IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civ. No. 07-468-LPS
	:	
RYMED TECHNOLOGIES, INC.,	:	
	:	
Defendant.	:	

MEMORANDUM OPINION

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November 23, 2010
Wilmington DE

Stark, U.S. District Judge:

Plaintiff ICU Medical, Inc. ("ICU") filed this case against Defendant RyMed Technologies, Inc. ("RyMed") alleging infringement of United States Patent Nos. 5,865,866 (the "'866 Patent"); 5,873,862 (the "'862 Patent"); 5,928,204 (the "'204 Patent"); and 6,572,592 (the "'592 Patent") (collectively, "the patents-in-suit") under 35 U.S.C. § 271. ICU further alleges that RyMed has induced and/or contributed to infringement of the asserted claims of the '862 and '592 patents.[1]

Pending before the Court are the following motions: (i) a motion for judgment on the pleadings or for partial summary judgment; (ii) eight motions in limine[2]; (iii) a motion to exclude expert testimony; (iv) a motion to exclude Section 282 notice; and (v) a motion to preclude the assertion of a prosecution history estoppel defense. The Court held a hearing on these motions on September 2, 2010. *See* Transcript ("Tr.") (D.I. 448). The Court's decisions on each of these motions are given below.

BACKGROUND

[1]ICU has asserted against RyMed the following claims of the patents-in-suit: claims 1, 2, 3, 5, and 6 of the '866 Patent; claims 1-3 of the '862 Patent; claims 1, 2, 3, 6, and 9-12 of the '204 Patent; and claim 45 of the '592 Patent. (D.I. 116 at 1) All of the patents-in-suit share a common specification.

[2]While twelve motions in limine were originally presented to the Court, four motions are no longer at issue. RyMed withdrew its motion in limine No. 5 (D.I. 279) at the September 2, 2010 hearing. (Tr. at 17) In addition, pursuant to a letter dated September 2, 2010 (D.I. 446) ICU's counsel represented that the parties met and conferred and subsequently agreed that the following motions are not withdrawn or moot: ICU's motion in limine No. 1 (D.I. 267); Rymed's motion in limine No. 1 (D.I. 272); and Rymed's motion in limine No. 6 (D.I. 286).

A. The Patents-In-Suit

The patents-in-suit relate to needleless intravenous medical connector valves. (D.I. 296 at 1) As noted by now-retired Judge Joseph J. Farnan, Jr. in his claim construction opinion:

> Such valves are used to facilitate both the transmission of medication and fluids into a patient's bloodstream, as well as the withdrawal of a patient's blood. Before the patents-in-suit, the traditional technique for changing or adding fluid bags to an existing intravenous line required the insertion of an external needle into a needle access port, which was then connected to the existing intravenous line. Numerous problems existed with this traditional practice, for example, detachment of the needle, or contamination of the needle posed serious safety risks to patients, and accidental needle sticks posed the risk of infection to medical personnel.

(*Id.*) ICU's products are known as the CLAVE and MicroCLAVE. Rymed's accused product is known as the InVision-Plus. (*See, e.g.*, D.I. 271)

B. Procedural History

ICU commenced suit on July 27, 2007. (D.I. 1) The case was originally assigned to Judge Farnan. Rymed filed its answer on October 12, 2007. (D.I. 14) Rymed has filed several subsequent amended responses. (D.I. 87; D.I. 359)

A pretrial conference is scheduled for December 1, 2010. (D.I. 441) A jury trial on the issues of infringement, validity, and willfulness is scheduled to begin on December 13, 2010. (*Id.*) A bench trial, on all issues to be tried to the Court – including inequitable conduct, prosecution history estoppel, ensnarement, vitiation, obviousness-type double patenting, indefiniteness, and standing – is scheduled to begin on January 6, 2011. (*See id.*; D.I. 458) The issues of damages and injunctive relief have been severed for a separate trial, if necessary. (*See* D.I. 441; D.I. 458)

To the extent it is necessary to address additional portions of the complicated procedural history of this case, the Court does so below in connection with analysis of the pending motions.

