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## I. INTRODUCTION

This Court has opined that if Defendants have infringed the '083 patent, Janssen will be entitled to reasonably foreseeable lost profits unless an acceptable non-infringing alternative was available to the Defendants. *See Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, 239 F. Supp. 3d 328, 330 (D. Mass. 2017). In briefing leading to that guidance, Janssen argued that the relevant date on which to analyze the availability of non-infringing alternatives was the beginning of the period of infringement for which it sought lost profits (the accounting period), while Defendants argued that the relevant date was the date of first infringement, whether or not the infringement led to recoverable lost profits. The Court agreed with Defendants and opted for the date of first infringement. In this motion, Janssen applies that ruling to the undisputed facts. On the undisputed facts, Defendants cannot show that an acceptable non-infringing alternative was available on October 6, 2009, the date of first infringement, and so the Court should grant summary judgment dismissing that defense to lost profits.

The non-infringing alternatives defense to lost profits is almost always invoked where the proposed alternative is both acceptable and actually on the market on the date of first infringement. Where, as here, there were no actual alternatives on the market on the date of first infringement, the defense is all but impossible to establish. In a narrow exception to the rule, the Federal Circuit has only once approved reliance on an alleged alternative that was not actually on the market. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1347 (Fed. Cir. 1999). The alternative in *Grain Processing*, however, was not hypothetical. It was real and readily available. It was implemented by the defendant in two weeks.

This case is not another *Grain Processing*. With damages discovery now complete, it is beyond reasonable dispute that there was no acceptable non-infringing alternative to the accused

Celltrion cell media on the market or readily available at the time of first infringement.

Defendants contend that they could have avoided infringement by using various alternative cell culture media instead of the accused media, or by manufacturing the accused media offshore.

But to this date, none of these supposedly non-infringing alternatives has been successfully implemented and most of them have never even been tried. Indeed, Defendants freely admit that their proposed non-infringing alternatives were not actually available, but merely “*hypothetically* ‘available.’” Dkt. No. 155 at 14 (emphasis added).

Defendants’ non-infringing alternatives theory fails as a matter of law. As the Federal Circuit made clear in *Grain Processing*, to preclude lost profits a non-infringing substitute not on the market must actually be available at the time of first infringement; “substitutes only theoretically possible” or “speculat[ive]” do not suffice. *Grain Processing Corp.*, 185 F.3d at 1353. In subsequent case law, the Federal Circuit clarified that a non-infringing alternative must be “*readily available*” as of the date of first infringement. *Micro Chemical, Inc. v. Lextron, Inc.*, 318 F. 3d 1119, 1123 (Fed. Cir. 2003) (emphasis added). In *Micro Chem.*, the Federal Circuit held that because a four-month period was required to design and implement an alleged non-infringing alternative, it was unavailable as a matter of law – even though it had been successfully implemented at the conclusion of the four-month period. *Id.* Because Defendants’ proposed alternatives here are only “theoretically possible” and in any event were not “readily available” on October 6, 2009, Janssen is entitled to lost profits as a matter of law.

Defendants give little attention to what would have been “readily available” on October 6, 2009, because the answer is “nothing.” Instead, they view October 2009 as just the start of a *seven year period* in which they were supposedly entitled to design, develop and implement a non-infringing alternative – infringing all the while to make sales around the world – so long as

they succeeded in developing an acceptable alternative before they began sales in the United States in 2016. But the cases require that the alternative be “readily available” on the date of first infringement, not hypothetically possible after a period of time. And the reasons for that are fundamental. The “but for” world of damages imagines a world in which there is no infringement, not one in which seven years of infringement precede the development of an alternative. And the non-infringing alternative defense cannot be theoretical or speculative. There is no room for a “woulda, coulda, shoulda” stroll through seven years of imaginary development, testing, validation, regulatory approval, manufacturing and sales.

