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| 8 | UNITED STATES DISTRICT COURT | |
| 9 | SOUTHERN DISTRICT OF CALIFORNIA | |
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| 11 | REMBRANDT DIAGNOSTICS, LP, | Case No.: 16-CV-00698-CAB-NLS |
| 12 | Plaintiff, | ORDER VACATING ORDER |
| 13 | v. | DISMISSING REMBRANDT'S |
| 14 | INNOVACON, INC., | CLAIM FOR INFRINGEMENT OF THE '019 PATENT |
| 15 | Defendant. | |
| 16 | | |
| 17 | INNOVACON, INC., | |
| 18 | Counter Claimant, | [Doc. Nos. 63, 207, 209, 224-230] |
| 19 | v. | |
| 20 | REMBRANDT DIAGNOSTICS, LP and | |
| 21 | ASSURANCE BIOTECH LLC, | |
| 22 | Counter Defendants. | |
| 23 | | |
| 24 | This case is before the Court on a host of summary judgment and <i>Daubert</i> motions | |
| 25 | filed by all parties. Plaintiff Rembrandt Diagnostics, LP ("Rembrandt") filed this case as | |
| | one for patent infringement against multiple defendants concerning multiple accused | |
| 26 | one for patent infringement against multip | ble defendants concerning multiple accused |

28 | 2016 order dismissing one of the infringement claims and Plaintiff's subsequent voluntary

dismissal of the second, the only remaining claims concern alleged breach of an alleged patent license agreement by one remaining defendant as a result of sales of one accused product. The Court's order dismissing Rembrandt's claim for infringement of U.S. Patent No. 6,548,019 (the "'019 Patent"), however, was premised on an erroneous understanding of the existence and effect of a 2004 Patent License Agreement (the "2004 License Agreement") between Counter Defendant Assurance Biotech LLC ("Assurance") and Defendant Innovacon, Inc.'s predecessor, Applied Biotech, Inc. ("Applied Biotech"). In light of facts and evidence revealed in the parties' motions for summary judgment and response to an order to show cause ("OSC"), it is now clear that the 2004 License Agreement terminated by its own terms shortly after it was signed. The Court's October 19, 2016 Order [Doc. No. 85] is therefore vacated, and the motion to dismiss [Doc. No. 63] is instead denied with respect to Rembrandt's claim for infringement of the '019 patent. The Court therefore considers the pending summary judgment and *Daubert* motions in this

I. Introduction

Both procedurally and factually, this case is, for lack of a better word, a mess. No party has acquitted themselves particularly well in how they have framed the issues and argued their positions before the Court, but Defendants are the most blameworthy for the judicial resources this case has wasted. What started as, and should have remained, a straightforward patent infringement case, has devolved unnecessarily into a morass of jurisdictional, contractual, and statute of limitations issues based on Defendants' arguments as to the continued existence of a license based on an agreement executed by two entities that were not original parties to this litigation. The evidence, however, indicates that the 2004 License Agreement terminated by its own terms in 2005, and that both the licensor (Assurance) and the licensee (Applied Biotech) had repudiated the license long before this litigation was instituted. There is simply no evidence that any of the actual parties to this litigation believed this license to be in effect before this litigation began.

context.

None of the parties bothered to read the 2004 License Agreement itself, the actual terms of which resulted in termination of the license in 2005 due to the termination of a separate manufacturing agreement that had been executed at the same time. When the Court brought this contractual language to the parties' attention, Innovacon, Inc., who is the last remaining defendant, scrambled to explain that the language in question contained a typo, and maintained its argument that, all evidence to the contrary, the license remained in effect and does so to this day. Indeed, Innovacon even admitted in its original answer that in 2012, its parent corporation, Alere, Inc., entered into negotiations for license with the inventor of the '019 Patent. If Innovacon and Alere already had a license, as Innovacon argues now, then there would not have been any reason to enter into such negotiations.

For its part, Rembrandt has half-heartedly indicated that it thinks the license is no longer valid, but it never made any formal argument or motion asking the Court to rule that the 2004 License Agreement was no longer effective and that this case should proceed on patent infringement. Instead, Rembrandt asserted alternative claims for infringement and breach of the 2004 License Agreement, and left it to the Court to sort out the details. Rather than actively prosecuting this case and sticking to its original infringement claims, Rembrandt has reacted passively to arguments by the defendants concerning the enforceability of the 2004 License Agreement and Court orders concerning its effect on Rembrandt's claims and the Court's jurisdiction, content so long as some avenue for recovery of damages remained.

The Court has now sorted the details, and as set forth below, found no evidence that any of the parties actually acted as if the 2004 License Agreement provided Defendants with a license to practice the '019 Patent after 2005, or at a minimum as of 2012. Instead, Defendants have simply used the 2004 License Agreement as part of shell game of arguments somehow hoping to avoid any liability even if they are found to infringe the

¹ In an argument thick with irony, Innovacon argued that the "precision" of the language of the 2004 License Agreement demonstrates that the section in question contained a typo.

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'019 Patent or make products that are covered by the supposed license. Accordingly, upon consideration of the entire record and all of the recent motions, all claims and defenses based on the supposed existence of a license are dismissed, and a jury shall resolve this dispute in the posture it should have been in all along—a claim for infringement of the '019 Patent.

II. **The Patents**

Initially, two patents were at issue in this litigation, U.S. Patent No. 6,548,019 ("the '019 patent") and U.S. Patent No. 8,623,291 ("the '291 patent"). Both these patents issued to named inventor Jin Po Lee.² The '019 Patent describes a urine testing cup, and the '291 Patent describes a urine dip testing device. Claim 10 of the '019 Patent is the only claim allegedly practiced by the only accused product still at issue in this lawsuit. Rembrandt's claims related to infringement of the '291 patent have since been dismissed and remain out of this case notwithstanding the instant order.

The Players III.

A. **Counterdefendant Assurance Biotech**

Assurance is a company Lee founded to commercialize his inventions. Lee assigned the '291 Patent and '019 Patent to Assurance, and Assurance is the "Licensor" on the 2004 License Agreement. Innovacon made Assurance a party to this lawsuit in its answer and counterclaims to the second amended complaint, asserting claims against Assurance for breach of the 2004 License Agreement and seeking declaratory judgment that Innovacon did not breach the 2004 License Agreement. [Doc. No. 114.]

B. Plaintiff Rembrandt Diagnostics

On or about April 7, 2015, Assurance entered into a Patent Acquisition Agreement (the "Acquisition Agreement") with Rembrandt IP Management, LLC ("RIPM"). [Doc.

² The '019 patent has two named inventors, Lee and Poyi Tseng, but reflects Lee as the assignee when it issued. [Doc. No. 1 at 24.]

No. 63-1 at 3.]³ The Acquisition Agreement set out terms for the acquisition of certain Assurance patents, including the '019 Patent and '291 Patent, by RIPM or its designated affiliate. RIPM exercised its assignment right, and on September 18, 2015, Assurance sold, assigned, transferred and conveyed the patents to Rembrandt, subject only to amended licenses with two of Assurance's affiliate companies, Syntron Bioresearch, Inc. ("Syntron"), and Tianjin New Bay Bioresearch Co Ltd. ("Tianjin"), all right, title and interest in the '019 Patent, including all past, present and future infringement claims and the right to sue and collect damages for all past, present, and future infringement. [*Id.* at 53.] The Court determined, however, that the 2004 License Agreement between Assurance and Applied Biotech precluded the transfer by Assurance to Rembrandt of all substantial rights under the '019 Patent and therefore found that Rembrandt did not have constitutional and prudential standing to bring suit in its own name. [Doc. No. 85.]

On June 8, 2016, after filing this lawsuit, Rembrandt obtained from Assurance the right to sue and collect damages for breach of the 2004 License Agreement. [Doc. No. 41 at ¶ 68; Doc. No. 63-1 at 50.]

C. Applied Biotech

Applied Biotech is the "Licensee" under the 2004 License Agreement (*see* § V., *infra*) with Assurance. [Doc. No. 94.] According to Innovacon's counterclaim, on or about January 31, 2011, Applied Biotech merged into and with Innovacon, with Innovacon as the surviving corporation acquiring all rights to the 2004 License Agreement. [*Id.* at 25, ¶ 23.]

D. Innovacon

Innovacon is a wholly owned indirect subsidiary of Alere, Inc. ("Alere"), and reports its business operations in Alere's consolidated financials. [Doc. No. 25 at ¶ 8.] As stated above, Innovacon is the successor corporation to Applied Biotech.