DISCUSSION

I. Motions In Limine

A. ICU Motions

1. To preclude RyMed from presenting evidence and argument from prior ICU patent litigations (D.I. 269)

Pursuant to Federal Rules of Evidence 402 and 403, ICU requests exclusion of "arguments, positions, opinions, orders or any other characterization of the evidence from prior ICU patent litigations" involving entities other than RyMed. (D.I. 269 at 1)[3] ICU contends that such evidence would be irrelevant, confusing, time-wasting, and unnecessarily prejudicial. ICU does not seek by this motion to exclude evidence from prior litigations between ICU and RyMed. Nor does ICU seek to exclude "basic documentary evidence" from ICU's litigations with other entities. (D.I. 339 at 1) However, ICU does request exclusion of "prior claim construction orders, rulings on motions for summary judgment, arguments the parties made relating to

[3]Specifically, ICU's motion relates to: (1) *Medex v. ICU* (2:99-CV-00679-JDH-MRA), an unrelated case about an unrelated patent owned by unrelated third party Medex, alleging infringement against ICU's CLAVE product; (2) *ICU v. B. Braun* (CV-01-3202 CRB (MEJ)), an unrelated action about whether an unrelated party's (Braun's) accused product infringes ICU's patents, including the '204 Patent; (3) *ICU v. Alaris* (SA CV 04-0689 MRP (VBKx)), an unrelated action about whether an unrelated party's (Alaris's) accused products infringe ICU's patents, including the '866, '862, and '592 patents; and (4) *Medegen v. ICU* (Case No. 06-CV-619), a patent litigation against ICU's CLC2000, a product not at issue in the instant case. (D.I 269 at 3-6)

infringement or invalidity of the patents, any judgments or orders, or expert opinions." (*Id.*)[4]

RyMed responds that ICU's motion is overbroad and would preclude clearly admissible evidence under Federal Rule of Evidence 801. (*See* D.I. 316) RyMed contends that evidence from prior ICU litigations is relevant to the willful infringement analysis that will have to be undertaken in the instant case. (*Id.*) RyMed relies primarily on materials from the *ICU v. Alaris* case in the Central District of California (SA CV 04-0689 MRP (VBKx)). In particular, RyMed finds relevance in a portion of the *Alaris* court's claim construction ruling – which construed some of the same terms at issue in the instant case – as it goes to an assessment of the objective reasonableness of RyMed's belief that its products did not infringe the patents asserted here.[5]

ICU's motion arises under Federal Rules of Evidence 402 and 403. Rule 402 provides that "[a]ll relevant evidence is admissible." Rule of Evidence 403 adds, however: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

ICU's motion is DENIED to the extent it seeks to exclude the *Alaris* claim construction rulings on the same claim terms that are involved in this case. The court in *Alaris* construed claims in 2004 and 2006. (Tr. at 73-74, 76) Until Judge Farnan issued his claim construction

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[4]The parties agree that the request to exclude references to the existence of prior patent litigations to suggest that ICU engages in a pattern of suing other companies is moot. (*See* D.I. 316 at 1, 4; D.I. 339 at 3-4)

[5]RyMed also seeks to introduce the *Alaris* court's decision awarding attorneys' fees and invalidating 23 claims of the '592 patent, a patent which is also asserted here. (D.I. 316 at 4) These, too, RyMed asserts, are relevant to its contention that it had a good faith belief it did not infringe ICU's patents. (*Id.*) ICU's separate motion to preclude this evidence is addressed below.

ruling in the instant case in December 2009, it was reasonable for RyMed to rely on the *Alaris* court's constructions in evaluating whether its products infringed ICU's asserted patents. *See Pandora Jewelry, LLC v. Cappola Capital Corp.*, 2009 WL 2176068, at *3 (M.D. Fla. July 13, 2009) (finding relevant evidence of party's reliance on prior claim construction rulings in different court until court where case was pending issued its claim construction ruling); *see also* D.I. 296 at 4 (Judge Farnan writing in claim construction opinion, "[s]everal of the disputed terms have been considered or construed by other courts in prior proceedings concerning this family of ICU patents"). Thus, portions of the *Alaris* claim construction rulings are pertinent to RyMed's defense to willful infringement. (Tr. at 75-76) (RyMed's counsel explaining: "We're only relying on the *Alaris* construction of the terms. . . . So what we're talking about here is just trying to bring in the *Alaris* opinions because they are relevant to show both on the objective and subjective tests, and we agree it's only up [until] . . . Judge Farnan issued the claim construction.").