The cases in which the non-infringing alternatives defense has succeeded and failed make these points clear. Unlike this case, all the reported cases involve real alternatives that had been proven to work in the real world, even if they did not exist at the time of first infringement. In both *Grain Processing Corp.*, and *Micro Chem.*, the alternatives had actually been implemented after infringement had been found. The difference between the two cases was that the alternative was implemented in “only two weeks” in *Grain Processing*, while it took about “four months” in *Micro Chem.* The Federal Circuit approved the two weeks switch-over in *Grain Processing* because the alternative was available “practically instantaneous[ly]”, *Grain Processing Corp.*, 185 F.3d at 1346, but held that four months in *Micro Chem* was too long. In other words, the alternative, even if real and not speculative, was not “readily available” on the date of first infringement where it took four months to implement. In *Micro Chem.*, nine years of infringing activity was not excused just because an alternative was – in reality – designed and implemented at the end of that period. There is no reason here to excuse seven years of infringing activity because of *speculation* that an alternative could have been designed and implemented by the end of that period. The argument fails as a matter of law.

**II. DEFENDANTS’ ALLEGED NON-INFRINGEMENT ALTERNATIVES  
CONSIST OF TWO POSSIBILITIES TIED TO SOME REAL WORLD  
EVENTS AND THE REST ARE ENTIRELY THEORETICAL**

**A. The Real World: Defendants’ Unsuccessful Attempt to Avoid  
Infringement by Shifting Media Production to Singapore**

In assessing Defendants’ alleged non-infringing alternatives, the most relevant evidence is how Defendants actually sought to avoid infringement in the real world. We now know from documents over which Defendants initially asserted privilege that in June 2015, shortly after Janssen filed suit on the ‘083 patent in March 2015, Defendants decided to move production of their cell culture media from Utah to Singapore [REDACTED]

[REDACTED] Statement of Material Facts (SOMF)

¶ 72. Celltrion employees explained that the [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] *Id.* ¶¶ 68-82.

[REDACTED]

[REDACTED] *Id.* ¶ 76.

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 79.

But even these hurry-up efforts did not succeed in avoiding infringement. Because switching raw material suppliers is time consuming and risks regulatory problems, [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 81. Thus, because all or a substantial portion of the raw materials used at the Singapore facility to make the cell culture media for Celltrion are supplied from the United States, the Singapore media continues to infringe the ‘083 patent under 35

U.S.C. § 271(f)(1) to this day. *Id.* ¶ 80. In the real world, despite substantial incentives to avoid infringement, Defendants have failed to do so over a three year period. [REDACTED]

[REDACTED] It was not “readily available” at any time before Defendants’ market entry in 2016. And it is not “readily available” today.

**B. The Real World: Defendants** [REDACTED]

When accused of infringement in 2015, [REDACTED]

[REDACTED] *Id.* ¶¶ 22, 45. Setting aside for the moment Defendants’ speculation about what they could do and how long it would take, there is a real world example from Celltrion’s work in 2008 that is instructive in considering whether there were any acceptable and readily available non-infringing cell media alternatives on the date of first infringement in October 2009.

[REDACTED] *Id.* ¶ 13. [REDACTED]

[REDACTED] *Id.* ¶ 14. [REDACTED]

[REDACTED] *Id.* ¶ 14. [REDACTED]

[REDACTED] *Id.* ¶ 29. [REDACTED]

[REDACTED]

[REDACTED] *d.* ¶¶ 14-15, 29. [REDACTED]

[REDACTED] *Id.* ¶¶ 13-

14. [REDACTED]

[REDACTED] *Id.* ¶¶ 13-20. [REDACTED]

[REDACTED] *Id.* ¶ 16.

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 30. [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 24-37. [REDACTED]

[REDACTED] *Id.* ¶¶ 30-35. [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 26-28.

