United States Court of Appeals for the Federal Circuit

STRECK, INC.,
Plaintiff-Appellee,

v.

RESEARCH & DIAGNOSTIC SYSTEMS, INC. AND TECHNE CORPORATION,
Defendants-Appellants.

2011-1044

Appeal from the United States District Court for the District of Nebraska in Case No. 06-CV-0458, Chief Judge Joseph F. Bataillon.

Decided: January 10, 2012

FLOYD R. NATION, Winston & Strawn LLP, of Houston, Texas, argued for plaintiff-appellee. With him on the brief was MERRITT D. WESTCOTT. Of counsel on the brief was RICHARD L. STANLEY, of Houston, Texas.

KURT J. NIEDERLUECKE, Fredrikson & Byron, P.A., of Minneapolis, Minnesota, argued for defendants-appellants. With him on the brief was GRANT D. FAIRBAIRN. Of counsel on the brief was MARTIN M. ZOLTICK, Rothwell, Figg, Ernst & Manbeck, of Washington, DC.

Before NEWMAN, O'MALLEY, and REYNA, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

In this patent case, Streck, Inc. ("Streck") filed suit against Research & Diagnostic Systems, Inc. and Techne Corporation (collectively, "R&D") in the United States District Court for the District of Nebraska alleging that R&D infringed three of Streck's patents for hematology control technology: U.S. Patent Nos. 6,200,500 ("the '500 Patent"), 6,221,668 ("the '668 Patent"), and 6,399,388 ("the '388 Patent") (collectively, "the patents-in-suit"). R&D counterclaimed for declaratory judgment of noninfringement and invalidity.

R&D appeals from the district court's: (1) dismissal of R&D's invalidity counterclaims with respect to claims Streck did not include in its infringement allegations (the "unasserted claims"); (2) denial of summary judgment for R&D and grant of summary judgment for Streck on written description; (3) denial of judgment as a matter of law ("JMOL") for R&D and grant of JMOL for Streck on enablement; (4) denial of R&D's renewed motion for JMOL and motion for a new trial on priority; and (5) issuance of a permanent injunction. *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 658 F. Supp. 2d 988 (D. Neb. 2009) ("*Summary Judgment Order*"); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, No. 8:06cv458, 2010 U.S. Dist. LEXIS 104461 (D. Neb. Sept. 30, 2010) ("*Denial of Renewed JMOL Order*"). Because we conclude that the district court did not err in refusing to address the validity of the unasserted claims and correctly denied R&D's written description and enablement defenses as a matter of law, and because the issue of priority is controlled by

this court's resolution in Appeal No. 2011-1045,[1] we affirm the district court's judgment against R&D and its decision granting a permanent injunction in favor of Streck.

BACKGROUND

A. Factual Background

The technology involved in this case relates to hematology controls. These controls are used to monitor and test the accuracy and consistency of hematology analyzers, which clinical laboratories use to analyze patient blood samples. Specifically, hematology analyzers measure the various components of whole blood, including red blood cells, white blood cells, platelets, and reticulocytes,[2] and the information gathered is used to diagnose and treat diseases. Both Streck and R&D manufacture and sell hematology control products.

Prior to 1996, hematology instruments measured reticulocytes and white blood cells separately and thus required separate stand-alone hematology controls – i.e., those that measured only a single component of blood. Stand-alone controls using true reticulocytes[3] and reticulocyte analogs were well-known in the art before the applications that matured into the patents-in-suit were filed. Dr. Alan Johnson, a senior scientist at R&D, is a

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[1] Streck, Inc. v. Research & Diagnostic Sys., Inc., 659 F.3d 1186 (Fed. Cir. 2011).

[2] Reticulocytes are "anucleate immature red blood cells containing some ribonucleic acid." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, No. 8:06cv458, 2008 U.S. Dist. LEXIS 91865 (D. Neb. Nov. 12, 2008) ("*Claim Construction Order*").

[3] The terms "true reticulocytes" and "natural reticulocytes" are used interchangeably to refer to naturally-occurring reticulocytes. For consistency, we refer to them as "true reticulocytes."

named co-inventor on U.S. Patent No. 5,736,402 ("the '402 Patent"), which claims stand-alone true reticulocyte controls. In the mid-1990s, Dr. Wayne Ryan, the majority owner and Chief Executive Officer of Streck, invented and patented a method for making reticulocyte analogs and using those analogs in a stand-alone control. *See* U.S. Patent No. 5,432,089 ("the '089 Patent"). The '089 Patent explains that reticulocyte analogs "exhibit a reticulocyte continuum and distribution that is similar to that of normal human reticulocytes." '089 Patent col.8 ll.36-39.

Hematology instrument manufacturers began developing a hematology analyzer that could measure both reticulocytes and white blood cells simultaneously in the same blood sample. Accordingly, there was a need for an integrated hematology control containing at least: (1) a stabilized reticulocyte component; and (2) a fixed and stabilized white blood cell component. Over time, both R&D and Streck began working on projects aimed at developing an integrated hematology control.