³ Pinpoint citations to pages of documents in the record that do not include a "¶" are to the page reflected on the ECF generated watermark appearing at the top of the page.

E. Other Alere Defendants

In addition to Innovacon, the original complaint named as defendants: Alere, Inc. ("Alere"), Alere Toxicology Services, Inc. ("Alere Toxicology"), Amedica Biotech, Inc. ("Amedica"), Amedica Biotech, Inc. ("Amedica"), Instant Technologies, Inc. ("Instant Technologies"), US Diagnostics, Inc. ("US Diagnostics"), and Branan Medical Corporation ("Branan"). Innovacon and the latter six companies are wholly owned indirect subsidiaries of Alere, and they all report their business operations on Alere's consolidated financials. [Doc. Nos. 1, 25 at ¶¶ 5-11.] The first amended complaint ("FAC") added Instant Tech Subsidiary Acquisition, Inc., dba U.S. Diagnostics ("Instant Tech"), another Alere subsidiary, as a defendant. [Doc. No. 41 at ¶¶ 5-12.] All claims against these other defendants have since been dismissed in light of the Court's rulings concerning the 2004 License Agreement and Plaintiff's abandonment of claims involving the '291 Patent. Innovacon is currently the only defendant in this case.

IV. The Accused Products

In the various iterations of its complaint in this litigation, Rembrandt has contended that Defendants make, use, import, offer to sell, or sell a variety of products that infringe, or would infringe but for the 2004 License Agreement, the '019 patent. In the currently operative second amended complaint ("SAC"), Rembrandt identified products marketed and sold under the trade names "iCup Dx Pro," "iCup A.D.," "AmediCheck," "DrugSmart," and "UScreen" as the accused products. [Doc. No. 90 at ¶ 23.] However, in its January 8, 2018, second amended disclosure of devices subject to the 2004 License Agreement, i.e., devices that would infringe the '019 patent but for the 2004 License Agreement, Rembrandt only identified AmediCheck, Uscreen, and iCup A.D. as the products covered by the '019 patent. [Doc. No. 207-5 at 3.] Rembrandt has since conceded that based on the Court's claim construction, the AmediCheck and UScreen products do not infringe. [Doc. No. 214 at 5.] Thus, the only accused product still at issue is the iCup A.D.

V. Procedural History

On March 23, 2016, Rembrandt filed this lawsuit against Alere, Alere Toxicology, Amedica, Ameditech, Innovacon, Instant Technologies, US Diagnostics, and Branan asserting two claims: (1) infringement of the '019 Patent; and (2) infringement of the '291 Patent. The complaint alleged that each defendant infringed the '019 Patent, and that all but Amedica and Branan infringed the '291 Patent, by their sales of a host of products.

In their answer to the original complaint, the defendants asserted an affirmative defense that Rembrandt's claims were precluded in whole or in part based on a license. [Doc. No. 25 at 14.] In addition, Alere, but not any of the other defendants, asserted counterclaims against Rembrandt seeking declaratory relief of non-infringement and invalidity of the '019 Patent. [*Id.* at 15-20.]

On August 5, 2016, the parties filed a joint motion for leave for Rembrandt to file a first amended complaint. According to the motion, the reason for the amendment was to add defendant Instant Tech, and, based on the affirmative defense of the existence of a license, alternative claims for breach of that license agreement and breach of the covenant of good faith and fair dealing. [Doc. No. 36.] The Court granted the motion and the first amended complaint was docketed on the same day. [Doc. No. 41.] The first amended complaint retained the previously admitted allegations related to license negotiations between Alere and Lee in 2012. [Id. at ¶¶ 30-32.] It asserted a claim for infringement of the '019 Patent against all of the defendants, a claim for infringement of the '291 Patent against all defendants except Amedica and Branan, and the alternative contract claims against Alere only. [Doc. No. 41 at 13-22.]

On October 19, 2016 the Court granted Defendants' motion to dismiss the claim for infringement of the '019 Patent, holding that the 2004 License Agreement precluded a finding that Rembrandt's interests in the '019 Patent at the time the complaint was filed were sufficient to provide standing. [Doc. No. 85 at 15.] The Court also dismissed the contract claims against Alere because only Innovacon, as successor to Applied Biotech, was a party to the 2004 License Agreement, but the Court gave Rembrandt leave to file an

amended complaint for infringement of the '291 Patent, and for breach of the 2004 License Agreement against Innovacon. On the same day, by a separate order, the Court granted a temporary stay of the litigation pending a decision from the United States Patent Office as to whether it would institute *Inter Partes* Review ("IPR") of the two patents. [Doc. No. 86.] Notwithstanding the stay, Rembrandt was instructed to file its amended complaint by October 31, 2016.

Consistent with the Court's order, on October 31, 2016, Rembrandt filed a second amended complaint asserting claims against Innovacon for breach of the 2004 License Agreement and against all of the previously named defendants except for Amedica and Branan for infringement of the '291 Patent. [Doc. No. 90.] The second amended complaint remains the operative complaint in this case. It alleges breach of the 2004 License Agreement via sales by Defendants of five urine test cup products. As stated above, however, the iCup A.D. is the only accused product still at issue in this case.

On March 16, 2017, while the stay was still in effect and before Defendants had responded to the complaint, the Court granted a joint motion to dismiss the claim for infringement of the '291 Patent. [Doc. No. 104.] As a result, Rembrandt's only remaining claims in this case as it is currently constituted are against Innovacon for breach of the 2004 License Agreement.

Meanwhile, on March 3, 2017, Rembrandt moved to lift the stay on the grounds that the IPR proceedings no longer warranted a stay because, in light of the soon to be filed dismissal of the '291 Patent infringement claims, this was simply a breach of contract case. Defendants opposed the motion, arguing that the stay should continue until the IPR, which the Patent Office instituted on February 13, 2017, was completed. [Doc. No. 102.]⁴ On

⁴ In their opposition, Defendants contended that if the '019 is declared invalid, any obligation to pay royalties under the 2004 License Agreement would cease on May 13, 2016, based on Alere's counterclaim seeking a declaration of invalidity. [Doc. No. 102 at 6, 10.] Presumably, this argument was in reference to the *Lear* doctrine, pursuant to which a licensee is not estopped from challenging the validity of the licensor's patent and may cease royalty payments "during the time it is challenging patent validity in the courts." *See Go Med. Indus. Pty., Ltd. v. Inmed Corp.*, 471 F.3d 1264, 1273 (Fed. Cir. 2006) (citing *Lear*,

April 12, 2017, the Court granted Rembrandt's motion, lifted the stay, and ordered Innovacon, the only remaining defendant, to respond to the second amended complaint by April 28, 2017. [Doc. No. 109.]

On April 28, 2017, Innovacon answered the second amended complaint. Notably, Innovacon asserted affirmative defenses that Rembrandt's breach of contract claims were barred because Rembrandt or its predecessor breached the 2004 License Agreement and the implied covenant of good faith and fair dealing. [Doc. No. 110 at 20.] In addition, for the first time in this litigation, Innovacon asserted counterclaims against Rembrandt and Assurance, seeking declaratory relief that the '019 Patent was invalid and that Innovacon did not infringe. Innovacon also sought a declaration that any breach by Innovacon was excused by Rembrandt's breach first. [Id. at ¶¶ 3, 82-88.]

Rembrandt and Assurance answered the counterclaims [Doc. Nos. 120, 124] and the case proceeded through discovery and claim construction. On March 27, 2018, Innovacon filed a motion for summary judgment that it did not breach sections 3.2 and 3.5 of the 2004 License Agreement, which concerned payment of royalties. [Doc. No. 207.] Two days later, Innovacon filed a separate motion for summary judgment that it did not breach section 2.3 of the 2004 License Agreement, which concerned the licensee's obligation to use reasonable commercial efforts to promote products subject to the license granted by the 2004 License Agreement. [Doc. No. 209.] On April 23, 2018, Rembrandt moved for summary judgment that Innovacon breached section 3.3 of the 2004 License Agreement,

Inc. v. Adkins, 395 U.S. 653, 673 (1969)). Yet, as of March 10, 2017, the date of Defendants' opposition to the motion to lift the stay, Innovacon, who according to Defendants was the only licensee under the 2004 License Agreement, had yet to challenge the validity of the '019 Patent. "[T]he Lear doctrine does not prevent a patentee from recovering royalties until the date the licensee first challenges the validity of the patent." See id. (emphasis added); see generally Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co., 112 F.3d 1561, 1568 (Fed. Cir. 1997) ("[A] licensee cannot invoke the protection of the Lear doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid."). Thus, even if the 2004 License Agreement provided a license to Innovacon, Innovacon could not avoid royalties until Innovacon challenged the validity of the '019 Patent, which it did not do until answering the second amended complaint.

which concerned payment of an annual minimum royalty of \$30,000. [Doc. No. 224.] Rembrandt also filed a separate motion for summary judgment that the '019 Patent is not invalid. [Doc. No. 225.] On the same day, Assurance moved for summary judgment on Innovacon's counterclaims, arguing among other things, that the claims are time-barred. [Doc. No. 229.]

