

**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

**PUBLIC
REDACTED VERSION**

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL
SUMMARY JUDGMENT THAT THERE WERE AVAILABLE AND ACCEPTABLE
NON-INFRINGEMENT ALTERNATIVES TO THE ASSERTED PATENT**

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Fed. R. Civ. P. 56(a)5

I. INTRODUCTION

Because Janssen seeks to prove entitlement to lost profits using the *Panduit* test, it bears the burden of establishing the “absence of acceptable noninfringing alternatives.” *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F. 2d 1152, 1156 (6th Cir. 1978). But it cannot possibly satisfy that obligation. Defendants have identified numerous available, acceptable, non-infringing alternatives to the claimed cell culture media. As to one in particular—modifying the accused media to eliminate the claimed ingredient magnesium chloride—Janssen cannot and has not raised any material fact dispute. Thus, Defendants are entitled partial summary judgment holding that there is at least one available, acceptable non-infringing alternative, which precludes Janssen from seeking lost profits.

Janssen’s expert, Dr. Butler, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 115:24-116:13; SOF¹ ¶ 12. He further confirmed that [REDACTED]

[REDACTED] *Id.* at 120:9-121:13; SOF ¶ 13.

Dr. Butler cannot credibly claim otherwise, because his infringement theory looked to active components rather than the chloride or sulfate attached to them. For example, Dr. Butler argued a limitation directed to another trace metal, copper sulfate, was met because “[w]hether the source of [active component] copper(II) in the media is a sulfate salt (as in the claim), or a mixture

¹ “SOF” herein refers to Defendants’ Rule 56.1 Statement of Undisputed Material Facts filed concurrently in support of the instant motion.

of chloride and sulfate salts (as in the Celltrion Media), in solution cells will encounter free copper(II).” Dkt. 221-3, Butler Op. at ¶ 59; SOF ¶ 8.

Dr. Butler further [REDACTED]

[REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 120:9-121:13; SOF ¶ 13. There is no dispute that this easily-implementable alternative media was both available and acceptable.

Nor is there any dispute that this alternative is non-infringing. In fact, Dr. Butler—Janssen’s infringement expert—refused to take any position on the issue. [REDACTED]

[REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 115:24-118:16; SOF ¶¶ 12, 15.

In fact, he could not credibly claim that the modified media would infringe, because it completely lacks a required claim limitation: the ingredient magnesium chloride. As the Supreme Court stated, “[i]t is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 29 (1997). The Federal Circuit has considered and rejected analogous attempts by patentees to satisfy two recited claim elements by pointing to one of them. For example, in *Power Integrations*, the Federal Circuit held that the claimed “first feedback signal” and “second feedback signal” cannot be satisfied by a single feedback signal without vitiating a limitation. *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 843 F.3d 1315, 1344-45 (Fed. Cir. 2016). Likewise, as a matter of law, the first claimed magnesium source (magnesium chloride) and second claimed magnesium source (magnesium sulfate) cannot both be satisfied by one magnesium source (magnesium sulfate) alone.

Dr. Butler's admissions foreclose Janssen's ability to recover lost profits as a matter of law, such that summary judgment of no lost profits should be entered.

II. STATEMENT OF UNDISPUTED FACTS

Janssen asserts infringement of U.S. Patent No. 7,598,083 ("083 Patent"), which claims a specific formulation of cell culture media. Dkt. 1 (Complaint) at ¶ 1. Janssen contends that two GE HyClone cell culture media products—Growth Powder (HyClone Catalog No. SH3A2713) and Production Power (HyClone Catalog No. SH3A2800)—are covered by the asserted claims of the '083 Patent under the doctrine of equivalents. Dkt. 221-1 at ¶ 12; SOF ¶ 5. Defendants use the accused cell culture media as part of a process to grow cells in the production of the drug infliximab. SOF ¶ 6.

There is no dispute, however, that the cell culture media claimed in the '083 Patent is not the only media that could be used in producing infliximab. [REDACTED]

[REDACTED]

[REDACTED]

Ex. 1, Butler 4/17/18 Dep. Tr. at 45:16-21; SOF ¶ 9. [REDACTED]

[REDACTED] *Id.* at 43:6-45:21; SOF ¶ 10.

Defendants thus proffered as one non-infringing alternative a simple change to the accused products that necessarily avoids infringement. *E.g.* Ex. 2, Frohlich Rep. at ¶ 23; SOF ¶ 11. The '083 Patent contains two limitations directed to magnesium salts: "anhydrous MgCl₂ [magnesium chloride], 15-50 mg" and "anhydrous MgSO₄ [magnesium sulfate], 20-80 mg." Dkt. 227-13, '083 Patent at Claim 1; SOF ¶ 3. Janssen's expert Dr. Butler [REDACTED]

[REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 114:14-16; SOF ¶ 4. GE HyClone

includes both magnesium chloride and magnesium sulfate in the allegedly infringing media. Ex. 2, Frohlich Rep. at App'x C; SOF ¶ 7. In Defendants' proffered non-infringing alternative, one of the claimed magnesium salts is eliminated and the other claimed magnesium salt is increased to compensate, such that the same total amount of magnesium is provided. *E.g.*, Ex. 2, Frohlich Rep. at ¶ 273; SOF ¶ 11. To illustrate, Defendants could have eliminated magnesium chloride and increased the magnesium sulfate to compensate. *Id.*

Janssen's expert Dr. Butler does not dispute that this magnesium change would work;

[REDACTED]