On August 20, 1999, Streck filed a patent application directed to an integrated reticulocyte control. That application became the '500 Patent, which issued on March 31, 2001. Ryan is the named inventor on the '500 Patent. The '668 Patent, which issued on April 24, 2001, and the '388 Patent, which issued on June 4, 2002, are continuations of the '500 Patent. Ryan and John Scholl, Streck's research and development manager, are named as co-inventors on the '668 and '388 Patents. Both Ryan and Scholl assigned their rights in the patents to Streck.

The parties agree that Claim 1 of the '668 Patent is representative for this appeal. It claims "[a] hematology control composition comprising: a) a stabilized reticulocyte component; and b) a fixed and stabilized white blood cell component capable of exhibiting a five-part differen-

tial." '668 Patent col.16 ll.41-45. The specification explains that:

> the control may suitably contain stabilized reticulocytes (that is, immature anucleate red blood cells containing some ribonucleic acid) or an analog thereof. For example, among possible embodiments, the reticulocyte component may comprise true mammalian reticulocytes prepared for instance by mammalian (e.g. human) red blood cell encapsulation or by isolation from whole blood. The reticulocyte component is prepared in any suitable manner. *See, e.g.*, [the '089 Patent]. Alternatively, it is possible to obtain suitable reticulocytes by obtaining blood from an anemic animal (e.g., a pig, goat, rabbit or the like).

'668 Patent col.3 ll.14-25. The district court construed the patents-in-suit to encompass an integrated reticulocyte control using either true reticulocytes or reticulocyte analogs.

On October 18, 1999, roughly two months after Streck filed its application, R&D filed its own patent application relating to integrated reticulocyte controls. Dr. Johnson is the named inventor of the control composition in R&D's application. In 2003, after some of Streck's patents had issued, R&D copied claims from Streck's patents into its still-pending application and asked the United States Patent and Trademark Office ("the PTO") to declare an interference to determine priority of invention. Facts relating to the parties' priority dispute are set forth in companion Appeal No. 2011-1045, which was previously decided by this court. To the extent necessary, those facts are incorporated by reference herein.

While R&D's interference request was pending, R&D began manufacturing and selling integrated hematology

controls, the first of which was referred to as CBC-XE. R&D subsequently began producing controls under the names CBC-4K Plus Retics and CBC-5D Plus Retics as well. It is undisputed that Ryan used his reticulocyte analog as the reticulocyte component of the integrated control when he reduced his invention to practice. In contrast, R&D's integrated controls use true reticulocytes as the reticulocyte component.

B. Procedural History

On June 29, 2006, Streck filed suit against R&D in the District of Nebraska alleging willful infringement of the patents-in-suit. R&D counterclaimed seeking a declaration that the asserted claims of the patents-in-suit are invalid and not infringed.

1. Identification of the Asserted Claims

On December 14, 2006, the parties agreed to be bound by the Patent Local Rules of the United States District Court for the Northern District of California. *Summary Judgment Order*, 658 F. Supp. 2d at 993. Patent Local Rule 3-1 requires that, "[n]ot later than 10 days after the Initial Case Management Conference, a party claiming patent infringement shall serve on all parties a 'Disclosure of Asserted Claims and Preliminary Infringement Contentions'" which sets forth, among other things, "[e]ach claim of each patent in suit that is allegedly infringed by each opposing party." N.D. Cal. Patent L.R. 3-1(a).[4] Likewise, Rule 3-3 provides that "[n]ot later than 45 days after service upon it of the 'Disclosure of Asserted Claims and Infringement Contentions,' each party oppos-

[4] The Patent Local Rules for the Northern District of California were revised in 2008. The versions cited herein were in effect from January 1, 2001 to February 29, 2008.

ing a claim of patent infringement, shall serve on all parties its 'Invalidity Contentions'" identifying each item of prior art that allegedly anticipates a claim or renders it obvious. Patent L.R. 3-3(a). The parties agreed that, consistent with Rule 3-7, supplementation of invalidity contentions "was allowed only by order of [the] court on a showing of good cause." *Summary Judgment Order*, 658 F. Supp. 2d at 994.

Pursuant to the Patent Local Rules, in a document dated December 15, 2006, Streck provided its "Disclosure of Asserted Claims and Preliminary Infringement Contentions," which identified the following "claims asserted to be infringed":

> R&D directly infringes, induces others to infringe, and/or contributes to third-party infringement of at least claims 28 and 29 of the '500 patent, claims 1, 4, 5, 6, 8-9, 13, 15, and 26-29 of the '668 patent, and claim 13 of the '388 patent literally and/or under the doctrine of equivalents through the manufacture, use, sale, offer to sell (including R&D's related promotion and advertising), and/or importation of R&D's hematology controls designated "CBC-XE" and "CBC-4K Plus Retics."