The Court's review of the evidence included with the parties' motions, and of the 2004 License Agreement itself, raised the question of whether the 2004 License Agreement remained an exclusive license or even whether it had been terminated in 2005. The Court then issued the OSC as to why the breach of contract claims should not be dismissed as a result of the termination of the 2004 License Agreement. Both remaining parties responded and the Court held a hearing on June 14, 2018.

VI. Reconsideration of Motion to Dismiss [Doc. No. 63]

In their September 1, 2016 motion to dismiss for lack of standing, the Alere Defendants argued that because the 2004 License Agreement gave Applied Biotech (which subsequently became part of Innovacon), (1) "an *exclusive license agreement* . . . to practice the '019 patent . . . [that] extended to . . . all the current Alere Defendants;" (2) "an expansive right to *sublicense* the licensed patents, including the '019 patent;" and (3) the "*first right' to 'institute infringement . . . actions in the Field of Use against Third Parties based on any Licensed Patents*,' and to recover damages therefrom," Rembrandt did not have "all substantial rights" in the '019 Patent, meaning Rembrandt lacked standing to sue for infringement. [Doc. No. 58 at 7-8; Doc. No. 63 at 7-8 (*emphasis* in original).]⁵ The Alere Defendants also argued that the claims in the first amended complaint for breach of the 2004 License Agreement should be dismissed because Alere, the only defendant to those claims, was not a party to the agreement. According to Defendants, only Innovacon,

Defendants' representation to the Court in September 2016 that Innovacon continued to hold an "exclusive license" to the '019 patent under the terms of the 2004 License Agreement was a gross misrepresentation of the facts that Innovacon subsequently acknowledged in response to the OSC.

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as successor to Applied Biotech, the named licensee, had any obligation to pay royalties under the 2004 License Agreement. [Doc. No. 58 at 4-5.]

In its opposition to the motion to dismiss, Rembrandt stated that it understood the 2004 License Agreement to have been terminated and that "a primary issue to resolve in this action" is whether it is still in force. [Doc. No. 67 at 5.] Rembrandt even attached a 2010 letter from Assurance terminating the 2004 License Agreement because Applied Biotech had not made any royalty payments. [Doc. No. 71-1.] Yet Rembrandt did not argue that it had standing *because* the 2004 License Agreement had been terminated or repudiated. Instead, it argued that the 2004 License Agreement did not affect Rembrandt's standing regardless of whether it was still in effect. [*Id.* at 9.] As to Defendants' argument that Alere was not a proper defendant to the breach of contract claims, Rembrandt contended that the argument improperly went outside the allegations in the complaint, but it also sought permission to name Innovacon as a defendant to the breach of contract claims. [*Id.* at 16-17.]

In its October 19, 2016, order on the motion to dismiss, the Court found that the terms of Assurance's transfer to Rembrandt of all substantial rights to the '019 and '291 Patents gave Rembrandt constitutional and prudential standing to bring suit in its own name. However, based on its understanding that the 2004 License Agreement transferred an exclusive license to the '019 Patent to Applied Biotech, the Court held that the 2004 License Agreement precluded a finding that Rembrandt's interests in the '019 Patent at the time the complaint was filed were sufficient to provide standing. [Doc. No. 85 at 15.] The Court also dismissed the contract claims against Alere, but gave Rembrandt leave to file an amended complaint for infringement of the '291 Patent, and for breach of the 2004 License Agreement against Innovacon with respect to sales of products that allegedly infringe the '019 Patent.

The record since the Court's order, including Innovacon's litigation positions, and the materials submitted in connection with the summary judgment motions, reveals that the 2004 License Agreement terminated by its own terms in 2005. Moreover, even if it did

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not terminate by its own terms, it was effectively repudiated by Assurance and Applied Biotech long before this lawsuit began. Thus, the Court's reliance on the 2004 License Agreement was misplaced, and the dismissal of the '019 Patent infringement claims for lack of standing was erroneous.

General 2004 License Agreement Background

The 2004 License Agreement gave Applied Biotech and its affiliates "the exclusive right and license, including the right to sublicense under the Licensed Patents to make, have made, manufacture, have manufactured, produce, have produced, use, import, export, market, distribute, use, offer to sell, or sell, either in whole or in part, Products in the Field of Use throughout the [world]." [Doc. No. 94 at 4.] The 2004 License Agreement defines "Product" as "any urine test cup for use in the drugs of abuse market that is made by Licensee or its Affiliates or sublicensees using the Licensed Patents that would infringe any claim of any Licensed Patents absent this Agreement." [Id. at 4.] "Field of Use" is defined as "all point of care and consumer markets worldwide." [Id. at 3.]

On September 29, 2004, the same date as the 2004 License Agreement, Applied Biotech entered into a Supply and Manufacturing Agreement (the "Manufacturing Agreement") with Tianjin. [Doc. No. 52.] The Manufacturing Agreement provided that Tianjin would be the exclusive manufacturer of the Products that Applied Biotech was licensed to market and sell under the 2004 License Agreement with Assurance Biotech. However, the Manufacturing Agreement was conditioned on the completion of a due diligence audit, and if the audit results were not satisfactory, the Manufacturing Agreement was void *ab initio*. [*Id.* at 19.]

Section 8.2.2 of the 2004 License Agreement

Section 8.2.2 of the 2004 License Agreement states that termination of the Manufacturing Agreement results in termination of the "exclusivity provision" of the 2004 License Agreement. Therefore, if Tianjin was not contracted to exclusively manufacture the Products (the licensed urine cups) for Applied Biotech, the license to Applied Biotech to practice the patents would no longer be exclusive. The parties agree that the

Manufacturing Agreement was voided following the due diligence period. [Doc. Nos. 174-2 at 10; 207-4 at 5-6; 214 at 4; 242 at 8.] Thus, pursuant to Section 8.2.2, and contrary to Innovacon's arguments in connection with its motion to dismiss, it is undisputed that, at a minimum, the 2004 License Agreement was not exclusive after 2005.⁶

One problem arising from this occurrence is that it is unclear what constitutes the "exclusivity provision" in the 2004 License Agreement. Language throughout the 2004 License Agreement is consistent with the provision of an exclusive license (and incongruous with a non-exclusive license), but there is no singular "exclusivity provision." Nevertheless, there is no need to determine how to excise the "exclusivity" aspects of the 2004 License Agreement because pursuant to Section 8.3, termination of the Manufacturing Agreement ultimately resulted in loss of all license rights.

Section 8.3 of the 2004 License Agreement

Section 8.3 of the 2004 License Agreement states:

Effect of Termination. Upon termination of this Agreement pursuant to Section 8.2.2, for any reason, Licensee shall lose its right and license to manufacture, market, distribute, use, and sell Products. Provided, however, upon termination of this Agreement for any reason other than a failure by Licensee to cure a material breach of this Agreement in any particular country within the Territory or expiration of this Agreement in a particular country within the Territory, and provided that Licensee has commenced marketing of the Product hereunder, Licensee and its Affiliates and sublicensees shall have the right to continue to sell all inventory of the Product in such country for a period of no more than six(6) months from and after the effective date of such termination. Upon termination of this Agreement, in whole or in part, all sublicensees [sic] granted by Licensee under this Agreement shall terminate simultaneously, subject to the provisions of this Section.

Although stated inelegantly, when read in conjunction with Section 8.2.2, the first sentence of Section 8.3, as currently written, means that termination of the Manufacturing

⁶ Regardless of whether Defendants had a good faith belief in 2016 that they retained some license rights under the 2004 License Agreement, it is inconceivable that they had a good faith belief they had an *exclusive* right to the '019 Patent when they represented as much to the Court.

Agreement would result in loss of the license rights granted by the 2004 License Agreement, effectively terminating the 2004 License Agreement in its entirety. Thus, because there is no dispute that Section 8.2.2 was in fact triggered by virtue of the termination of the Manufacturing Agreement in 2005, any right to a license under the '019 Patent terminated no later than in 2005. Because none of the parties had addressed Section 8.3 in any filings, the Court issued the OSC as to how this section should apply.