Ex. 1, Butler 4/17/18 Dep. Tr. at 115:24-116:13; 120:9-121:13; SOF ¶¶ 12-13.²

III. SUMMARY JUDGMENT LEGAL STANDARD

Summary judgment should be granted when “there is no genuine dispute as to any material fact” and “the movant party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue is “genuine” when a reasonable fact-finder could find for the non-moving party; a fact is “material” when it might affect the outcome of the suit under the applicable law. *Morris v. Gov’t Dev. Bank of P.R.*, 27 F.3d 746, 748 (1st Cir. 1994). The non-moving party bears the burden of placing at least one material fact into dispute after the moving party shows the absence of any disputed material fact. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 15 (1st Cir. 1994) (discussing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

IV. ARGUMENT

To obtain lost profits under *Panduit*, Janssen “must prove . . . [the] absence of acceptable noninfringing substitutes.” *Panduit*, 575 F. 2d at 1156; *Presidio Components, Inc. v. Am. Technical Ceramics Corp.*, 875 F.3d 1369, 1380 (Fed. Cir. 2017) (the “*Panduit* test requires the patentee to show . . . an absence of acceptable, noninfringing substitutes.”).

A. **The magnesium switch was an interchangeable alternative, and thus acceptable.**

There is no genuine dispute of material fact that [REDACTED]

[REDACTED]

[REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 115:24-116:13; 120:9-121:13; SOF ¶¶ 12-13. As Dr. Butler [REDACTED]

² All emphases added and objections omitted from deposition quotes in this memorandum.

GE HyClone added both forms of magnesium to the accused products. Ex. 2, Frohlich Rep. at App'x C; SOF ¶ 7. Thus, Celltrion could have simply asked GE HyClone to remove one of the magnesium salts and compensate with an equal amount of the other using the same materials. Indeed, there is no actual evidence that the modified magnesium media formulation would take any longer than a typical purchase order. And in any event, even Dr. Butler [REDACTED] [REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 120:18-23; SOF ¶ 13.

That change would have caused not even a single day of delay in Inflectra®'s ultimate introduction to the marketplace. On the relevant date in October 2009, Celltrion [REDACTED] [REDACTED] [REDACTED] Ex. 2, Frohlich Rep. ¶ 109; SOF ¶ 16. Thus, with literally no delay whatsoever, Celltrion could have simply appended the magnesium change [REDACTED], and then proceeded along the very same development and regulatory path that ultimately led to Inflectra®'s product launch seven years later in 2016. Ex. 2, Frohlich Rep. ¶ 101; SOF ¶ 6. Again, as noted above, the two different forms of magnesium are [REDACTED] and Janssen has offered no evidence to the contrary. [REDACTED] [REDACTED] [REDACTED] Ex. 1, Butler 4/17/18 Dep. Tr. at 121:7-13; SOF ¶ 13.

C. Janssen cannot (and does not) argue the magnesium switch infringes.

Without the claimed magnesium chloride, the asserted claims cannot be literally infringed, and Janssen cannot rely on the doctrine of equivalents without vitiating the claim element requiring magnesium chloride. As the Supreme Court has made clear, “[i]t is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such

broad play as to effectively eliminate that element in its entirety.” *Warner-Jenkinson*, 520 U.S. at 29.

Where a claim requires multiple sources, a single source cannot satisfy the claim without vitiating the limitations at issue. For example, in *Power Integrations*, the Federal Circuit held that the claimed “first feedback signal” and “second feedback signal” cannot be satisfied by a single feedback signal without vitiating a limitation. *Power Integrations*, 843 F.3d at 1344-45. Likewise, it has held that “finding a signal from one source to be equivalent to ‘signals from a plurality of sources’ would vitiate that claim limitation by rendering it meaningless.” *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1339 (Fed. Cir. 2011). Whether claim vitiation precludes application of the doctrine of equivalents is a question of law and is appropriately considered on summary judgment. *Seachange Int’l, Inc. v. C-Cor, Inc.*, 413 F. 3d 1361, 1378 (Fed. Cir. 2005); *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) (affirming vitiation summary judgement). “[I]f a court determines that a finding of infringement under the doctrine of equivalents ‘would entirely vitiate a particular claimed element,’ then the court should rule that there is no infringement under the doctrine of equivalents.” *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003).

Here, the patent claims two sources of magnesium: magnesium chloride and magnesium sulfate. Dkt. 227-13, ’083 Patent at Claim 1. But the proposed alternative lacks one of those two claimed sources altogether (magnesium chloride), and Janssen cannot argue that the claimed magnesium chloride and magnesium sulfate limitations are legally equivalent to magnesium sulfate alone without vitiating the limitations. *Power Integrations*, 843 F.3d at 1344-45; *Am. Calcar*, 651 F.3d at 1339. “Under the doctrine of equivalents, an infringement theory thus fails if it renders a claim limitation inconsequential or ineffective.” *Akzo Nobel Coatings, Inc. v. Dow*

Chem. Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016). But that is exactly what would occur if Janssen were to try to use the doctrine of equivalents to cover this modified alternative media. Thus, the modified media does not infringe the '083 Patent claims as a matter of law.

In fact, Janssen's expert reports proffered to rebut Defendants' asserted non-infringing alternatives fail to allege infringement of the magnesium switch and Dr. Butler refused to answer if it would infringe:

[REDACTED]

Ex. 1, Butler 4/17/18 Dep. Tr. at 117:13-118:16; SOF ¶ 15. Accordingly, Janssen has offered no evidence of infringement.

V. CONCLUSION

For the reasons above, the Court should grant summary judgment that Janssen has failed to prove the absence of non-infringing alternatives and preclude Janssen from seeking lost profits.

Dated: May 4, 2018

Respectfully submitted,

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

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/s/Andrea L. Martin, Esq.

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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 May 4, 2018.

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