Streck, Inc. v. Research & Diagnostic Sys., Inc., No. 8:06cv458 (D. Neb. Apr. 16, 2007), ECF No. 32-4 at 2-3. In response, on January 19, 2007, R&D submitted its "Preliminary Invalidity Contentions" stating that the "Johnson Inventions anticipate each claim asserted by Streck, including at least claims 28 and 29 of the '500 patent, claims 1, 4, 5, 6, 8-9, 13, 15, and 26-29 of the '668 patent, and claim 13 of the '388 patent." *Id.* ECF No. 32-5 at 3. On December 16, 2008, Streck informed R&D that it was asserting only the following ten claims: Claims 28-29 of the '500 Patent; Claims 1, 4, 5, 6, 8, 9, and 13 of the

'668 Patent; and Claim 13 of the '388 Patent. *Summary Judgment Order*, 658 F. Supp. 2d at 994. Subsequently, in March 2008, R&D amended its invalidity contentions to assert that all claims of the patents-in-suit, except Claim 20 of the '388 Patent, were invalid for failure to satisfy enablement and written description requirements.[5]

2. Claim Construction and Final Invalidity Contentions

On June 5, 2008, the district court conducted a hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The court issued its claim construction order on November 12, 2008. In that order, the court noted that the "claims of the patents make it clear that the reticulocyte component of the control composition can be either a reticulocyte or an analog of a reticulocyte." *Claim Construction Order*, 2008 U.S. Dist. LEXIS 91865, at *23. The court construed "reticulocyte analog" to mean "particles made from a source other than naturally occurring reticulocytes, such particles appearing to the instrument as reticulocytes that naturally occur in the whole blood for which the instrument is intended." *Id.* at *33.

On January 2, 2009, R&D served its final set of invalidity contentions alleging that: (1) Johnson's inventions anticipated each of Streck's asserted claims; (2) each claim of the patents-in-suit, except Claim 20 of the '388 Patent, was invalid for failure to satisfy enablement and written description requirements; and (3) Claim 3 of both the '500 and the '668 Patents was invalid for indefinite-

[5] In its summary judgment order, the district court states that R&D amended its invalidity contentions in March 2007, but R&D admits, and the record reflects, that the amendment did not occur until March 2008. Appellants' Reply Br. 3; J.A. 43368.

ness. *See Summary Judgment Order*, 658 F. Supp. 2d at 994.

3. Summary Judgment Motions

On March 27, 2009, the parties filed cross-motions for summary judgment. Streck's motion requested judgment that: (1) its asserted claims were valid and contained sufficient written description; and (2) R&D had infringed the asserted claims.

R&D's motion asserted that: (1) Claim 3 of the '500 and '668 Patents was invalid as indefinite, inoperative, or not enabled; (2) all claims of the patents-in-suit (except Claim 20 of the '388 Patent) were invalid for lack of written description and lack of enablement; (3) the '388 Patent was invalid for misjoinder[6]; and (4) there was no evidence to support a finding of willful infringement. Specifically, with respect to invalidity, R&D argued that the patents-in-suit described an integrated control with reticulocyte *analogs* and did not adequately describe an integrated control with true, naturally occurring reticulocytes.

On September 9, 2009, the district court denied R&D's motion for summary judgment on its written description defense and granted Streck's cross-motion. First, the court held that, as a matter of law, Streck's patents adequately described an integrated control with true reticulocytes. *Summary Judgment Order*, 658 F. Supp. 2d at 999. The court noted that R&D's arguments focused primarily on enablement, rather than written description, and that R&D relied heavily on Claim 3 of '500 Patent, which was not asserted in Streck's initial

[6] The misjoinder issue related to whether Dr. John Scholl was properly listed as an inventor on one of Streck's patents.

disclosures. *Id.* The court further found that the level of skill in the art was high, and that a person of such skill would understand that the patents were meant to encompass both natural and analog reticulocytes. The court denied R&D's motion for summary judgment on enablement, finding that "there is a genuine issue of material fact with respect to the enablement issue." *Id.* at 999-1000.

Next, the court dismissed R&D's invalidity counterclaims with respect to Claim 3 of the '500 and '668 Patents. The court found that Streck did not assert infringement of those claims, and that R&D had "no 'reasonable apprehension' it will face an infringement suit on any claims other than those that Streck asserts it has infringed in this action." *Id.* at 1000. Finally, the court found that R&D had, as a matter of law, literally infringed the claims at issue, and that there was evidence from which a jury could find willfulness.[7] *Id.*

4. Motions *in Limine*

On September 4, 2009, both parties filed motions *in limine*. R&D sought, among other things, to exclude evidence relating to Streck's conception prior to 1997, on grounds that conception is irrelevant to the question of the priority of invention. Streck sought to exclude any evidence challenging the validity of the seventy-four unasserted claims of the patents-in-suit. Streck explained