**C. The Theoretical World: Defendants’ Proposed Non-Infringing Alternatives**

The supposed non-infringing alternatives proposed by Defendants do not exist in the real world and all are speculative. Meanwhile, even in Defendants’ unrealistically optimistic calculus, all would take months (or years) to develop; none would have been “readily available” on October 6, 2009. Defendants propose to spend many days of trial time on this subject, making speculation the centerpiece of the damages trial. Thus, they have submitted two expert reports totaling 219 pages on their various hypothetical alternatives, prompting similarly long and complex responses from two Janssen experts. *Id.* Exs. 1, 10, 13, 22. Since none of these proposed choices was “readily available” on October 6, 2009 (or thereafter), the particular facts

of the different theoretical alternatives do not matter for purposes of this motion. We sketch them out here and they are addressed in detail in the Statement of Material Facts. *Id.* ¶¶ 22-90. Similarly, the date of first infringement does not matter for purposes of this motion. The date of first infringement will be determined at trial. Defendants contend the date of first infringement was October 6, 2009, the date the ‘083 patent issued. *Id.* ¶ 2. We accept that date for purposes of this summary judgment motion.

Turning to Defendants’ supposed alternatives, Defendants contend that they could have developed one or more of a list of hypothetical non-infringing alternatives over seven years beginning in October 2009. These speculative suggestions fall into two categories. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] SOMF Ex.

10 (Nagaich Report) ¶¶ 147-48. [REDACTED]

[REDACTED] *Id.*

¶¶ 168, 172-77. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 168, 172. Needless to say, all of this is speculation in the extreme.

And, even if credited, none of it results in a non-infringing alternative that was “readily available” to Defendants on October 6, 2009. SOMF ¶¶ 67-90.

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 22, 45. [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 16. [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 18-19. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 22-44.

Other proposed media choices are even more speculative, as they involve risky and time-consuming efforts to reverse engineer the HyClone product to avoid infringement. *Id.* ¶ 45. Even today, Defendants have not undertaken that course. Reverse engineering runs the risk of continued allegations of patent infringement. *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1366-68 (Fed. Cir. 2010) (affirming jury finding of willful infringement and damages where infringer reverse-engineered a patented product). [REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 49-50. Moreover, the hypothetical modifications of the accused media proposed by Defendants’ experts have never been made or tested – not even by Defendants’ experts. *Id.* ¶ 47. These alleged non-infringing alternatives do not exist in the real world and are, in the most literal sense, “substitutes only theoretically possible,” which cannot defeat lost profits. *Grain Processing Corp.*, 185 F.3d at 1353. None of these ideas results in an acceptable non-infringing media that was “readily available” on October 6, 2009. *Id.* ¶¶ 45-66.

Recognizing that none of their proposed non-infringing alternatives was readily available

in October 2009, Defendants instead argue that they could have made up for the delay one way or another over the following seven years and still managed to introduce Inflectra on the U.S. market by November 2016. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶ 67, 85, 91, 97. These complex hypotheticals only confirm that none of these proposed non-infringing alternatives was readily available on the date of first infringement, and that all are speculative and theoretical. *Id.* ¶¶ 67-84, 85-90, 91-96, 97-102. There is no basis in the law for the Court to entertain such proof. Defendants did not have seven years to avoid infringement once they started infringing in October 2009. Under the case law, they had about two weeks in which to solve that problem. Since that was impossible on the facts of this case, Defendants must answer to Janssen's claim for lost profits.

**III. THE COURT SHOULD GRANT SUMMARY JUDGMENT THAT NO ACCEPTABLE NON-INFRINGEMENT ALTERNATIVES WERE AVAILABLE TO DEFENDANTS**

**A. Summary Judgment on Non-Infringing Alternatives Is Frequently Granted**

The question whether alleged non-infringing alternatives preclude lost profits is suitable to be determined on summary judgment. On numerous occasions, courts have granted judgment as a matter of law to the patentee on the issue where, as here, there are no facts from which a jury could conclude that an acceptable non-infringing substitute was available to the defendant. *See*

*Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1126 (Fed. Cir. 2003) (holding that plaintiff was entitled to summary judgment on the issue because “the record shows no genuine issue of material fact”); *Conceptus, Inc. v. Hologic, Inc.*, 771 F. Supp. 2d 1164, 1178-1179 (N.D. Cal. 2010) (granting summary judgment that “there were no acceptable and available, non-infringing alternatives to the claimed inventions during the relevant damages period”); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 2011 U.S. Dist. LEXIS 5422, at \*9-12 (E.D. Tex. Jan. 20, 2011) (no non-infringing alternative as a matter of law where there was “only speculation that it might have been theoretically possible for [the infringer] to produce his non-infringing alternatives”).