The jury will be instructed, however, that the claim construction ordered by this Court in this action is the one the jury must follow in evaluating infringement and invalidity of the patents-in-suit. The jury may consider the prior courts' claim construction opinions solely for the purpose of evaluating RyMed's defense to willfulness.

In all other respects, ICU's motion is GRANTED.

2. To preclude RyMed from referencing invalid claims of the '592 patent and attorneys' fee award against ICU in the Alaris litigation (D.I. 270)

ICU seeks to preclude (1) any reference to the invalidity of Claims 17-26, 31-42, and 46 of ICU's '592 patent, which have not been asserted in this case, or (2) the award of attorneys'

fees under 35 U.S.C. § 285 against ICU in the *Alaris* litigation. (D.I. 270 at 1)

On February 21, 2007, in the *Alaris* litigation referred to above, Judge Mariana R. Pfaelzer found Claims 17-26, 31-42, and 46 of the '592 patent invalid for lack of sufficient written description as required by 35 U.S.C. § 112. (*See* January 22, 2007 Order, D.I. 317 Ex. A; *see also* February 21, 2007 Judgment, D.I. 285 Ex. 23) Based on that finding, the court then determined, in part, that ICU's assertion of those claims against Alaris' accused product were objectively baseless and brought in bad faith, and consequently awarded attorneys' fees to Alaris under 35 U.S.C. § 285. (*See ICU Medical, Inc. v. Alaris Medical Sys., Inc.*, 2007 WL 6137003 (C.D. Cal. Apr. 16, 2007); *see also* September 21, 2007 Final Judgment, D.I. 317 Ex. B) The Federal Circuit affirmed the district court's decision on March 13, 2009. *See ICU Medical, Inc. v. Alaris Medical Sys., Inc.*, 558 F.3d 1368, 1379-81 (Fed. Cir. 2009).

Here, the only claim of the '592 patent asserted by ICU against RyMed is claim 45. (*See* D.I. 270 at 1-2) This is an independent claim, having no relationship to those deemed invalid (except for being part of the same patent). (*Id.*)

ICU's motion is GRANTED. Telling the jury that the *Alaris* court found certain of ICU's patent claims to be invalid would introduce irrelevant evidence and would risk unduly prejudicing ICU, as the jury must make that very same assessment with respect to claim 45 of the same ('592) asserted patent in this case. Likewise, any relevance to the fact that another court, presiding over an entirely separate litigation, found it necessary to award attorneys' fees to a party litigating against ICU, would be outweighed by the risk of undue prejudice to ICU and confusion.

3. To preclude evidence comparing the ICU Clave/MicroCLAVE to RyMed's InVision-Plus (D.I. 271)

ICU seeks to preclude Rymed from relying on or presenting arguments, evidence, or opinions which compare ICU's CLAVE/MicroCLAVE products to the accused InVision-Plus in response to ICU's charge of infringement. To the extent it is not moot, the Court GRANTS ICU's motion.

Infringement requires comparison of the accused product to the claims at issue. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1577 (Fed. Cir. 1992). The only relevant question for infringement is whether the accused product contains each and every limitation of the asserted claims, either literally or under the doctrine of equivalents. In ICU's view, RyMed wants to avoid this test by focusing instead on the differences between ICU's CLAVE/MicroCLAVE products and RyMed's accused products. ICU emphasizes infringement cannot be determined by a comparison between the accused product and the patent holder's commercial products. *See, e.g., Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481-82 (Fed. Cir. 1984).