[7] The district court also dismissed R&D's misjoinder claim (relating to inventorship) on grounds that R&D failed to raise that claim in its final invalidity contentions and that even if it had, R&D failed to provide clear and convincing evidence that the inventorship was incorrect. *Summary Judgment Order*, 658 F. Supp. 2d at 1000. Misjoinder is not an issue on appeal.

that it had informed R&D that it was only asserting infringement with respect to nine out of the total eighty-three claims of the patents-in-suit and that R&D should be prohibited from presenting evidence or testimony relating to the seventy-four unasserted claims.[8] On October 15, 2009, the district court denied R&D's motion, without prejudice to reassertion at trial, on grounds that it "involve[d] the weight rather than the admissibility of the evidence." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, No. 8:06cv458, 2009 U.S. Dist. LEXIS 96196, at *9 (D. Neb. Oct. 15, 2009). The court also denied Streck's motion:

> Although the court finds the subject of the motion is more properly viewed as an objection to be raised at trial, the court notes it will generally sustain such an objection. . . . The validity of claims other than those alleged to have been infringed is not an issue in this case and evidence with respect to those claims is generally not relevant. That said, some evidence that touches on the unasserted claims could be relevant for some purpose. Accordingly the court finds that the motion in limine should be overruled at this time, without prejudice to its reassertion via timely ob-

[8] As noted above, in its December 2006 infringement contentions, Streck identified fifteen asserted claims. In its December 2008 correspondence to R&D, Streck reduced the number of asserted claims to a total of ten (Claims 28-29 of the '500 Patent; Claims 1, 4, 5, 6, 8, 9, and 13 of the '668 Patent; and Claim 13 of the '388 Patent). In May 2009, Streck removed Claim 4 of the '668 Patent from the list of asserted claims, thus reducing the number to a total of nine claims. *Streck, Inc. v. Research & Diagnostic Sys. Inc.*, No. 8:06cv458 (D. Neb. Sept. 4, 2009), ECF No. 236-5 at 2.

> jection to the admissibility of such evidence at trial.

Id. at *3-4. Prior to trial, however, the district court excluded R&D's evidence on the unasserted claims. Specifically, the court orally ruled that, "[t]here is an issue about the declaratory judgment and jurisdiction over the unasserted claims of the patents. The validity of the unasserted claims will not go to the jury. That's the way I intend to proceed." J.A. 45134.

5. Jury Trial and JMOL Motions

Beginning on October 19, 2009, the court conducted an eight-day jury trial to address priority of invention, enablement, damages, and willfulness. At the close of the evidence, both parties moved for JMOL on the issues of enablement and priority. The court noted that it had permitted the presentation of enablement evidence to the jury so that the court could get a clear understanding of the issue. Based on the evidence adduced at trial, and before submitting the case to the jury, the court granted JMOL for Streck on enablement, explaining that "[e]verybody agrees that if you use encapsulated reticulocytes that you could use Dr. Ryan's invention to describe that." J.A. 46724. The court further explained that "a pig reticulocyte is not a human reticulocyte, so it's obviously an analog of a human reticulocyte." *Id.* Finally, the court stated that, according to the evidence, it would make no difference whether analog or true reticulocytes were used in Ryan's claimed invention. With respect to priority, the court found that Ryan was the first to conceive, but that there were substantial factual disputes as to whether Johnson was the first to invent. Accordingly, the only issues submitted to the jury were R&D's priority counterclaim, and Streck's damages and willful infringement claims.

On October 28, 2009, the jury found that: (1) R&D had not proven, by clear and convincing evidence, that it was the first to invent; and (2) R&D had not willfully infringed Streck's patents. The jury found that Streck was entitled to a royalty for R&D's infringing sales and awarded damages of 12.5%, which amounted to $92,298.88 plus costs and interest. The court entered judgment in favor of Streck on October 29, 2009.

6. The Concurrent Interference Proceedings and Streck's § 146 Action

While the infringement litigation was progressing, R&D's interference request was pending with the PTO, and, on March 21, 2007, the PTO declared an interference ("the PTO Interference") between five of Streck's patents (the patents-in-suit as well as U.S. Patent Nos. 6,403,377 and 6,406,915) and R&D's pending patent application. The sole count in the PTO Interference was Count 1, which corresponded to Claim 1 of Streck's '668 Patent, and is identical to the representative claim in this appeal.[9] On August 14, 2007, the district court denied R&D's motion to stay the infringement suit pending resolution of the PTO Interference, and the two cases proceeded concurrently.

The PTO Board of Patent Appeals and Interferences ("the Board") heard the parties' arguments regarding priority of invention in February 2009. On November 2, 2009, just four days after the district court entered judgment in this case, the Board issued its priority decision. Unlike the jury in this case, which found priority for

[9] The sole count in the PTO Interference recited a "hematology control composition comprising: (a) a stabilized reticulocyte component; and (b) a fixed and stabilized white blood cell component capable of exhibiting a five-part differential."

Streck, the Board found that R&D had proven, by a preponderance of the evidence, that Johnson was the first to invent the claimed integrated control.

