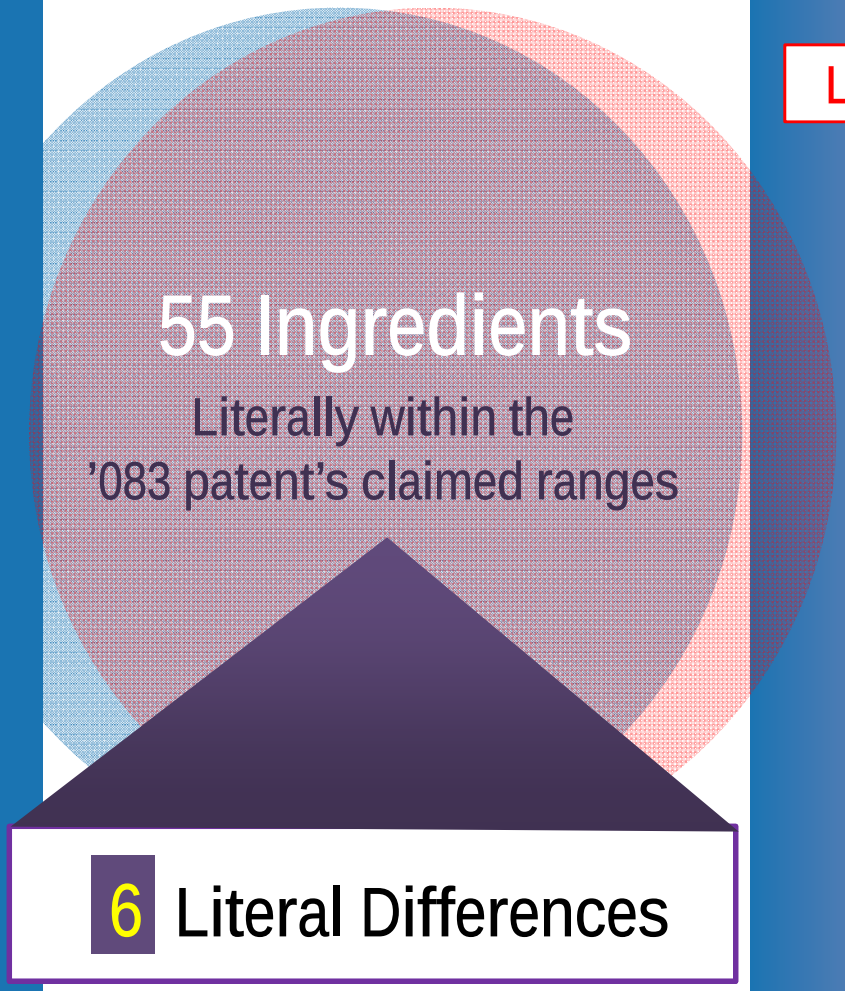
- ferric fructose stock solution, 50-1000 µL
- $NaVO_3$, 0.00001-0.2 mg/L
- L-histidine.HCl.H_2O, 15-70 mg/L

Glacken Rebuttal Rep. (Dkt. 282, Ex. 62) at 51-53; Defs. Supp. Resp. to Pls. SOF (Dkt. 318) at 10

Janssen's Patent Is Closer to the Prior Art than GE HyClone's Powders

'083 Patent

- ferric ammonium citrate, 0.04-200 mg/L
- $MnSO_4 \cdot H_2O$, 0.000070-0.0080 mg/L
- Na_2SeO_3, 0.004-0.07 mg/L
- $SnCl_2.2H_2O$, 0.000025-0.0005 mg/L
- NH_4VO_3, 0.0001-0.0025 mg/L
- putrescine.2HCl, 0.025-0.25 mg/L



Life Tech. Application

- ferric citrate chelate, 0.01-2 mg/L
- $MnCl_2 \cdot 4H_2O$, 0.000001-0.001 mg/L
- H_2SeO_3, 0.00001-0.005 mg/L
- $SnCl_2$, 0.000001-0.0001 mg/L
- $NaVO_3$, 0.00001-0.001 mg/L
- putrescine.2HCl, 0.0001-0.01 mg/L

Glacken Rebuttal Rep. (Dkt. 282, Ex. 62) at 48-51; Defs. Supp. Resp. to Pls. SOF (Dkt. 318) at 10