In response, RyMed agrees that the determination of infringement must be based on a comparison between the accused product and the asserted claims of the patent. To the extent that ICU's motion is limited to this comparison, RyMed does not object, assuming that it applies equally to ICU's technical expert as well. (D.I. 318)

However, RyMed insists that a comparison between accused product (RyMed's InVision-Plus) and alleged commercial embodiment of the patents-in-suit (ICU's CLAVE) is relevant to refute ICU's allegations that RyMed copied its CLAVE and MicroCLAVE products as part of its

willfulness and nonobviousness contentions. (*Id.*) Thus, in RyMed's view, as long as ICU maintains its "copying" contention, it remains necessary and appropriate for RyMed in response to elicit opinions comparing the RyMed InVision product and the ICU CLAVE and MicroCLAVE products to show that they are not substantially similar, either in their components and functions, or their outcomes. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc*, 392 F.3d 1317,1325 (Fed. Cir. 2004) (stating "substantial similarity to, the patented product (as opposed to the patent)" is a relevant factor in assessing "copying").

ICU confirmed in its reply that its motion does not seek to preclude RyMed from presenting evidence comparing the InVision-Plus to ICU's CLAVE/MicroCLAVE as part of its willfulness and obviousness contentions. (D.I. 341 at 2) Accordingly, it appears to the Court that the issues raised in this motion are no longer in dispute. To the extent ICU's motion is not moot, it is GRANTED.

4. Regarding RyMed's "inventorship" claims as to Bui, Duffield, Mayer, and Kipe (D.I. 275)

Three of the pending motions in limine relate to RyMed's Tenth Affirmative Defense, of inequitable conduct. They are: ICU's motion regarding RyMed's "inventorship" claims as to Bui, Duffield, Mayer, and Kipe (discussed here); ICU's motion to exclude evidence regarding Jean Bonaldo (discussed immediately below); and RyMed's motion to preclude ICU from introducing new Bui documents (discussed further below). (D.I. 275)

On December 16, 2009, after the motions in limine had been fully briefed, Judge Farnan granted RyMed's motion for leave to amend the pleadings to introduce its Tenth Affirmative Defense. (D.I. 357; *see also* D.I. 374) Concluding that RyMed "demonstrated good cause to

amend its answer," Judge Farnan granted RyMed leave to do so, over ICU's objection. (*Id.* at 356 at 6) In granting leave, Judge Farnan considered – and rejected – essentially the same arguments ICU also asserts in connection with this motion in limine that relates to RyMed's inequitable conduct defense. Because ICU's contentions have already been considered and rejected by Judge Farnan – and, importantly, because Judge Farnan decided to permit the inequitable conduct defense to come into the case, and it will be tried as part of the bench trial next January – ICU's position on this motion in limine must also be rejected. Accordingly, ICU's motion is DENIED.

5. To exclude evidence regarding Jean Bonaldo and related defenses (D.I. 280)

ICU also seeks to exclude evidence and argument in support of RyMed's assertion that Jean Bonaldo is an inventor on the patents-in-suit, that he is a prior inventor under 35 U.S.C. §102(g), or that Dr. George Lopez derived the inventions of the patents-in-suit from Mr. Bonaldo (collectively the "Bonaldo Defense"). ICU contends that RyMed's Bonaldo Defense is untimely, confusing, and unfairly prejudicial.

This motion is DENIED. The Court has granted Rymed leave to add its Tenth Affirmative Defense, of inequitable conduct. ICU's concerns go to the merits of that defense, a matter that will be litigated at the January 2011 trial.

B. RyMed Motions

1. To preclude ICU from introducing new Bui docs (D.I. 274)

RyMed seeks to preclude ICU from introducing any documents relating to former employee Dennis Bui that ICU has refused to disclose in discovery. RyMed recently learned that

Mr. Bui made material contributions to the conception and reduction to practice of the patents-in-suit (relevant to inventorship and a possible license defense). While RyMed has agreed to produce documents it has uncovered relating to Mr. Bui's contributions to the patents-in-suit and has agreed to make Mr. Bui available for a deposition at a mutually agreeable time, exclusion of any documents from ICU that would have been responsive to RyMed's requests for production that were refused is necessary, in RyMed's view, to prevent unfair surprise.

ICU had opposed production of its Bui documents on the grounds that they related only to RyMed's Tenth Affirmative Defense of inequitable conduct. (*See* D.I. 307) At the time RyMed's motion in limine was being briefed, the Court had not yet ruled on RyMed's motion to amend its pleadings to add this defense. Now, as already explained, that defense is part of the case, and will be tried in January 2011.