In response to the OSC, Assurance, Rembrandt, and Innovacon each take different positions as to Section 8.3. Assurance, who is the only one of the three involved in the actual drafting and execution of the 2004 License Agreement, argues that Section 8.3 accurately states the intent of the parties as reflected by their subsequent actions (or lack thereof) after the Manufacturing Agreement was voided. Assurance points to an October 27, 2005 email from counsel for Innovacon's predecessor's general counsel acknowledging that neither party "contemplated that the license agreement would stand alone" in the absence of the Manufacturing Agreement. [Doc. No. 257 at 4; Doc. No. 257-2 at 2.] Assurance also points to Alere's efforts in 2012 to negotiate a license for the '019 Patent [Doc. No. 257-4 at 2.], which would not have been necessary if the 2004 License Agreement remained in force.

Innovacon, meanwhile, argues that section 8.3's cross-reference to section 8.2.2 is a typographical error and that "8.2.2" was intended to be "8.2." It argues that any other interpretation would render section 8.2.2 illusory and conflict with other parts of the agreement. According to Innovacon, if the parties wanted to terminate the entire 2004 License Agreement upon voiding of the Manufacturing Agreement, they could have done so directly in 8.2.2 and there would have been no need for language stating that termination of the Manufacturing Agreement would result only in termination of the "exclusivity provision" of the 2004 License Agreement.

Finally, consistent with its actions throughout this litigation, Rembrandt yet again fails to take any concrete position on this issue. It acknowledges that the reference to "Section 8.2.2" in Section 8.3 may have been a drafting error, but differing from

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Innovacon, suggests that the reference to "8.2.2" was actually intended to be "8.2.3." In support, Rembrandt offers a series of earlier drafts of the 2004 License Agreement showing the progression of the language in Section 8 and demonstrating that the parties may have failed to update Section 8.3's cross-reference from "8.2.2" to "8.2.3" upon the insertion of the final Section 8.2.2 language concerning the termination of the Manufacturing Agreement, which moved the language that used to be at section 8.2.2 to section 8.2.3. [Doc. Nos. 259-4-259-6.] Unsurprisingly, Rembrandt does not argue for any particular resolution of this issue, arguing only that if the 2004 License Agreement was terminated pursuant to Section 8.3, this case should move forward as one for infringement, like it was originally filed.

Ultimately, the only way to avoid a finding that the termination of the Manufacturing Agreement terminated any license rights under the 2004 License Agreement is to reform Section 8.3 of the 2004 License Agreement. Delaware law governs the 2004 License Agreement. [Doc. No. 94 at 14.] Under Delaware law:

a contract may be reformed in rare instances to express the "real agreement" of the parties. *Cerberus Int'l, Ltd. v. Apollo Mgmt. L.P.*, 794 A.2d 1141, 1151 (Del. 2002). Delaware law recognizes three grounds for reformation: (1) mutual mistake, (2) unilateral mistake coupled with knowing silence of the other party, and (3) fraud by the other party. *See id.* (mutual mistake and unilateral mistake); *Emmert v. Prade*, 711 A.2d 1217, 1219 (Del.Ch.1997) (fraud). Because a duly executed formal instrument may not be lightly set aside, a party seeking to reform a contract must prove by clear and convincing evidence that, before executing the written instrument, the parties came to a specific prior understanding that differed materially from the written agreement, and that it mistakenly believed that the final, executed contract accurately expressed that prior understanding. *Cerberus*, 794 A.2d at 1150–52, 1155; *Hob Tea Room, Inc. v. Miller*, 89 A.2d 851, 856–57 (Del.1952).

Monsanto Co. v. E.I. Du Pont de Nemours and Co., 748 F.3d 1189, 1198 (Fed. Cir. 2014). Here, only Innovacon is seeking to reform the 2004 License Agreement, so the burden is on Innovacon to demonstrate by clear and convincing evidence that before executing the 2004 License Agreement, Assurance and Applied Biotech specifically intended that the

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2004 License Agreement to remain in effect even if the Manufacturing Agreement was terminated. Innovacon does not meet this high burden.

Notably, Innovacon offers no actual evidence that the parties had a specific prior understanding of the 2004 License Agreement that differed from the written agreement, and in particular Section 8.3. *See id.* (noting that the subjective belief of the parties to the contract is relevant to the issue of reformation). Instead, Innovacon's primary argument for reformation is essentially that if the parties intended for termination of the Manufacturing Agreement to terminate the license rights, they could have said so in Section 8.2.2. Although Innovacon is correct, that the parties could have drafted the 2004 License Agreement differently or with more precision or clarity is hardly clear and convincing evidence that they did not intend the language actually used. Nor is the Court convinced that interpreting Section 8.3 as written would result in any of the inconsistencies claimed by Innovacon. That the parties used two provisions (Sections 8.2.2 and 8.3) to state that termination of the Manufacturing Agreement would result in loss of license rights, when they could have used only one, is inartful but not inconsistent. Shoddy contract drafting, without more, is not clear and convincing evidence of an intent contrary to the written terms of the agreement.

Further, while the "<u>Provided, however</u>" clause following the first sentence of Section 8.3 is somewhat incongruously located, it does not render the cross-reference to Section 8.2.2 in the previous sentence nonsensical. Sections 8.2.1, 8.2.3, and 8.2.4 each provide for termination of the 2004 License Agreement as a whole. Necessarily, termination of the 2004 License Agreement as a whole would result in loss of license rights granted thereunder. Section 8.2.2, however, specifies that termination of the Manufacturing Agreement would result only in termination of the exclusivity provision of the 2004 License Agreement. Thus, if the parties intended for termination of the Manufacturing

⁷ Section 8.2.1 allows for termination upon one year's notice. Section 8.2.3 allows for termination upon failure to cure default. Section 8.2.4 allows for termination upon bankruptcy of the other party.

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Agreement also to result in loss of license rights, they needed to state as much in a separate provision, which they did in the first sentence of Section 8.3.

In reality, changing the cross-reference in the first sentence of Section 8.3 from "8.2.2" to "8.2", which Innovacon argues means that termination of the Manufacturing Agreement does not result in loss of license rights, would result in a sentence that is completely superfluous. The obvious and necessary result of termination of the 2004 License Agreement (as stated in sections 8.2.1, 8.2.3, and 8.2.4) would be loss of the license rights granted under the agreement, so there would be no need to say so in the first sentence of Section 8.3. Indeed, the outcome sought by Innovacon here, that termination of the Manufacturing Agreement did not lead to loss of Applied Biotech's license rights, could most easily have been accomplished by the parties, had that been their intent, by simply eliminating the first sentence of Section 8.3 along with the "Provided, however," and beginning the section with "Upon termination of this Agreement for any reason. . . ." In the end, the 2004 License Agreement undoubtedly could have been drafted with more precision, but the lack of clarity of the language chosen by the parties is not clear and convincing evidence that the parties intended the cross-reference in Section 8.3 to be to "Section 8.2" and not "Section 8.2.2" as written.

The earlier drafts of the 2004 License Agreement submitted by Rembrandt in response to the OSC also undermine Innovacon's argument. In the first of the four drafts, attached to an email dated July 26, 2004, Section 8.3 of the 2004 License Agreement actually cross-referenced "Section 8.2." [Doc. No. 259-3 at 11.] Yet in each of the three succeeding drafts, all of which were attached to emails from September 2004, Section 8.3 cross-references "Section 8.2.2." [Doc. No. 259-4 at 13; Doc. No. 259-5 at 11; Doc. No. 259-6 at 16.] Thus, if anything, it appears that the parties consciously decided to crossreference Section 8.2.2, which is a subsection of Section 8.2, instead of Section 8.2 as a whole as argued by Innovacon.

Finally, as emphasized by Assurance in its response to the OSC, the parties' actions after the Manufacturing Agreement terminated are at least circumstantial evidence that they

always intended for termination of the Manufacturing Agreement to result in loss of license rights, consistent with the as-written language of Section 8.3. *Cf. Monsanto*, 748 F.3d at 1199 (finding that the district court did not err in considering subsequent statements by the negotiators of a contract in its determination of the subjective understanding of one of the parties to the contract). Contemporaneous communications between representatives of Assurance and Applied Biotech after the Manufacturing Agreement was voided reflect that neither Assurance nor Applied Biotech believed the 2004 License Agreement would stand alone in the absence of the Manufacturing Agreement and that new terms and conditions needed to be discussed for any license to continue. [Doc No. 217-6 at 16; Doc. No. 257-2 at 2.] Innovacon offers no evidence that any party in fact acted as if the 2004 License Agreement remained in force following termination of the Manufacturing Agreement. The lack of such evidence contradicts Innovacon's position that the parties intended otherwise.