Here, viewing the “evidence in the light most favorable to [Defendants] and draw[ing] all reasonable inferences in [its] favor,” no jury could conclude that any acceptable non-infringing substitute was readily available to Celltrion on October 6, 2009. *Hicks v. Johnson*, 755 F.3d 738, 743 (1st Cir. 2014) (internal citations omitted). Janssen has met its burden of showing that no on-the-market product was an acceptable substitute for the infringing media and Defendants have produced no evidence from which they can meet their burden of showing that an alternative *not* on the market in October 2009 was nonetheless readily available.

**B. To Preclude Lost Profits, An Acceptable Non-Infringing Alternative Must Have Been Readily Available at the Date of First Infringement**

For a proposed non-infringing alternative to bar lost profits, it must be both acceptable and available. *See Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1332 (Fed. Cir. 2009) (affirming award of lost profits because “no acceptable noninfringing alternative was available”). An acceptable alternative is one that is a “perfect substitute” and “effectively identical” to the infringing product. *Grain Processing*, 185 F.3d at 1355; *see also Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1361-62 (Fed. Cir. 2012) (proposed non-infringing alternative not acceptable where purchasers would not choose the

alternative in place of the infringing product); *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 901-02 (Fed. Cir. 1986) (proposed non-infringing alternative not acceptable where it “lack[s] the advantages” and “beneficial characteristics” of the patented product). As this Court has ruled, the existence of an acceptable non-infringing alternative is determined starting on the date of first infringement, not some later date. *Janssen Biotech*, 239 F. Supp. 3d at 331 (“To decide whether it was feasible for Celltrion to have used a non-infringing media powder to produce Inflectra, it must be determined whether, starting on the date of first infringement, Celltrion could have switched to using a non-infringing alternative.”).

**1. The General Rule: An Acceptable Non-infringing Alternative Must Be On the Market at the Date of First Infringement**

Prior to 1999, Federal Circuit case law adopted a bright-line rule that a non-infringing alternative that had not actually been commercialized at the time of infringement could not foreclose lost profits. *See Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1571 (Fed. Cir. 1996) (“It is axiomatic . . . that if a device is not available for purchase, a defendant cannot argue that the device is an acceptable non-infringing alternative for the purposes of avoiding a lost profits award.”); *see also Cent. Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1579 (Fed. Cir. 1983) (“The dispositive determination at trial, for which Central Soya had the burden of proof, was whether or not there was an acceptable substitute *on the market.*”) (emphasis added); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1579 (Fed. Cir. 1989) (purported non-infringing alternative not considered because it was not “on the market” until after the date of first infringement). On the facts here, there was no acceptable non-infringing alternative available on the market as of October 6, 2009. SOMF ¶¶ 22-44. [REDACTED]

[REDACTED] *id.* ¶¶ 67, 85, [REDACTED] *id.*

¶¶ 29-30, 41-42, 46-47. As discussed below, for such alternatives, which have never been on the market, Defendants bear the burden of proof. *Grain Processing*, 185 F.3d at 1353.

**2. *Grain Processing* Recognizes a Narrow Exception to the On-the-Market Rule, with the Burden Shifting to the Infringer**

In *Grain Processing*, the Federal Circuit recognized a limited exception – which it applied in that case and never since – to the general rule that a substitute must have been on the market to qualify as a non-infringing alternative. But as the *Grain Processing* opinion and subsequent case law makes clear, no exception was made to the rule that non-infringing substitutes must have been *actually available*, as opposed to possibly or theoretically available.