At the motions hearing, RyMed indicated that if ICU produced the previously-withheld Bui documents soon, RyMed would have sufficient time prior to trial to deal with them. (Tr. at 70) The Court recognizes that nearly three months have passed since the motions hearing. Nonetheless, the Court believes that there still remains sufficient time before the January trial for RyMed to review ICU's Bui documents and not be unduly prejudiced at that trial by unfair surprise.

Accordingly, RyMed's motion is DENIED. ICU shall produce the previously-withheld Bui documents within seven days of the date of this Memorandum Opinion.

2. To exclude evidence relating to Lanham Act action (D.I. 277)

Rymed seeks to preclude ICU from introducing any evidence relating to the allegations made in or the results of the separate litigation between RyMed and ICU in the Central District of

California. *See RyMed Technologies, Inc. v. ICU Medical, Inc.*, Case No. SA-CV 07-1199 MRP (VBKx) (C.D. Cal.). The parties have stipulated that certain discovery from the California case may be treated as taken in this case. RyMed contends, however, that there is no need to admit evidence of the allegations made in that case (*i.e.*, allegations that ICU violated the Lanham Act, infringed trademarks, and engaged in unfair competition), or the results of that litigation (*i.e.*, after discovery, the California court granted ICU summary judgment of non-liability). *See* Tr. at 72 (RyMed counsel stating, "We're saying the result and the allegations made in that [California] case should not come in"). RyMed argues that such evidence is irrelevant and would unfairly prejudice RyMed if admitted.

The Court agrees with RyMed. Accordingly, RyMed's motion is GRANTED.

3. To preclude ICU from offering evidence of prior alleged copying to support allegations of copying in instant case (D.I. 278)

Rymed seeks to preclude ICU from offering evidence to show alleged prior incidents of "copying" by RyMed or its CEO, Dana Ryan, under Rules 402 and 403. Such evidence, which relates to ICU's allegations that RyMed many years ago copied other ICU products – not the ones at issue here – is, in RyMed's view, not probative, and would cause substantial confusion and delay and unfair prejudice to RyMed, basically necessitating "mini-trials" into whether each of a series of prior (non-accused) products was or was not a copy of an ICU product.

ICU counters that this evidence is highly relevant and admissible under Rule 404(b). (*See* D.I. 309) RyMed's prior copying goes to at least two significant issues in the case: copying as a secondary consideration to obviousness, and RyMed's intent to willfully infringe ICU's patents. *See, e.g., State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985)

(knowledge of the patent is relevant to show willful infringement); *In re Brimonidine Patent Litig.*, 666 F. Supp. 2d 429, 446 (D. Del. 2009) (recognizing that efforts by others to copy is one of the secondary considerations relevant to non-obviousness). ICU argues that the fact that Mr. Ryan and his prior companies have followed ICU's products and patents closely, and routinely come out with similar ones, is directly tied to Mr. Ryan's awareness of and intent to copy ICU's patented CLAVE.

The Court concludes that the alleged prior copying by Mr. Ryan and RyMed of unrelated products is irrelevant to infringement and non-obviousness under Rule 402. ICU does not contend that the earlier Click-Lok device embodies any of the asserted claims in the patents at issue. Furthermore, the Court agrees with RyMed that introduction of such contentions would cause substantial delay, wasted time, and confusion because it would require mini-trials to determine whether Mr. Ryan actually copied the unrelated ICU devices nearly twenty years ago. *See, e.g., Santrayll v. Burrell*, No. 91 Civ. 3166 (PKL), 1998 WL 24375, at *3 (S.D.N.Y. Jan. 22, 1998) (excluding evidence of defendant's alleged prior acts of copying in a copyright case in part because "[i]t would seriously prejudice the defendants for the Court to . . . permit what would in essence be a series of 'mini-trials' on other acts of copying").

RyMed's motion is GRANTED.

