

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

JANSSEN BIOTECH, INC.,

Plaintiff,

v.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.

Defendants.

No. 1:17-cv-11008

**DEFENDANTS' MOTION FOR LEAVE TO FILE MOTION FOR
SUMMARY JUDGMENT OF NON-INFRINGEMENT BASED ON ENSNAREMENT,
AND RELATED MOTIONS FOR LEAVE TO FILE EXCESS PAGES
AND TO SET BRIEFING SCHEDULE**

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., And Hospira, Inc. (collectively “Defendants”) respectfully request that they be granted leave to file the attached summary judgment motion, that the Court enter Defendants’ proposed briefing schedule and page limits, and that the Court hear Defendants’ motion for summary judgment the week of June 11, 2018. Plaintiff Janssen Biotech, Inc. (“Janssen”) does not oppose leave to file for summary judgment, the proposed page limits, or schedule, but does oppose the underlying motion for summary judgment.

After seeing a preview of Defendants’ obviousness case, the Court recognized that “Janssen has to walk a tightrope with regard to its arguments on equivalents and its arguments against obviousness.” Dkt. 180 (2/2/18 Hr’g Tr.) at 26:15–19. In reality, Janssen cannot do so. While the accused media products differ from the claims in twelve ways, they differ from the prior art in *only three* ways. Janssen cannot make out its twelve-way doctrine of equivalents case without stretching the claims so far that they cover the prior art. Janssen runs squarely into the

doctrine of ensnarement, “the longstanding principle that the prior art restricts the scope of equivalency that the party alleging infringement under the doctrine of equivalents can assert.”

Conroy v. Reebok Int’l, Ltd., 14 F.3d 1570, 1576 (Fed. Cir. 1994).

There is every reason for the Court to consider ensnarement on a motion for summary judgment. The ensnarement doctrine is a “legal limitation on the application of the doctrine of equivalents,” one that is to “be determined by the court” “as a matter of law,” and that may be disposed of “on a pretrial motion for partial summary judgment.” *Depuy Spine*, 567 F.3d at 1323. Moreover, as explained below and in more detail in the attached memorandum of law, the ensnarement issue in this case is not a close one. And granting Defendants’ motion would spare the Court and parties from an immensely costly and time-consuming trial, along with a substantial portion of the work leading up to trial.

Ensnarement is typically evaluated using a “hypothetical claim” analysis “to determine whether an equivalent would impermissibly ensnare the prior art.” *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017) (citation omitted). The “[h]ypothetical claim analysis is a two-step process. The first step is to construct a hypothetical claim that literally covers the accused device.” *Id.* (citation omitted). Then, the hypothetical claim is compared with the prior art “to determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art.” *Id.* “[S]ince prior art always limits what an inventor could have claimed,” ensnarement “limits the range of permissible equivalents of a claim.” *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 771 (Fed. Cir. 1996) (citation omitted). When a patentee’s DOE theory ensnares the prior art, it “cannot be asserted.” *Jang*, 872 F.3d at 1285.

Importantly, while ordinarily an accused infringer bears the burden of showing that an asserted claim is obvious over the prior art, ensnarement places the “burden of persuasion...on the

patentee to establish...that the asserted scope of equivalency would not ensnare the prior art.” *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1323-24 (Fed. Cir. 2009).

There can be no genuine dispute of material fact that hypothetical claim 1 of the '083 patent is obvious in view of the GSK prior art reference. For 50 out of the 52 ingredients and concentrations required by hypothetical claim 1, GSK discloses the exact same ingredients at concentration ranges that overlap with the claimed concentrations. As Janssen's expert Dr. Butler agreed, this degree of similarity between the '083 patent and GSK is “not surprising,” because for people who make cell media, “there's a convergence of ideas and a convergence of opinions on what kind of ingredients ought to be included in the mix.” Dkt. 177 (1/30/18 Hr'g Tr.) at 88:16–25.

Under the law, such “overlapping ranges,” with “even a slight overlap,” “establish[] a *prima facie* case of obviousness” (*In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)) and a “presumption of obviousness.” *Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006). Overcoming the presumption requires a showing that the ranges are “critical.” *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997). But the entire premise of Janssen's infringement case is that the claimed ranges are *not* critical—that is, that concentrations outside the claimed ranges “are insubstantially different from” those within the claimed ranges. No. 15-10698 Dkt. 434 at 12. Indeed, Janssen describes the claims as having “a broad plateau of interchangeable concentrations in cell media,” with the claimed concentrations not “defin[ing] the thresholds of that plateau.” Dkt. 178 (1/31/2018 Hr'g Tr.) at 11:17-18; Dkt. 177 (1/30/2018 Hr'g Tr. (Butler)) at 83:1-3.