In *Grain Processing*, the infringer sold a maltodextrin, a food additive made from starch. 185 F.3d at 1343. Once the infringer’s maltodextrin was found to infringe – many years after the date of first infringement – the infringer quickly adopted a new process to produce and sell a non-infringing maltodextrin. *Id.* at 1346. The new process was able to be “mass produc[ed]” and used in commercial applications only “two weeks” after the infringer decided to switch processes, “practically instantaneous[ly].” *Id.* at 1346. The existence of this alternative was not speculative or theoretical; the infringer had actually switched to the non-infringing alternative by the time of trial. *Id.* at 1347. Although the substitute was not on the market as of the date of first infringement, the infringer showed it had been able to make the non-infringing alternative practically instantaneously “whenever it chose to do so.” *Id.*

Based on these “specific, concrete” facts, the Federal Circuit concluded that the non-infringing alternative was available from the time of first infringement, despite not being on the market at that time. *Id.* at 1353. The court emphasized, however, that it was the infringer’s burden to prove the availability of a non-infringing alternative that was not being sold on the market, and that “[m]ere speculation” and “theoretical[] possib[ilities]” would not suffice to meet

this burden. *Id.*

When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time. ***The accused infringer then has the burden to overcome this inference by showing that the substitute was available during the accounting period.*** Mere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement. Acceptable substitutes that the infringer proves were available during the accounting period can preclude or limit lost profits; substitutes only theoretically possible will not.

*Id.* (emphasis added) (internal citations omitted).

### **3. Post-Grain Processing, the Federal Circuit Makes Clear that a Non-Infringing Alternative Must Have Been “Readily Available”**

In the nearly 20 years since *Grain Processing*, to Janssen’s knowledge, the Federal Circuit has never again applied that exception to defeat a lost-profits claim. *Grain Processing* thus represents the outside boundary of when a non-infringing alternative is “available” if it was not actually on the market. Indeed, subsequent case law has made clear how narrow the exception is: a non-infringing alternative must be “*readily available*” as of the date of first infringement – able to be implemented in a very short period of time as in *Grain Processing*.

In *Micro Chem.*, the Federal Circuit held that, as a matter of law, an alternative non-infringing machine developed by the infringer nine years after infringement began was not available in the “but-for” world as a non-infringing alternative at the time of first infringement. 318 F.3d at 1123. The design-around did not take long; the infringing machines were converted to a non-infringing model “within a few weeks” of the Federal Circuit decision upholding the validity of the patent. *Micro Chem., Inc. v. Lextron, Inc.*, 161 F. Supp. 2d 1187, 1194 (D. Colo. 2001). The “design of the new tanks . . . was completed and in place . . . only a month after the project began.” *Id.* Nevertheless, it took “over four months to convert all of [the] infringing . . .

machines.” *Micro Chem.*, 318 F.3d at 1123. Based on this, the Federal Circuit held that, as a matter of law, the non-infringing alternative was not “**readily available**” when infringement began. *Id.* (emphasis added).

The post-*Micro Chem.* cases are all the same. In *Synqor Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1382 (Fed. Cir. 2013), the Federal Circuit held that a design that was actually made available for commercial use after “nearly a year, if not longer” of development was not “**readily available**” for purposes of a lost profits analysis. (emphasis added). Similarly, in *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics, Plastics, Inc.*, 637 F.3d 1269, 1288 (Fed. Cir. 2011), the Federal Circuit confirmed that “if the substitute cannot be commercialized ‘**readily**,’ then it is not available for purposes of a lost profits determination.” (citing *Micro Chem.*, 318 F.3d at 1123) (emphasis added). *Accord Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009) (an “acceptable noninfringing substitute [must be] **readily available**”) (emphasis added); *see also Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109, 1120 (Fed. Cir. 1996) (“[T]estimony that an infringer might have been able to design around a patent does not, in itself, defeat a claim for lost profits.”); *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1373 (Fed. Cir. 2008) (although the infringer “had the ability, the resources, and the desire to design around [the patentholder’s] patents” and “it could probably figure out a way to avoid infringement,” there was “no available and acceptable noninfringing alternative, . . . merely the possibility that it could have come up with one.”).