II. ICU's Motion To Preclude Rymed from Asserting Prosecution History Estoppel (D.I. 417)

ICU seeks to preclude Rymed from asserting a prosecution history estoppel defense, on the grounds that Rymed's defense is untimely. The Scheduling Order (D.I. 74) set June 26, 2009 as the deadline for fact discovery and November 16, 2009 as the deadline for case dispositive

motions. In its pleadings, interrogatory responses, and throughout the discovery period, RyMed never alerted ICU to its prosecution history estoppel defense.

Rymed contends that prosecution history estoppel is the most important defense in the case and should not be excluded. (*See* D.I. 423) Rymed adds that it put ICU on notice that it was asserting this defense, any delay in detailing its defense was substantially justified and not in bad faith, there is no prejudice to ICU, the caselaw cited by ICU is inapposite, and its assertion of the defense is not untimely under the Court's Scheduling Order.

The Court will DENY ICU's motion. The original Scheduling Order has been vacated and this case has proceeded in a different manner than was anticipated in that earlier Order. Among other things, this case was originally assigned to Judge Farnan, and Rymed appears to have reasonably relied on what it understood to be Judge Farnan's view that prosecution history estoppel could be raised at a late point in the case.[6] Excluding Rymed's defense would be an inappropriately extreme remedy. *See UCB, Inc. v. KV Pharmaceutical Co.*, 692 F.Supp. 2d 419, 422 (D. Del. 2010). The issue of prosecution history estoppel presents a question of law for the Court to address at a bench trial now scheduled for January 2011.

If ICU believes it needs additional discovery or an expert report in light of the Court's denial of this motion, ICU shall be prepared to discuss this matter at the upcoming pretrial conference. The Court is not persuaded by ICU's contention that much discovery is necessitated

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[6]Rymed cites Judge Farnan's decision in *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 724, 775 (D. Del. 2002), in which Judge Farnan ruled that the Court may address prosecution history estoppel "either on dispositive pretrial motions or post-trial motions for judgment as a matter of law." Rymed further relies on *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997), for the proposition that prosecution history estoppel is a legal issue that may be raised either on summary judgment or at trial or through a motion for judgment as a matter of law.

by this ruling or that it threatens ICU's ability to be fully-prepared for the January trial.

III. ICU's Motion to Strike Rymed's Section 282 Notice (D.I. 406)

Section 282 of the Patent Act provides, in relevant part:

> In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial . . . of any publication to be relied upon as anticipation of the patent in suit or . . . as showing the state of the art.

35 U.S.C. § 282. Section 282, which traces its roots to the Patent Act of 1836, is designed to "prevent patentees [from] being surprised, at the trial of the cause, by evidence of a nature which they could not be presumed to know, or be prepared to meet, and thereby subject them either to most expensive delays, or to a loss of their cause." *Eaton Corp. v. Appliance Valves Corp. et al.*, 790 F.2d 874, 879 (Fed. Cir. 1986) (internal citations omitted).

Rymed provided ICU with Rymed's Section 282 Notice ("282 Notice") (D.I. 362) on December 18, 2009. This was one month before the original January 19, 2010 trial date and nearly six months after the close of fact discovery. It was also more than two months after Rymed provided ICU with Rymed's expert report on invalidity. Rymed's 282 Notice contains twenty-eight references, twelve of which RyMed had not previously disclosed. ICU asks that RyMed's 282 Notice be stricken in its entirety, or, at a minimum, that the Court exclude the twelve previously-undisclosed references.[7] (*See* D.I. 406)

In response, Rymed explains that it will not use any of the twelve new references as the basis for an obviousness or anticipation invalidity defense. Rymed listed these new references in

[7]The Court will not address ICU's alternative request for a limiting jury instruction. Jury instructions will be addressed during the upcoming pretrial conference and again during trial.

its 282 Notice only "so that [ICU] could not complain about a lack of notice of these patents for other purposes, . . . including but not limited to prosecution history estoppel." (D.I. 406 at 3; D.I. 409 at 4)

ICU's motion is DENIED. Rymed will not be permitted to use the newly-disclosed twelve prior art references as a basis for invalidating the patent. Hence, ICU will not be prejudiced in any manner sought to be prevented by Section 282.