On November 13, 2009, Streck appealed the Board's interference decision to the district court under 35 U.S.C. § 146. The § 146 appeal was assigned to the same judge who presided over the infringement case. Because there was a complete evidentiary record on the issue of priority – between the trial and the proceedings before the Board – the parties agreed to submit the § 146 action to the district court on the admitted record without further discovery or offers of proof.

7. Renewed Motion for JMOL, Motion for a New Trial, and Injunctive Relief

Following the jury verdict and the Board's priority decision, the parties filed three motions on November 12, 2009. First, R&D filed a renewed motion for JMOL and motion for a new trial. In the motion, R&D argued that the court should enter judgment as a matter of law on its counterclaim for invalidity because there was "insufficient evidence as a matter of law to sustain the jury's verdict that Defendants did not meet their burden of proving that Dr. Johnson was the prior inventor by clear and convincing evidence." J.A. 45059. Second, in light of the Board's decision in the PTO Interference proceedings, R&D moved to vacate the judgment in this case, stay proceedings, and hold a new trial. Finally, Streck filed a motion for permanent injunction against R&D to prevent future infringement of the patents-in-suit. The parties agreed to defer judgment on Streck's motion for injunctive relief and R&D's motion for a new trial until the district court ruled on the § 146 action, so both could be appealed together to this court.

The district court issued three decisions on September 30, 2010. First, in the co-pending § 146 action, the court reversed the Board's decision and found priority for Streck. As discussed below, the § 146 action was at issue in a companion appeal – Appeal No. 2011-1045 – which was previously decided by this court. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186 (Fed. Cir. 2011). Second, in this case, the court denied R&D's renewed motion for JMOL and motion for a new trial. The court found, in relevant part, that the evidence at trial supported: (1) "the jury's finding that R&D did not prove by clear and convincing evidence that Dr. Johnson was the first to invent an integrated reticulocyte control composition"; and (2) "the court's finding as a matter of law that Streck's patents were adequately enabled." *Denial of Renewed JMOL Order*, 2010 U.S. Dist. LEXIS 104461, at *32. Finally, the court granted Streck's motion for a permanent injunction and assessed additional damages of $36,690.18 for infringement occurring since the jury trial. The court then enjoined R&D from making, using or selling the products at issue in this case "as well as any hematology control products that are only colorably different therefrom in the context of the infringed claims . . . and from otherwise infringing the asserted claims of [the patents-in-suit] until the expiration of the last to expire of the Patents-in-Suit." J.A. 40047.

The district court denied R&D's motion to stay the injunction pending appeal to this court. Specifically, the court held that R&D: (1) did not demonstrate a likelihood of success on the merits regarding enablement, priority, or lack of written description; (2) did not show it would be irreparably harmed absent a stay because hematology controls are only a small part of their business; and (3) did not show that an injunction would hurt the public interest because there was no showing that Streck would

be unable to meet the industry's demands for controls. R&D was, however, granted a sixty-day grace period to clear its inventory because hematology controls are perishable products.

R&D timely appealed the September 30, 2010 district court decisions to this court. This opinion relates solely to the infringement action. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, R&D does not challenge the district court's decision that its accused products literally infringe the patents-in-suit as a matter of law. Instead, R&D argues that the district court erred when it: (1) dismissed R&D's invalidity counterclaims relating to the unasserted claims; (2) granted summary judgment to Streck and denied R&D's cross-motion on written description; (3) granted JMOL for Streck and denied R&D's cross-motion on enablement; (4) denied R&D's motion for renewed JMOL and motion for a new trial on priority; and (5) issued an overbroad permanent injunction.

For the reasons set forth below, we find that: (1) the district court did not err in limiting the action to the claims Streck asserted, given R&D's failure to establish a case or controversy with respect to the other claims; (2) the patents-in-suit satisfy the written description requirement as a matter of law, because the specification clearly discusses true reticulocytes as well as analogs; (3) R&D's evidence failed to create a jury question on the issue of whether the patents-in-suit failed to enable one skilled in the art to make the claimed integrated controls using true reticulocytes; (4) the priority issue is controlled by this court's ruling in Appeal No. 2011-1045, and R&D's related evidentiary challenges are without merit; and

(5) properly construed, the language in the permanent injunction is not overbroad. Accordingly, we affirm the district court in full.

A. Jurisdiction Over the Unasserted Claims

R&D sought summary judgment of invalidity with respect to all claims of the patents-in-suit. In its summary judgment order, the district court noted that: (1) Streck did not assert infringement with respect to Claim 3 of the '500 and '668 Patents; (2) R&D "has no 'reasonable apprehension' it will face an infringement suit on any claims other than those that Streck asserts it has infringed in this action"; and (3) there is "nothing in the record to suggest any intent to sue on the nonasserted claims." *Summary Judgment Order*, 658 F. Supp. 2d at 1000. Although the district court initially denied Streck's motion *in limine* to exclude argument and evidence regarding the unasserted claims, just before trial, the court stated that: "[t]here is an issue about the declaratory judgment and jurisdiction over the unasserted claims of the patents. The validity of the unasserted claims will not go to the jury." J.A. 45134.