The only two ingredient differences between GSK and hypothetical claim 1 are minor, and obvious. The '083 patent supplies two nutrients important to cell growth—vanadium and iron—using two well-established alternatives to the ingredients used in GSK's media. And Janssen's

expert agreed that if there are two different forms of a given nutrient you have the option to choose between them. This simple substitution of known alternatives is the very definition of obviousness under *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 416 (2007), which holds that the “mere substitution of one element for another known in the field” that does no “more than yield a predictable result” is unpatentably obvious. *Id.* Accordingly, the '083 patent hypothetical claims are obvious as a matter of law over GSK. And as explained in the attached memorandum, they are also obvious over a second prior art reference, called Life Techs, for the same reasons—the presumption of obviousness created by overlapping ranges, and simple substitution of known alternatives.

Although ensnarement was originally proposed to be addressed after the liability jury trial scheduled for February 2017 (*see* No. 15-10698 Dkt. 430 at 28), this was a function of the case schedule including only about seven weeks between close of expert discovery and trial, with no specified time for summary judgment. *See* No. 15-10698 Dkt. 246, 261. Despite the fact that the liability phase of the case is closed, there is time now to properly address Defendants' ensnarement defense before a costly and time-consuming trial. This, and the potential for ensnarement to dispose of the case, constitute good cause for it to be briefed and heard on summary judgment. *See* Fed. R. Civ. P. 16(b)(4); *Vulcan Tools of Puerto Rico v. Makita U.S.A., Inc.*, 23 F.3d 564, 565–66 (1st Cir. 1994) (finding “good cause for lifting the deadline for filing dispositive motions,” noting that “pretrial orders are to be liberally construed” and are left to judge's discretion); *Eischeid v. Dover Const., Inc.*, 217 F.R.D. 448, 455-56 (N.D. Iowa 2003) (finding good cause to adjust summary judgment deadline to permit motion addressing “legal issues that the court must inevitably address,” noting that “a well-founded summary judgment motion might present the most efficient method” for addressing them).

WHEREFORE, Defendants respectfully request that the Court:

- Grant Defendants leave to file their Motion For Summary Judgment Of Non-Infringement Based On Ensnarement, supporting memorandum, LR 56.1 Statement of Fact and exhibits thereto; Defendants’ proposed Motion for Summary Judgment and Memorandum in Support are attached as Exhibits 1 and 2, respectively;¹
- Grant Defendants leave to file a 30-page brief in support of the motion for summary judgment, in order to facilitate fulsome presentation of the relevant legal issues and undisputed facts;
- Grant Janssen leave to file a 30-page opposition brief;
- Schedule the motion for summary judgment for hearing during the week of June 11, 2018, when the Court has already set aside time for hearings, and before the Court proceeds to other issues that may be disposed of by the motion; and
- Enter the proposed briefing schedule set forth below, and ensure that briefing is completed sufficiently in advance of June 11.²

Event	Timing
Defendants file motion for summary judgment and accompanying papers	Promptly upon Court granting leave
Janssen files its opposition or, if the Court has not yet granted leave, serves its opposition on Defendants	May 10, 2018 ³
Defendants file their reply brief or, if the Court has not yet granted leave, serves their reply brief on Janssen	May 28, 2018

¹ Defendants’ attached summary judgment motion and memorandum of law refer to Defendants’ Rule 56.1 Statement of Facts and various exhibits in support of summary judgment. So as not to burden the present motion for leave with numerous attachments, Defendants will file the Rule 56.1 Statement of Facts and exhibits in support of summary judgment if leave is granted (or if otherwise requested by the Court). However, Defendants are concurrently serving the Rule 56.1 Statement of Facts and exhibits in support of summary judgment on Janssen.

² The parties have negotiated this schedule in light of the current damages discovery schedule, including Plaintiffs’ reply expert reports on non-infringing alternatives due April 10 and the six damages expert depositions scheduled between April 17 and April 27.

³ Local Rules 7.1 and 56.1 permit 21 days for an opposition to a motion for summary judgment. However, Janssen will have had Defendants’ motion, memorandum, and statement of facts for over one month before the May 10 deadline for opposition by virtue of Defendants having submitted the papers with their motion for leave.

Dated: April 3, 2018

Respectfully submitted,

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

By their attorneys,

/s/Andrea L. Martin, Esq.

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*Attorneys for Defendants Celltrion Healthcare
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LR 7.1(a)(2) CERTIFICATION

I, Andrea L. Martin, hereby certify that Defendants' counsel has conferred with Plaintiff's counsel and attempted in good faith to resolve or narrow the issue raised in this motion. Plaintiff does not oppose leave to file for summary judgment, the proposed page limits, or schedule, but does oppose the underlying motion for summary judgment.

/s/ Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

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 April 3, 2018.

/s/ Andrea L. Martin, Esq.
Andrea L. Martin, Esq.