In briefing in connection with the Court’s guidance of last year, Defendants relied on *Apple, Inc. v. Samsung Elecs. Co.*, 2013 U.S. Dist. LEXIS 160189, at \*48 (N.D. Cal. Nov. 7, 2013) (“*Apple I*”), where Judge Koh stated that “designing around the patented intellectual property – starting on the date of first infringement” could constitute a non-infringing alternative.

But Judge Koh did not suggest that defendants can defeat lost profits by hypothesizing about extended design-around projects that had not been implemented in the real world. Rather, Judge Koh plainly recognized that “reconstructing the hypothetical market requires one to factor out infringement entirely,” *i.e.*, the non-infringing alternative must be available right away so as to eliminate infringement “entirely.” *Id.* at \*44. Implementing this approach at trial, the court affirmed the jury’s lost profits award because the defendant could not “have *easily and quickly* implemented the noninfringing” alternative. *Apple, Inc. v. Samsung Elecs. Co.*, 2014 U.S. Dist. LEXIS 17204, at \*54-55 (N.D. Cal. Feb. 7, 2014) (emphasis added). The Federal Circuit affirmed. 786 F.3d 983, 1004 (Fed. Cir. 2015). In sum, the case law is unequivocal: a non-infringing alternative must be “readily available” at the date of first infringement.<sup>1</sup>

### C. Celltrion Does Not Have Seven Years in Which to Develop an Alternative

Having won a favorable ruling from the Court that the relevant date for analyzing the availability of non-infringing alternatives is the date of first infringement – and not the later onset of the accounting period – Defendants try to have it both ways. Mixing and matching these two separate concepts, they contend that the right question is whether they could have developed a non-infringing alternative in the *seven year period* that starts on the date of first infringement (October 2009) and that concludes with the start of the accounting period (November 2016). In

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<sup>1</sup> In recent comments, this Court recognized that the *Grain Processing* exception to the on-the-market rule is limited to situations where the infringer had an alternative “readily” or “quickly” available to it. *See* Feb. 16, 2018 Tr. at 14:21-25 (“If it’s not on the market . . . you have to prove that you could have *quickly* developed your own noninfringing alternative.”) (emphasis added); *id.* at 33:25-34:2 (“[A]ssuming it’s not available on the market, then the question would be could Celltrion have *quickly* developed its own . . . noninfringing alternative.”) (emphasis added); *id.* at 44:7-10 (“If there was not an adequate noninfringing alternative available or *readily available* on the date of first infringement, then Janssen will be entitled to recover its proven lost profits . . . .”) (emphasis added).

so doing, they ignore the case law that says that a non-infringing alternative should be “readily available” on the date Defendants proposed, the date of first infringement – October 6, 2009.

And they ignore the fact that, in their scenario, they would continue to infringe the ‘083 patent for seven years. Defendants’ argument is crystallized in this sentence from one of their expert reports: [REDACTED]

[REDACTED]

[REDACTED]

SOMF Ex. 10 (Nagaich Report) ¶ 37 (emphasis in original).

There is no support in the case law for this approach. Under *Grain Processing* and its progeny, the non-infringing alternative must be “readily available” on the date of first infringement. That is, it must be available within perhaps two weeks of October 6, 2009, but not four months. And certainly not *seven years* after infringement began. Consider the facts of *Micro Chem*. The defendant infringed the patent for nine years, from 1988 to 1997. 318 F.3d at 1121. At the end of that period, in response to litigation, it designed around the patent and implemented new machines in four months. *Id.* at 1123. The new machines were real, not speculative. By Defendants’ theory, all but four months of damages should have been cut off because a “but for” world could be imagined in which a non-infringing alternative could have been implemented in the four months after first infringement. But the Federal Circuit held that four months was too long; the design around was not “readily available” in 1988 and so the defendant did not have a non-infringing alternative that would allow it to avoid lost profits for the entire period. *Id.* at 1123-24. In *Micro Chem.*, an actual design around implemented in the real world after nine years of infringement could not eliminate lost profits damages. Defendants’ theoretical design around that does not exist but that might be created in seven years is of no

relevance whatsoever.