IV. ICU's Motion to Exclude Testimony of Dr. William R. Jarvis (D.I. 292)

ICU seeks to exclude the testimony of one of RyMed's rebuttal experts, Dr. William R. Jarvis, pursuant to the standards set forth in *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993), and Federal Rules of Evidences 401, 403, and 702. The Court will GRANT ICU's motion.

The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence and the Supreme Court's *Daubert* decision. Rule 702 governs the admissibility of expert testimony, subject to the relevancy provisions of Rules 401 through 403. Pursuant to Rule 702, in order to be admissible, expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." The Supreme Court has assigned "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*, 509 U.S. at 597.

A trial court's gatekeeping role under Rule 702 of the Federal Rules of Evidence is intended to ensure that all "expert testimony or evidence is not only relevant, but also reliable." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). A trial judge does so by determining whether: (1) an expert witness is qualified to testify about the subject matter; (2) the

methodology the expert uses is reliable; and (3) the opinion fits the facts of the case. *See, e.g., Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

Dr. Jarvis, an epidemiologist, filed a rebuttal expert report in October 2009. (D.I. 293 at 2) RyMed offers Dr. Jarvis to rebut ICU's expert, Claude Vidal, on whether RyMed has copied ICU's product and on whether RyMed's product has the same results as ICU's for purposes of infringement under the doctrine of equivalents. The essence of Dr. Jarvis' opinion is that "the RyMed products and the ICU Medical products that ICU contends practice the asserted patents do not give substantially the same results," a conclusion he bases on "in vitro data (both from published studies and manufacturer funded studies or product information) show[ing] that the RyMed and ICU Medical products are not substantially the same and do not result in substantially the same outcomes." (D.I. 294 ¶ 19; *see also* Tr. at 38, 52)

ICU contends that Dr. Jarvis' report is not "rebuttal" to anything, and suggests that his report does not satisfy any of the qualification, reliability, and fit requirements. The Court is satisfied that Dr. Jarvis is qualified to offer his opinions and satisfied with the reliability of his methodology. A closer question is presented with respect to "fit,"[8] but it is not necessary to resolve this issue. This is because the Court will exclude Dr. Jarvis' opinion under Rule 403, as the risk of prejudice and confusion from this evidence greatly outweigh its minimal relevance.

Essentially, the Court views Dr. Jarvis' report (and, consequently, his testimony) as a back-door way of encouraging the jury to conclude that RyMed's products are safer than ICU's. But the relative safety of the two products is not relevant; it also risks unfairly prejudicing ICU, if

[8]ICU argues that Dr. Jarvis improperly compares the accused product to the patented product (rather than to the invention claimed in the patent itself), his analysis has nothing to do with the relevant equivalents, and that he looks at the wrong "result."

the jury were to punish ICU for having a less safe product, even if RyMed's competing product infringes ICU's patents.

RyMed defends the relevance of Dr. Jarvis on two grounds: as rebuttal to ICU's non-obviousness defense to invalidity based on copying, and as rebuttal to infringement by the doctrine of equivalents. In both instances, Dr. Jarvis basically opines that because RyMed's product is safer (e.g., produces fewer blood infections) than ICU's product, it is not a copy,[9] and it does not produce substantially equivalent results. The Court reiterates that the minimal relevance of both of these points is greatly outweighed by the implicit invitation that the jury decide which of the competing products it likes better – which one it would feel safer having used – and distracting it from the matters of infringement, invalidity, and willfulness that are its proper task to decide.[10] Moreover, permitting Dr. Jarvis' opinion to be presented to the jury would necessitate permitting ICU to retain its own epidemiological expert, to rebut Dr. Jarvis, thereby requiring ICU to use its limited time before the jury to put Dr. Jarvis' opinion in context. (Tr. at 44) At bottom, the Court agrees with ICU that presentation of this evidence would be an unjustified "sideshow."[11]

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[9]The Court intends to keep a tight limit on the evidence ICU may introduce in support of its copying allegation. If ICU opens the door to safety issues in making its copying case, RyMed will be permitted to respond appropriately.

[10]RyMed's offer at the hearing to refrain from using the word "safety" in connection with Dr. Jarvis' testimony (Tr. at 54-55), while helpful, would not greatly reduce the risk of unfair prejudice from this evidence.