R&D argues that the district court erroneously dismissed its written description and enablement challenges with respect to the unasserted claims. In support of this argument, R&D submits that the court applied an outdated "reasonable apprehension of suit test" and that Streck's withdrawal of claims "more than two years into this case" does not deprive the court of jurisdiction over its invalidity counterclaims.[10] Appellant's Br. 34. R&D

[10] As noted below, R&D's discussion of timing with respect to the unasserted claims ignores the fact that Streck served its preliminary infringement contentions, which narrowed significantly the scope of the asserted claims, only months after the action was filed.

also argues that its counterclaim was sufficient to put Streck on notice that all claims were at issue.

In response, Streck argues that the district court correctly dismissed R&D's challenges to its unasserted claims. Specifically, Streck contends that R&D's counterclaim only sought a declaration of invalidity with respect to the "asserted claims" and, therefore, the court had jurisdiction only over claims asserted at the time the relevant motions were filed. For the reasons that follow, we conclude that the district court did not err in finding that it lacked jurisdiction over the unasserted claims.

It is well-established that, in patent cases, the existence of a "case or controversy must be evaluated on a claim-by-claim basis." *Jervis B. Webb Co. v. So. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984) (citations omitted). A party claiming declaratory judgment jurisdiction has the burden of showing "that the facts alleged, 'under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007) (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). The party seeking a declaratory judgment must establish that jurisdiction "existed at the time the claim for declaratory relief was filed and that it has continued since." *Id.* at 1344. (citing *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974)). In other words, jurisdiction must exist "at all stages of review, not merely at the time the complaint [was] filed." *Id.* at 1345 (quoting *Steffel*, 415 U.S. at 459 n.10).

Prior to the Supreme Court's decision in *MedImmune*, this court applied a two-part test to determine whether there was an actual controversy in a declaratory judg-

ment action. Under the prior test, a declaratory judgment plaintiff had to show: (1) an explicit action by the patentee that creates the "reasonable apprehension" of an infringement suit; and (2) present activity by the declaratory judgment plaintiff that could constitute infringement or steps taken with intent to infringe. *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). In *MedImmune*, the Supreme Court rejected strict reliance on the "reasonable apprehension of suit" prong of the test. 549 U.S. at 132 n.11; *see also Sandisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 (Fed. Cir. 2007) ("The Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test.") The Court held that there is no bright-line rule for determining whether an action satisfies the case or controversy requirement and, instead, what is required is:

> that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

MedImmune, 549 U.S. at 127 (citations and quotations omitted). After *MedImmune*, courts must look at "all the circumstances" to determine whether a declaratory judgment plaintiff has shown a case or controversy between the parties. As this court has explained, moreover, although the Supreme Court rejected the reasonable apprehension of suit test as the *sole* test for jurisdiction, "it did not completely do away with the relevance of a reasonable apprehension of suit." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008) (citing *Caraco Pharm. Labs., Ltd. v. Forest Labs, Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008)). Instead, in the wake of *MedIm-*

mune, "proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test" to establish jurisdiction. *Id.* (citing *Caraco*, 527 F.3d at 1291).

Post-*MedImmune*, at least one district court has found that it lacked declaratory judgment jurisdiction over patent claims that were initially asserted in a broad complaint and subsequently not included in the narrower scope of claims alleged to be infringed. *See Hoffman-La Roche Inc. v. Mylan Inc.*, No. 2:09cv1692, 2009 U.S. Dist. LEXIS 114784, at *17-18 (D.N.J. Dec. 9, 2009). In *Hoffman*, the plaintiff alleged infringement of a patent that encompassed six claims. *Id.* at *8. After filing the complaint, the plaintiff served its infringement contentions pursuant to the local patent rules and asserted infringement with respect to only one of the six claims. *Id.* at *9. The district court found that, with respect to claims that were no longer asserted, the counterclaimant seeking declaratory judgment "must meet its burden under *MedImmune* and show that a live case or controversy exists and continues to exist on a claim-by-claim basis and at every stage of the litigation." *Id.* at *17. The court concluded that the plaintiff's decision to change its position did not automatically divest the court of jurisdiction, but the counterclaimant must show that jurisdiction continues to exist with respect to the now unasserted claims. *Id.* at *18. Because the counterclaimant failed to make that showing, the court found that it lacked jurisdiction over those discrete claims. *Id.* at *20. Although *Hoffman* is not binding on this court, we find its analysis persuasive and agree that, consistent with *MedImmune*, a counterclaimant must show a continuing case or controversy with respect to withdrawn or otherwise unasserted claims.