First, the simple fact that Applied Biotech never made a royalty payment and that Assurance did not sue for breach indicates that neither party considered the agreement to be in effect. Second, in 2012, representatives of Alere and Alere Toxicology met with Lee seeking a license to practice the '019 Patent, demonstrating that Alere, one of Innovacon's parent companies, did not consider the 2004 License Agreement to be in effect. [Doc. No. 1 at ¶¶ 29-31; Doc. No. 25 at ¶¶ 29-31.] Third, Assurance did not disclose the existence of the 2004 License Agreement to Rembrandt in connection with Rembrandt's acquisition of the '019 patent but subsequently assigned its rights under the 2004 License Agreement when the Alere Defendants raised it in this suit. If Assurance believed the 2004 License Agreement to still be in force, it presumably would have assigned its rights under that agreement at the same time as the assignment of the rights to the patents themselves. Fourth, Innovacon asserted a counterclaim arguing that Assurance breached the 2004 License Agreement by actions in 2005-07. Assuming the acts constituting the alleged breach occurred, the fact that neither Applied Biotech nor Innovacon asserted claims for them until the second amended complaint in this case almost a decade later contradicts Innovacon's position that Applied Biotech (and now Innovacon) believed the 2004 License

Agreement to remain in force. In sum, everything that happened after the Manufacturing 1 2 3 4 5 6

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Agreement terminated supports a finding that the parties intended for the license rights under the 2004 License Agreement to have terminated at the same time and acted as if that is what happened.⁸ If nothing else, these facts make it impossible for the Court to find, by clear and convincing evidence, that both parties to the 2004 License Agreement intended for Applied Biotech to continue to have a license if the Manufacturing Agreement was terminated.

In light of the foregoing, the Court declines to reform the 2004 License Agreement as sought by Innovacon. Pursuant to Sections 8.2.2 and 8.3, the termination of the Manufacturing Agreement resulted in the termination of any license rights held by Innovacon or its predecessor, Applied Biotech, under the 2004 License Agreement. Although Innovacon's proposed reformation is not unreasonable, the complete lack of evidence that the parties actually intended language consistent with the proposed reformation, combined with the fact that both sides to the 2004 License Agreement acted as if it terminated in 2005, prevents the Court from finding that Innovacon has established, by clear and convincing evidence, that the parties intended a license to remain in force if the Manufacturing Agreement terminated. See generally Cerberus Int'l, Ltd. v. Apollo *Mgmt.*, *L.P.*, 794 A.2d 1141, 1152 (Del. 2002) (holding that the party seeking reformation on the basis of mistake must show, by clear and convincing evidence, that the parties to the contract shared the same mistaken understanding about the contract terms, or that one party had such misunderstanding, and the other party was aware of the other party's mistake and remained silent). The 2004 License Agreement, therefore, does not deprive Rembrandt of standing to sue Innovacon for infringement of the '019 Patent. Accordingly, the Court's

⁸ Even without the language in Section 8.3 or with a reformation of that language as requested by Innovacon, the parties' actions after 2005, or more specifically the complete lack of evidence that either Assurance or Applied Biotech believed the 2004 License Agreement to remain in force, warrants a finding that the parties repudiated or terminated the 2004 License Agreement upon termination of the Manufacturing Agreement, and that no reasonable juror could find otherwise.

order dismissing the claim for infringement of the '019 Patent for lack of standing was erroneous and is vacated. This case shall proceed as one for patent infringement, not breach of contract.

VII. Innovacon's Motion for Summary Judgment Concerning Infringement of the '019 Patent [Doc. No. 207]

As a result of the above reconsideration, Innovacon's motions for summary judgment that it did not breach the 2004 License Agreement [Doc. Nos. 207, 209], and Rembrandt's motion that that Innovacon breached and Rembrandt did not breach [Doc. No. 224], are denied as moot. That being said, Innovacon's motion concerning its obligation to pay royalties under the 2004 License Agreement [Doc. No. 207] is premised entirely on argument that the accused product did not practice the '019 Patent. Thus, the analysis required to resolve that motion is no different from that required on a motion for summary judgment of non-infringement filed in a typical patent infringement case, the only difference being the potential damages if summary judgment is denied. Accordingly, to move this case forward, the Court has reviewed Innovacon's arguments for why the iCup A.D. did not practice the '019 Patent, and finds that genuine issues of material fact preclude summary judgment on that issue. A brief analysis follows.

Determining whether a patent claim has been infringed requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *PC Connector Solutions LLC v. Smartdisk Corp.*, 406 F.3d 1359, 1362 (Fed. Cir. 2005) (citation omitted). To prove direct infringement, "the plaintiff must establish by a preponderance of the evidence that the accused device infringes one or more claims of the patent either literally or under the doctrine of equivalents." *Advanced Cardiovascular Sys.*, *Inc. v. Scimed Life Sys.*, *Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). Thus, "[s]ummary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused

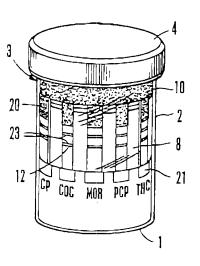
device either literally or under the doctrine of equivalents." *PC Connector Solutions*, 406 F.3d at 1364; *see also* Fed. R. Civ. P. 56(a).

As discussed above, the iCup A.D. is the only accused device still at issue in this case. Rembrandt contends that the iCup A.D. infringes only claims 2 and 10 of the '019 Patent. [Doc. No. 207-5 at 3.] Claim 2 has since been found invalid through IPR [Doc. No. 225-4 at 176.] Claim 10 is dependent on Claims 1 and 9, both of which Rembrandt disclaimed during IPR. Claim 1 states:

- 1. A device for collecting and assaying a sample of biological fluid, the device comprising:
- (a) a flow control channel defined by at least one liquid pervious side joined to liquid impervious sides, wherein the internal dimensions of the flow control channel are sufficient to permit placement therein of an assay test strip;
- (b) an assay test strip within the flow control channel, wherein the assay test strip has a sample loading zone therein, and wherein further the assay test strip is disposed within the flow control channel so that sample fluid contacts the sample loading zone at a liquid pervious side of the flow control channel; and, (c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth;

wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented [toward] the base of the sample fluid container so that the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure, and wherein entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel.

[Doc. No. 90-1 at 8.] Relevant here, the Court construed "the assay test strip is disposed within the flow control channel" as "the assay test strip is disposed *entirely* within the flow control channel." [Doc. No. 167 at 7.] Figure 1 from the patent depicts an embodiment of the product:

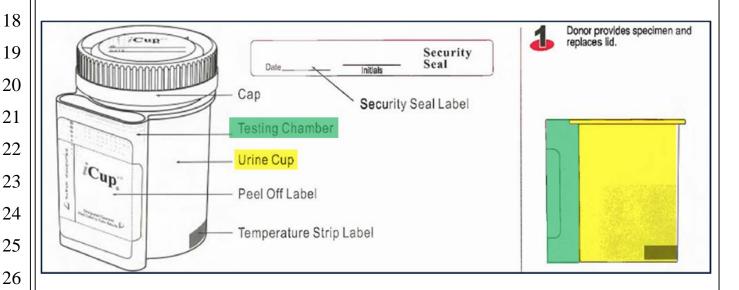


Claims 9 and 10 state:

- 9. A device according to claim 1, further comprising additional assay test strips, wherein the additional assay test strips detect the presence or absence of different analytes in biological fluid.
- 10. A device according to claim 9, wherein all of the assay test strips are disposed in a single flow control chamber.

[Doc. No. 90-1 at 9.]

With its motion, Innovacon included the following illustration of the iCup A.D. from the "Drug Screen Procedure Card" for the product:



[Doc. No. 207-1 at 26; Doc. No. 207-15 at 2.] Innovacon makes three arguments as to why the iCup A.D. does not practice the '019 Patent: (1) Rembrandt has admitted that the assay

test strips in the iCup A.D. protrude from the flow control panel; (2) Rembrandt does not have evidence that the iCup A.D. practices the ambient pressure limitation; and (3) the flow control channel is not disposed inside the sample fluid container. Genuine issues of disputed fact, however, preclude summary judgment on any of these grounds.