[11]*See* Tr. at 35: "[W]e think this is a sideshow that would be introduced into the case. We think we have a right to respond to it with an expert of like discipline, [an] epidemiologist. It's a[n] irrelevant sideshow which would convert the question in this case from whether or not the product infringes and whether the specific features in the RyMed device which we're trying to reach by equivalence do or do not represent insubstantial change, and would convert it into an

V. ICU's Motions with respect to RyMed's Inequitable Conduct Defense (D.I. 286)

Finally, ICU seeks relief with respect to RyMed's inequitable conduct defense to the validity of ICU's '592 patent. ICU seeks either judgment on the pleadings, pursuant to Federal Rule of Civil Procedure 12(c),[12] or summary judgment, pursuant to Rule 56(c).[13] More particularly, ICU seeks an order of judgment on the pleadings on the ground that RyMed has not alleged facts with sufficient particularity to support its Ninth Affirmative Defense relating to inequitable conduct, or, in the alternative, for an order of partial summary judgment dismissing RyMed's Ninth Affirmative Defense on the ground that there is no genuine issue of any material

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issue [of:] is one of these devices more efficacious or safer than the other."

[12]A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), alleging a failure to state a claim upon which relief can be granted, is analyzed under the same standard as a Rule 12(b)(6) motion to dismiss. *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir.1991). Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for "failure to state a claim upon which relief can be granted." Evaluating a motion to dismiss under Rule 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000) (internal quotation marks omitted).

[13]A grant of summary judgment is appropriate only where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Federal Rule of Civil Procedure 56(c). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Id.* at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

fact and ICU is entitled to judgment as a matter of law. ICU's motion will be DENIED.

Inequitable conduct, "while a broader concept than fraud, must be pled with particularity" pursuant to Rule 9(b)[14]. *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). "[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir.2009). Although a party may plead facts upon "information and belief," it must also set forth the "specific facts upon which the belief is reasonably based." *Id.* at 1330. An individual associated with the filing and prosecution of a patent application engages in inequitable conduct when he or she makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO, with a specific intent to deceive the PTO. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (noting that each element must be proven by clear and convincing evidence); 37 C.F.R. § 1.56 (2008) ("[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application . . . .").

Although RyMed initially identified eleven prior art references it alleged were material to the PTO's consideration of the '592 patent, it now relies on only two: the Bross '154 patent and the Mackal '629 patent. RyMed alleges that ICU or its agents, and specifically prosecuting attorney Nataupsky, deliberately withheld these references with the intent to deceive the PTO.

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[14]Federal Rule of Civil Procedure 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

ICU has failed to show either that it is entitled to judgment on the pleadings[15] or that there is no genuine dispute of material fact. As this Court has previously observed:

> [C]harges of inequitable conduct are particularly ill-suited to resolution by summary judgment, because they often involve questions of intent and materiality. . . . The question of intent is especially problematic because, intent being a subjective state of mind, the proof requires the fact finder to evaluate all the facts and circumstances in each case. Such an evaluation is *rarely* enabled in summary judgment.

Ampex Corp. v. Eastman Kodak Co., 460 F. Supp.2d 569, 570 (D. Del. 2006) (internal citations and quotation marks omitted). This statement is particularly apt here. RyMed points out that the record shows that attorney Nataupsky, on behalf of ICU, submitted the Bross '154 and Mackal '629 prior art references to the PTO in connection with patents he prosecuted before the '592 patent, and returned to a more fulsome view of what he must disclose after he prosecuted the '592 patent, but that he failed to disclose these references in connection with the '592 patent prosecution. (Tr. at 62-63) The Court needs to evaluate the credibility of Nataupsky's explanation for these decisions, and make a finding as to his intent, which requires observing his testimony at trial. Similarly, whether the Bross '154 and Mackal '629 prior art references are material is hotly contested by the parties' experts. Trial is necessary to determine which expert is correct.

CONCLUSION

An Order, consistent with the rulings described above, will be filed.

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[15]It was unclear at the motions hearing whether ICU was continuing to press its motion for judgment on the pleadings. *See* Tr. at 59.