Defendants’ argument confuses the tort of patent infringement with the lost profits remedy. Defendants began to infringe the ‘083 patent in the United States in 2009 and they have continued to infringe – and to damage Janssen – throughout the entire period. Even before any sales were made in the United States, that infringement subjects Celltrion to the risk of reasonable royalty damages and an injunction based on activities in the United States. Janssen’s lost profits damages claim does not begin until November 2016, however, because, under current Federal Circuit case law, the holder of a United States patent cannot recover damages resulting from overseas sales. *See Westerngeco L.L.C. v. Ion Geophysical Corp.*, 791 F.3d 1340 (Fed. Cir. 2015).<sup>2</sup>

But whether those ex-U.S. lost profits can be recovered or not, they are real, they have [REDACTED], and they were proximately caused by Defendants’ continuing infringement in the United States. [REDACTED]

[REDACTED]

[REDACTED]

SOMF ¶ 2. [REDACTED]

[REDACTED] *Id.* ¶ 3 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶ 4. [REDACTED]

[REDACTED]

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<sup>2</sup> That issue is currently before the Supreme Court and a decision is expected by the end of June. *See Westerngeco L.L.C. v. Ion Geophysical Corp.*, No. 16-1011 (S. Ct.) (Argument heard Apr. 16, 2018). Depending on what the Supreme Court says, Janssen may seek lost profits damages for the losses it has suffered in worldwide markets as a result of Defendants’ infringement.



not get to infringe for seven years, causing ongoing injury to Janssen, and then avoid lost profits damages by pulling a non-infringing rabbit out of a hat at the last minute. That did not work in *Micro Chem.*; it cannot work here.

Quite apart from the lack of any intellectual coherence to Defendants' argument, it is also the very essence of speculation to ignore what was "readily available" in October 2009 (nothing!) and instead imagine what Defendants might have done over the next seven years. In opening the door to non-infringing alternatives not actually on the market, the Federal Circuit was acutely aware of the risks posed by theoretical and speculative alternatives. A critical guard against such proof is the requirement that a non-infringing alternative is "available" only if it is "readily available" on the date of first infringement. *See Micro Chem.*, 318 F.3d at 1123. A non-infringing alternative that is only theoretically possible, whose availability depends on many variables over the course of months and years and which has not actually been developed in the real world, is far removed from the underlying objective: determining the profits the patent holder would have earned had there been no infringement. "To prevent the hypothetical from lapsing into pure speculation, [the Federal Circuit] requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture." *Grain Processing*, 185 F.3d at 1350. "Mere speculation or conclusory assertions will not suffice to overcome the inference" that a product not on the market was not available. *Id.* at 1353; *cf. Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983) ("[A]ny doubts regarding the amount [of damages] must be resolved against the infringer."). Of course, the only alternative not actually on the market that has ever been found to meet this standard was the non-infringing maltodextrin of *Grain Processing* that was actually made in the real world in exactly two weeks.

By limiting the search of non-infringing alternatives to those that are “readily available” on the date of first infringement, the factfinder can determine, with a reasonable degree of confidence, what a law-abiding patentee would have done but-for the infringement. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (“To recover lost profits damages, the patentee must show a reasonable probability that, ‘but for’ the infringement, it would have made the sales that were made by the infringer.”). Defendants’ suggestion that the fact finder analyze seven years of hypothetical activity to decide whether a non-infringing alternative was available is inconsistent with controlling law and demonstrates the wisdom of the Federal Circuit’s rule that non-infringing alternatives must be both readily available and non-speculative.

#### **IV. CONCLUSION**

Since *Grain Processing*, the Federal Circuit has rejected all attempts to base a non-infringing alternatives defense on an alternative not actually on the market at the time of first infringement. This case is no better than its predecessors. Defendants have failed to raise a genuine issue of material fact on an issue on which they bear the burden of proof: whether an acceptable non-infringing alternative was available as of the date of first infringement. Summary judgment on this issue is appropriate.

Respectfully Submitted,

Dated: May 4, 2018

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**CERTIFICATE OF SERVICE**

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