Whether the assay test strip is disposed entirely within the flow control channel

Innovacon's briefs point to several statements made by Rembrandt in various court filings as admissions that the iCup A.D. does not meet this claim limitation. The Court is not persuaded that any of the statements upon which Innovacon relies are dispositive of this issue. Moreover, Innovacon's briefs are notable for the lack of any argument that the assay test strip of the iCup A.D. actually does not meet this limitation, and if anything, photographs of the iCup A.D. demonstrate that the strips are entirely within the flow control channel of the product. At a minimum, there remains a material dispute as to the location of the assay test strips in the iCup A.D. A reasonable juror could find that the iCup A.D. satisfies this claim limitation. Accordingly, Innovacon is not entitle to summary judgment on this ground.

Whether the entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel.

In its opening brief, Innovacon argues that Rembrandt offers no evidence that the iCup A.D. practices this limitation. Once again, however, Innovacon does not affirmatively argue that the iCup A.D. *does not* practice this limitation. In its opposition, Rembrandt offers expert testimony from Dr. Salvatore Salamone that the iCup A.D. practices this limitation. In reply, Innovacon makes procedural arguments for why the Court should not accept Rembrandt's "new" expert report and otherwise critiques the substance of Dr. Salamone's report.

The Court is not persuaded by either Innovacon's procedural arguments or its substantive disputes as to why Dr. Salamone's report does not preclude summary judgment

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on this ground. Innovacon is free to argue to the jury as to why they should not accept Dr. Salamone's testimony, but it is not entitled to summary judgment on this ground.

Whether the flow control channel is disposed inside the sample fluid container

Finally, Innovacon argues that the iCup A.D. does not meet the claim limitation that the flow control channel be disposed inside the sample fluid container. According to the claim language, the sample fluid container has "a base, an open mouth, and walls connecting the base to the mouth." [Doc. No. 90-1 at 8 at col. 8 lines 55-56.] Innovacon argues that because the iCup A.D. is not perfectly round and instead places the flow control channel as an appendage to a round opening into which the fluid is deposited, the flow control channel is not disposed inside the sample fluid container. A reasonable juror could find that the iCup A.D. is a single structure with a base, an open mouth, and walls connecting the base to the mouth, meaning that the entire structure of the iCup A.D. is the "sample fluid container," with the flow control channel disposed inside. Accordingly, summary judgment on this ground is inappropriate as well.

In light of the foregoing, no further summary judgment motions concerning whether the iCup A.D. practices the '019 Patent will be entertained.

VIII. Rembrandt's Motion for Summary Judgment of No Invalidity of '019 Patent [Doc. No. 225]

Rembrandt moves for summary judgment of no invalidity of Claims 3-6 and 10 of the '019 Patent. Rembrandt, however, does not assert that the iCup A.D., which is the only accused product still in this case, infringes Claims 3-6, making the issue of whether those claims are invalid irrelevant. Accordingly, the motion is denied as moot as to Claims 3-6. As for Claim 10, as discussed below, Rembrandt's motion is denied.

Α. **Legal Standard for Validity Determination**

"Patents are presumed valid, and the challenger bears the burden of establishing invalidity." Massachusetts Inst. of Tech. v. Shire Pharm., Inc., 839 F.3d 1111, 1124 (Fed. Cir. 2016). "The presumption of validity, however, is just that—a presumption—which 1 | 2 | 3 | 4 | 5 | 6

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can be overcome by the patent challenger who meets its high burden of proving the factual elements of invalidity by clear and convincing evidence." *Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332, 1341 (Fed. Cir. 2018). "Where there is a material dispute as to the credibility and weight that should be afforded to conflicting expert reports, summary judgment is usually inappropriate." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1384 (Fed. Cir. 2011).

B. Written Description

A patent "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." 35 U.S.C.A. § 112. The "description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation marks omitted). The "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." Id. "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. . . . [I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation." LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). However, "it is not enough for the specification to show how to make and use the invention, i.e., to enable it." Amgen Inc. v. Sanofi, 872 F.3d 1367, 1377 (Fed. Cir. 2017) "Compliance with the written description requirement is a question of fact,' and summary judgment is proper if and only if 'no reasonable fact finder could return a verdict for the non-moving party" on the issue. Scriptpro, LLC v.

Innovation Assocs., Inc., 762 F.3d 1355, 1359 (Fed. Cir. 2014) (quoting PowerOasis, Inc. v. T–Mobile USA, Inc., 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

Innovacon contends that the '019 Patent does not satisfy this requirement because it does not adequately describe the limitations in claim 1 requiring a device wherein "entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel." [Doc. No. 90-1 at 8.] In particular, Innovacon contends that the lack of "pressure measurements, testing, data, examples, or other disclosure that would allow a skilled person to recognize that the inventors in fact invented and possessed a device" that satisfied these limitations renders the patent invalid for lack of a written description. [Doc. No. 237 at 15.] Innovacon calls these the "Pressure Limitations."

Rembrandt argues that Innovacon is estopped from arguing that the written description is inadequate because Innovacon admitted in its counterclaims that QuikScreen Multiple Drug Cup Tests ("QuikScreen"), a product sold by the inventor's company, Syntron, pursuant to a license from Assurance, practiced Claim 1 of the '019 Patent. [Doc. No. 114 at 28.] According to Rembrandt, this admission that QuikScreen practiced the limitations concerning the ambient pressure within and outside of the flow control channel is effectively an admission that the written description is adequate.

Innovacon responds that it made the admission before the Court construed the claim language as requiring the assay strip to be disposed entirely within the flow control channel, which is not the case with QuikScreen. As a result, Innovacon no longer contends that QuikScreen practices the '019 Patent. Likewise, Innovacon also argues that because there is no dispute that QuikScreen does not practice the '019 Patent in light of the Court's claim construction, the prior admission is unhelpful to the question of whether the written description requirement is satisfied. Rembrandt replies that the construction of the "disposed within the flow control channel" limitation is irrelevant to Innovacon's written

description invalidity contention and does not change the impact of Innovacon's admission that QuickScreen practiced the Pressure Limitations of the claim.

"Judicial admissions are formal admissions in the pleadings which have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact. Factual assertions in pleadings and pretrial orders, unless amended, are considered judicial admissions conclusively binding on the party who made them." *Am. Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 226 (9th Cir. 1988) (internal quotation marks and citation omitted); *see also E.C. McAfee A/C Bristol Metal Indus. of Canada Ltd. v. United States*, 832 F.2d 152, 154 n.* (Fed. Cir. 1987) ("[P]leadings are judicial admissions and a party may invoke the language of the opponent's pleading to render the facts contained therein indisputable.")(citing 4 J. Wigmore, Evidence § 1064, at 67 (Chadbourn rev. 1972)).

Here, Innovacon's allegation in its counterclaims that QuikScreen practices claim 1 of the '019 Patent is an admission of fact that QuikScreen practices the Pressure Limitations, which are part of claim 1 of the '019 Patent.⁹ Although Innovacon has since backed away from this allegation in light of the Court's construction of a different limitation of claim 1, Innovacon has never amended its counterclaims or otherwise argued that QuikScreen does not practice the Pressure Limitations.¹⁰ Nor does Innovacon provide any evidence or argument as to why the Court's construction of the limitation that test strips be disposed entirely within the flow control channel materially effects the Pressure Limitations.

⁹ Cf. Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 981 (Fed. Cir. 1997) (holding that "[1]iteral infringement requires that every limitation of the patent claim be found in the accused infringing device," and that this determination is a question of fact").

¹⁰ In its opposition, Innovacon states that it is "no longer advancing" the counterclaim to which the allegation about QuikScreen applied, but does not cite to anything in the record reflecting that Innovacon has abandoned any of its counterclaims. [Doc. No. 237 at 17.] To the contrary, Innovacon opposed Rembrandt's and Assurance's motions for summary judgment on Innovacon's counterclaims for breach the 2004 License Agreement. Innovacon even admits in its opposition to Assurance's motion that the QuikScreen cup was the design that Tianjin was to make for Applied Biotech pursuant to the Manufacturing Agreement. [Doc. No. 241 at 6.] In other words, the QuikScreen was the embodiment of the '019 Patent that Applied Biotech planned to sell pursuant to the 2004 License Agreement.