Citing *Scanner Technologies Corp. v. ICOS Vision Systems Corp.*, 528 F.3d 1365, 1382-83 (Fed. Cir. 2008), R&D argues that "a patentee cannot dictate the scope of a duly filed counterclaim simply by withdrawing some, but not all, of the asserted patent claims from the lawsuit." Appellants' Br. 34. As Streck argues, however, R&D's reliance on *Scanner Technologies* is misplaced, particularly since the circumstances here are readily distinguishable.

In *Scanner Technologies*, the patent holder filed suit alleging infringement, and the defendant counterclaimed seeking a declaration that both of the patents-in-suit were invalid, unenforceable, and not infringed. 528 F.3d at 1371. The parties stipulated that the case "would rise and fall" on one claim of one of the patents, and, based on that stipulation, the district court analyzed only that one claim in its infringement analysis. *Id.* The district court then found that the claims of both patents-in-suit were invalid as obvious and entered summary judgment of noninfringement. *Id.* at 1373. The patentee appealed, arguing, among other things, that the district court lacked jurisdiction to adjudicate and invalidate claims other than the single claim at issue in the infringement analysis. *Id.* at 1383. Although the parties had stipulated that the case would be tried on a representative claim, we found that the district court nonetheless had jurisdiction over all of the claims because the defendant asserted a counterclaim seeking declaratory judgment on all claims of the patents-in-suit. *Id.* at 1383-84. Specifically, we found that the "pleadings represented that 'the case' constituted allegations of infringement of both patents, and a declaratory judgment action seeking invalidity, noninfringement, and unenforceability of all the claims of the patent in suit." *Id.* at 1383-84. As such, the district court had

jurisdiction to invalidate the claims of both patents-in-suit.

Unlike the situation in *Scanner Technologies*, where the parties stipulated that the court need only analyze one "representative" claim to decide infringement, and the patentee never affirmatively disclaimed its allegations of infringement as to the other claims, here, as in *Hoffman*, the patentee narrowed the scope of its claims at the start of litigation pursuant to the local patent rules and did so even further before any dispositive rulings by the court. Streck filed its Complaint in June 2006, alleging infringement of "one or more claims" of each of the patents-in-suit. In December 2006, Streck served its preliminary infringement contentions, which narrowed the scope of claims at issue to fifteen specific claims.[11] In response, R&D's counterclaim was limited to the "asserted claims," and its initial invalidity contentions, which were served on January 19, 2007, addressed the same fifteen claims identified in Streck's infringement contentions. The number of asserted claims was narrowed again, moreover, by no later than May 2009, this time to only nine claims. Therefore, unlike the situation in *Scanner Technologies*, where all of the claims were at issue and were never withdrawn or altered by either party, here, both parties were on notice from the start of litigation that the scope of claims at issue was only a subset of the full patents-in-suit and, significantly, did not include Claim 3 of any patent. And, the parties knew precisely which claims were at issue well before the court ruled on the parties' summary judgment motions or conducted trial.

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[11] R&D's assertion that Streck did not narrow its asserted claims until 2008 is wrong. Although neither party cites to the preliminary infringement and invalidity contentions, a careful examination of the docket clarifies that the timing described here is, in fact, the correct one.

R&D relies primarily on its assertion that, under *MedImmune*, it need not prove reasonable apprehension of an infringement suit to vest jurisdiction over its invalidity counterclaims in the district court. Though R&D is correct that the reasonable apprehension of suit test is no longer the exclusive test for declaratory judgment jurisdiction, *MedImmune* does not stand for the proposition that an Article III case or controversy exists automatically whenever a competitor desires to mount a validity challenge. Under *MedImmune*, a party seeking declaratory judgment still "has the burden of establishing the existence of an actual case or controversy." 549 U.S. at 140. Thus, although the district court relied on pre-*MedImmune* case law in its summary judgment order, and incorrectly relied on the absence of a "reasonable apprehension" of suit to defeat jurisdiction, considering the totality of the circumstances, we agree with the district court's determination that it lacked jurisdiction over the unasserted claims. Importantly, there is no evidence that R&D met its burden of showing a continuing case or controversy with respect to the unasserted claims. Indeed, R&D does not seriously argue here that it did so, relying instead only on the district court's misstatement of current governing law.[12] Because, applying *MedImmune*, we find that the district court did not have jurisdiction over the unasserted claims, we affirm its decision not to address them.

B. Written Description

The district court found that Streck's patents-in-suit satisfied the written description requirement as a matter of law. *Summary Judgment Order*, 658 F. Supp. 2d at

[12] The fact that R&D amended its invalidity contentions in March 2008 and January 2009 does not alone create a case or controversy.

999. In support of this conclusion, the court found that: (1) Claim 4 of the '500 patent discloses a composition "wherein the reticulocyte component comprises reticulocytes prepared by isolation from whole blood"; and (2) the '668 and '388 Patents "contain additional disclosure of the use of reticulocytes isolated from the blood of anemic animals." *Id.*

R&D argues that the district court erred because "[t]he patents-in-suit failed to provide sufficient details for [a] person of ordinary skill in the art to understand that Ryan was in possession of a true reticulocyte integrated control." Appellants' Br. 35. R&D asks this court to grant its motion for summary judgment that Streck's patents are invalid for lack of written description or, in the alternative, remand the written description issue for a jury trial.