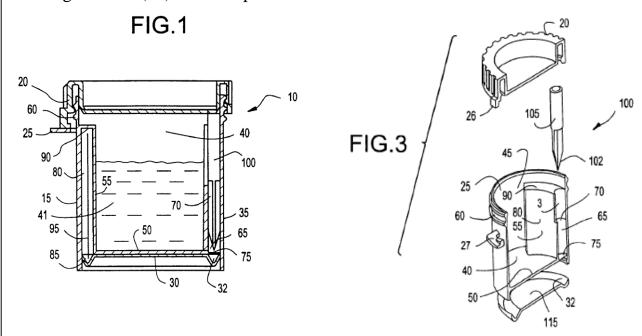
At the same time, it is now undisputed that in light of the Court's claim construction, QuikScreen does not practice the '019 Patent because its test strips are not contained entirely within the flow control channel. Therefore, Innovacon's admission that QuikScreen practiced the Pressure Limitations is relevant evidence, but it is not dispositive of whether the written description of the Pressure Limitations satisfies the requirements of section 112. Rembrandt is free to argue to a jury that Innovacon's admission undermines its position, while Innovacon is free to argue that the protrusion of the test strips from the flow control channel in QuikScreen impacts the Pressure Limitations and does not demonstrate an embodiment of the Pressure Limitations. It will be for the jury to decide whether Innovacon has met its burden to prove by clear and convincing evidence that the '019 Patent's written description of the Pressure Limitations does not satisfy Section 112. Rembrandt's motion for summary judgment is denied as to this invalidity argument.

C. Anticipation

Innovacon contends that the '019 Patent was anticipated by United States Patent No. 6,277,646 ("Guirguis") [Doc. No. 237-4], which was filed on November 17, 1997, while Rembrandt contends that the priority date of the '019 Patent is August 18, 1999. [Doc. No. 207-5 at 2.] "To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. . . . But disclosure of each element is not quite enough—. . . . '[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1334–35 (Fed. Cir. 2008) (quoting Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)); see also Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc., 642 F.3d 1031, 1038 (Fed. Cir. 2011)("A patent claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference.").

Guirguis describes a device "for both collecting and testing a fluid specimen," including "a specimen container having a collection chamber, an isolation chamber and a test chamber." [Doc. No. 237-4 at 2.] Rembrandt argues that Guirguis does not anticipate

the '019 Patent because Guirguis does not disclose a test strip disposed entirely within the flow control channel (the "Test Strip Limitation"). Rembrandt cites to the report of Innovacon's expert, Dr. Horowitz, describing Figure 1 from Guirguis as showing how "test strips (95) protrude from the opening of the flow control channel (80) and extend below the frangible wall (75) that runs parallel to and below the bottom wall of the container (50):



[Doc. No. 237-4 at 3-4]. Rembrandt argues that this explanation by Innovacon's expert that the test strips Guirguis protrude from the flow control channel in Figure 1 means Guirguis does not disclose the Test Strip Limitation. Thus, according to Rembrandt, Guirguis does not anticipate the '019 Patent.

Innovacon does not dispute Rembrandt's characterization Figure 1 as not disclosing the Test Strip Limitation. Instead, it argues that Guirguis discloses a second test strip configuration with test strips that do not protrude from the flow control channel. For this argument, Innovacon relies on language from the description that "[i]n one embodiment of the invention, . . . test agents **95** are positioned directly below or adjacent to the frangible wall." [Doc. No. 237-4 at 18; 9:27-31.] According to Innovacon, the phrase "or adjacent to" discloses a different embodiment of the invention where the test strips do not protrude consistent with the Test Strip Limitation.

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Innovacon's argument concerning an alternative embodiment that satisfies the Test Strip Limitation based on the "adjacent to" language is sufficient to avoid summary judgment. Dr. Horowitz's description of a figure showing one embodiment is not dispositive of the issue as to whether Guirguis discloses the Test Strip Limitation and it would be error to limit the disclosure of Guirguis to the preferred embodiment. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1372 (Fed. Cir. 2005). Guirguis discloses multiple embodiments and Rembrandt ignores all but the embodiment from Figure 1 in its motion. That one embodiment does not disclose the Test Strip Limitation does not mean that none of the embodiments of Guirguis disclose the Test Strip Limitation.

Rembrandt also argues that Innovacon is making a "practicing the prior art" defense by comparing Guirguis to the iCup A.D., instead of to the '019 Patent. This argument is a straw man. Innovacon is arguing that the interpretation of the '019 Patent promulgated by Rembrandt for its infringement contentions establishes that Guirguis anticipated the '019 Patent. "This argument d[oes] not rest on an improper 'practicing the prior art' defense, but instead correctly recognize[s] that claim terms must be construed the same way for both invalidity and infringement." *01 Communique Lab., Inc. v. Citrix Sys., Inc.*, 889 F.3d 735, 742 (Fed. Cir. 2018) (internal quotation marks and citation omitted) (holding that although "an accused infringer cannot defeat a claim of literal infringement or establish invalidity merely by pointing to similarities between an accused product and the prior art, . . . [a litigant may argue] that if a claim term must be broadly interpreted to read on an accused device, then this same broad construction will read on the prior art.").

Accordingly, Rembrandt's motion for summary judgment on Innovacon's anticipation argument is denied as well.

D. Obviousness

In the IPR, Alere challenged Claims 1 and 9 of the '019 Patent as anticipated and obvious over prior art, and in response, Rembrandt disclaimed these claims. [Doc. No.

¹¹ Innovacon also makes this argument as to Claims 2-6, but because Rembrandt does not contend that the iCup A.D. infringes those claims, their validity is irrelevant in this case, as currently constituted.

237-1.] Innovacon now argues that Claim 10, which is dependent on Claims 1 and 9,¹¹ is invalid because it is not patentably distinct from those disclaimed claims and therefore obvious. As set forth above, Claim 9 adds the limitation that the test cup have multiple assay test strips, each of which tests for different analytes. Claim 10 further adds the limitation that all of the test strips are disposed in a single flow control chamber. Thus, Innovacon contends that the limitation of multiple test strips being disposed in a single flow control chamber is not patentably distinct from Claim 9.

Rembrandt argues that Innovacon's analysis is flawed because it is comparing Claim 10 to disclaimed Claims 1 and 9. Rembrandt argues that the obviousness analysis requires comparison of Claim 10 to prior art, not other claims in the patent. Once again, this argument is a straw man.

"Section 103(a) forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (citing 35 U.S.C. § 103(a)). Innovacon argues that by disclaiming Claims 1 and 9 in response to the IPR, Rembrandt conceded that they are not different from prior art. Thus, the only possible difference between Claim 10 and the prior art is the specific limitation added by Claim 10—that multiple test strips be disposed in a single flow control chamber. Innovacon argues, citing its own expert's report, that this limitation was obvious based on the prior art describing a flow control chamber housing multiple test strips that was in existence as of the priority date of the '019 Patent. The logic of this argument is sound and consistent with Section 103. See id. at 419-20 ("One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution

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encompassed by the patent's claims."). Although Claim 10 of the '019 Patent is presumed valid, a reasonable juror could find that Innovacon has proven, by clear and convincing evidence, that the only difference between Claim 10 and prior art would have been obvious to a person having ordinary skill in the art, making Claim 10 invalid. Accordingly, Rembrandt's motion for summary judgment on Innovacon's obviousness argument is denied as well.

In light of the foregoing, Rembrandt's motion for summary judgment of no invalidity of the '019 Patent is denied in its entirety. No further summary judgment motions concerning the validity of the '019 Patent will be entertained.

IX. Assurance's Motion for Summary Judgment [Doc. No. 229]

Having determined that the 2004 License Agreement terminated in 2005 and that this case will proceed as one for patent infringement only, Innovacon's claims for breach of the 2004 License Agreement presumably cannot proceed. The alleged behavior constituting a breach occurred after the termination, and in any event, the claims are almost certainly time-barred. Nevertheless, the Court merely denies Assurance's motion for summary judgment as moot at this juncture in light of the pending amended complaint, with the assumption that the Court's finding that the 2004 License Agreement terminated in 2005 is fatal to Innovacon's claims against Assurance. If Innovacon believes, within the confines of Rule 11, that its claims against Assurance can proceed, and are appropriate for a third party claim in this lawsuit, notwithstanding the finding that the 2004 License Agreement terminated in 2005 and that this case will be one for patent infringement only, it may re-assert them in response to the third amended complaint. If Innovacon does so, the Court will issue an expedited summary judgment briefing schedule at that time.

X. Daubert Motions

Innovacon and Rembrandt have each moved to exclude several of the other's experts. Two of Rembrandt's motions [Doc. Nos. 226, 228] concern the opinions of Gregory Leonard and Karen Becker, respectively, as to whether Innovacon's actions were

commercially reasonable and therefore not in breach of Section 2.3 of the 2004 License Agreement. Because, these opinions are irrelevant now that this case is for patent infringement and not breach of 2004 License Agreement, the Court assumes Innovacon will no longer offer testimony from Mr. Leonard and Ms. Becker. Accordingly, Rembrandt's motions to exclude Mr. Leonard and Ms. Becker are denied as moot.

The experts in question in the other two motions offer opinions as to the infringement claim and validity of the '019 Patent. Presumably, the opinions of these experts are still relevant notwithstanding this case being re-framed as a patent infringement action, so the Court considers them here.

A. Legal Standards Governing Admissibility of Expert Testimony

Under Federal Rule of Evidence 702,

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

In determining the admissibility of expert testimony, "the Rules of Evidence—especially Rule 702—[] assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). In other words, the Court must undertake a two-step assessment of whether: "(1) the reasoning or methodology underlying the testimony is scientifically valid (the reliability prong); and (2) whether the reasoning or methodology properly can be applied to the facts in issue (the relevancy prong)." *Johns v. Bayer Corp.*, No. 09cv1935 AJB (DHB), 2013 WL 1498965, at *6 (S.D. Cal. Apr. 10, 2013).

"Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. "District courts must strike the appropriate balance between admitting reliable, helpful expert testimony and excluding misleading or

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27 28 confusing testimony to achieve the flexible approach outlined in *Daubert*." *United States* v. Cordoba, 104 F.3d 225, 228 (9th Cir. 1997) (citation omitted).

B. Innovacon Expert – Gary Horowitz [Doc. No. 227]

Innovacon's expert Gary Horowitz offers opinions on the invalidity of the '019 Patent and on whether iCup A.D. practices the '019 Patent. Rembrandt's arguments as to why his testimony should be excluded primarily go to the weight of the testimony, not its admissibility.

As for invalidity, Horowitz opines that Claim 10 is invalid as obvious in light of the disclaimer of Claim 9 in support of the obviousness argument.¹² Rembrandt contends that Horowitz compares Claim 10 to Claim 9 instead of to prior art. In fact, however, Horowitz opines that the limitation added in Claim 10 is obvious, meaning that in response to the disclaimer of Claim 9 based on Innovacon's IPR, Claim 10 is invalid. As discussed above, this position is consistent with applicable law and is not a grounds for excluding Horowitz's opinion on the matter.

Rembrandt also takes issue with Horowitz's opinion that Claim 10 is invalid as anticipated on the grounds that he compares Guirguis to Rembrandt's infringement contentions instead of Claim 10. Rembrandt asserts that this is akin to a practicing the prior art defense. Rembrandt misconstrues Horowitz's report. Horowitz uses Rembrandt's description of the claim limitations from its infringement contentions and then opines how Guirguis disclosed those limitations based on Rembrandt's description. As discussed above in connection with Rembrandt's summary judgment motion, this is not a practicing the prior art opinion. See 01 Communique Lab., 889 F.3d at 742.

Finally, Rembrandt argues that Dr. Horowitz's report concerning infringement should be excluded because it includes arguments Innovacon did not disclose during

¹² Horowitz also offers opinions about Claims 2-6 that Rembrandt addresses in its motion. Rembrandt, however, only argues that the iCup A.D. infringes Claim 10, making Horowitz's opinions about Claims 2-6 irrelevant.

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discovery. Innovacon responds that these opinions are in response to previously undisclosed theories and evidence contained in the report of Rembrandt's expert. The Court is not persuaded by Rembrandt's procedural arguments, particularly in light of the fact that it has offered expert testimony on the same issues.

In light of the foregoing, Rembrandt's motion to exclude testimony from Dr. Horowitz is denied.

C. Rembrandt Expert – Dr. Salvatore Salamone [Doc. No. 230]

Rembrandt's expert Dr. Salvatore Salamone offers opinions about how the iCup A.D. infringes the '019 Patent. Innovacon moves to exclude Dr. Salamone's opinions concerning (1) the pressures in the iCup, (2) the pressures in the QuikScreen, and (3) the orientation of the iCup's test strips and openings toward the base, on the grounds that they do not meet *Daubert*'s reliability, relevancy, and qualifications requirements. It moves to exclude his opinions that the iCup infringes the '019 Patent because he does not opine that it meets every limitation. Finally, Innovacon moves to exclude his opinions that the iCup infringes under the doctrine of equivalents because Rembrandt did not disclose this theory in discovery.

The Court is not persuaded. Innovacon's motion undertakes excessive parsing of the words Dr. Salamone uses in his reports and makes arguments that go to the weight of his testimony, not its admissibility. Innovacon does not contend that Dr. Salamone's opinions are misleading or confusing. Rather, it contends that they are wrong or not as persuasive or reliable as the opinions offered by the experts on whom Innovacon currently relies. Innovacon is free to argue to a jury that Dr. Salamone's opinions do not satisfy Rembrandt's burden to demonstrate infringement insofar as the iCup does not meet every limitation in the '019 Patent, including the Pressure Limitations. Innovacon is also free to argue that Innovacon's experts' opinions are more reliable than Dr. Salamone's. These arguments, however, do not warrant exclusion of Dr. Salamone's opinions at trial. Innovacon's motion to exclude Dr. Salamone's testimony is denied.

XI. Conclusion

As discussed herein, both sides have taken the position in this litigation that the 2004 License Agreement was terminated as early as 2005, and no later than 2012. Moreover, the plain language of the 2004 License Agreement indicates that it terminated in 2005 when the Manufacturing Agreement was terminated. Finally, based on the evidence in the record, no reasonable jury could find that any party to that agreement ever acted as if the 2004 License Agreement continued to provide a license beyond 2005. Accordingly, there is no genuine dispute of material fact that the 2004 License Agreement terminated in 2005. The 2004 License Agreement therefore did not deprive Rembrandt of standing to sue for infringement of the '019 patent, making the Court's dismissal of Rembrandt's claim for infringement of the '019 patent erroneous. That order [Doc. No. 85] is VACATED insofar as it dismissed Claim 1 of the first amended complaint without prejudice. Defendants' motion to dismiss Rembrandt's claim for infringement of the '019 Patent [Doc. No. 63] is instead DENIED.

In light of the foregoing, Innovacon's motions for summary judgment [Doc. Nos. 207, 209], both of which argue for summary judgment that Innovacon did not breach the 2004 License Agreement, as well as Rembrandt's motion for summary judgment concerning sections 3.3, 6.1 and 6.2 of the 2004 License Agreement, are **DENIED AS MOOT**. However, Innovacon's first motion for summary judgment [Doc. No. 207] that it was not obligated to pay royalties makes arguments that are equally applicable to a motion for summary judgment that the iCup A.D. did not infringe the '019 patent. For the reasons discussed in Section VII, *supra*, Innovacon (and any other defendants named in the third amended complaint) need not refile a summary judgment motion arguing that the iCup A.D. does not infringe the '019 patent because issues of fact preclude summary judgment of non-infringement.

Rembrandt's motion for summary judgment that Innovacon breached section 3.3 of the 2004 License Agreement [Doc. No. 224] is also **DENIED AS MOOT**. Rembrandt's

motion for summary judgment of no invalidity of the '019 Patent [Doc. No. 225] is **DENIED**.

Assurance's motion for summary judgment [Doc. No. 229] is also **DENIED AS MOOT** in light of the determination that the 2004 License Agreement terminated in 2005. Instead, because all of Innovacon's counterclaims against Rembrandt and Assurance were premised on the terminated 2004 License Agreement, those counterclaims are dismissed, and Assurance is dismissed as a party to this case.

Rembrandt's motions to exclude opinions from Gregory Leonard and Karen Becker [Doc. Nos. 226, 228] are **DENIED AS MOOT**. Rembrandt's motion to exclude opinions from Gary Horowitz [Doc. No. 227] is **DENIED**. Innovacon's motion to exclude opinions from Salvatore Salamone [Doc. No. 230] is also **DENIED**.

On or before <u>August 13, 2018</u>, Rembrandt shall file a third amended complaint asserting only a claim for infringement of claim 10 of the '019 patent against Innovacon and/or any of the other previously dismissed defendants whom it contends are liable for infringement based on the iCup A.D. A case management conference to set deadlines including a new trial date will be held on <u>August 17, 2018</u>, at <u>1:30 p.m.</u>, before the undersigned in Courtroom 4C. The parties shall meet and confer and jointly file a proposed case management schedule through trial on or before <u>August 15, 2018</u>.

It is **SO ORDERED**.

Dated: August 3, 2018

Hon. Cathy Ann Bencivengo United States District Judge