Streck responds by pointing to specific disclosures in the patents-in-suit as evidence that the asserted claims are adequately described. In light of these disclosures, which are discussed below, Streck argues that the district court correctly found that the claims and specifications of the patents-in-suit are sufficient to satisfy the written description requirement as a matter of law. We agree.

Written description is a statutory requirement set forth in 35 U.S.C. § 112. Section 112 provides, in relevant part, that:

> The 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 . . .

35 U.S.C. § 112, para. 1 (emphasis added). The written 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) (citation and quotations omitted). The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Id. This test requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." Id. Given this perspective, in some instances, a patentee can rely on information that is "well-known in the art" to satisfy written description. Boston Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366 (Fed. Cir. 2011). Where, however, the "four corners of the specification directly contradict information that the patentee alleges is 'well-known' to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention." Id.

It is well-established that the "hallmark of written description is disclosure." *Ariad*, 598 F.3d at 1351. The level of detail required to satisfy the written description requirement depends, in large part, on the nature of the claims and the complexity of the technology. *Id.* As we explained in *Ariad*, the written description requirement "does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Id.* at 1352 (citing *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006)). That said, a "mere wish or plan" to obtain the claimed invention is not sufficient. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (citing *Regents of the Univ. of Cal. v. Eli*

Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997)). "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party." *PowerOasis, Inc. v. T-Mobile, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).

The pivotal issue here is whether the patents-in-suit provide adequate written description for integrated controls using either true reticulocytes or reticulocyte analogs. According to R&D, the patents-in-suit fail to demonstrate that Ryan possessed and invented an integrated control using true reticulocytes. In support of this argument, R&D asserts that: (1) "Ryan was unable to locate any description of the use of true reticulocytes in his own patents" when asked to do so during his deposition; (2) Ryan did not consider true reticulocytes to be part of his invention; and (3) "Streck had never attempted to make a true reticulocyte integrated control." Appellants' Br. 36.

R&D mischaracterizes Ryan's testimony, however. Although Ryan initially testified that he did not know if he could point to anything specific in the '500 Patent describing the use of true reticulocytes rather than analogs in an integrated control, he subsequently reviewed the patent and pointed to language providing that "the reticulocyte component may comprise true mammalian reticulocytes prepared for instance by mammalian red blood cell encapsulation or by isolation from whole blood." J.A. 43601:2-13. Based on this language, Ryan clarified that the Patent specifically "covers both kinds" of reticulocytes. *Id.* And, the mere fact that Ryan chose to reduce his invention to practice using a reticulocyte analog rather than a true reticulocyte is not relevant to the written description inquiry. Although R&D contends that Streck "did not posses true reticulocyte integrated con-

trols," Streck is not required to prove an actual reduction to practice as to all disclosures. *See Ariad*, 598 F.3d at 1352. Instead, to satisfy written description, Streck need only show that the specification itself demonstrates "a constructive reduction to practice that in a definite way identifies the claimed invention." *See id.* at 1352. The relevant inquiry, therefore, is whether a person of ordinary skill in the art would reasonably find that the patent sufficiently described the invention using true reticulocytes. R&D's expert, Dr. Simson, testified that, in this case, a person of ordinary skill in the art is "someone with an advanced degree like an M.D. or a Ph.D. and with experience in the field." J.A. 46608:10-12.

Looking to the specifications, the patents-in-suit refer to several types of true reticulocytes:

> [T]he control may suitably contain stabilized reticulocytes (that is, immature anucleate red blood cells containing some ribonucleic acid) or an analog thereof. For example, among possible embodiments, *the reticulocyte component may comprise true mammalian reticulocytes prepared for instance by mammalian (e.g. human) red blood cell encapsulation or by isolation from whole blood*. The reticulocyte component is prepared in any suitable manner. See, e.g. U.S. Pat. No. 5,432,089, incorporated by reference. *Alternatively, it is possible to obtain suitable reticulocytes by obtaining blood from an anemic animal (e.g., a pig, goat, rabbit or the like).*

'668 Patent col.3 ll.17-25 (emphases added). Likewise, the '500 Patent provides that: "Among possible embodiments, the reticulocyte component may comprise true mammalian reticulocytes prepared for instance by mammalian (e.g. human) red blood cell encapsulation or by isolation

from whole blood." '500 Patent col.2 ll.37-42. These disclosures demonstrate that Ryan invented the claimed integrated control using *both* true reticulocytes and reticulocyte analogs. Further, as Streck points out in its brief, this is not a case where a patentee attempts to claim a broad genus without defining specific species. Instead, as noted, Streck listed several specific true reticulocytes in its specifications.

According to R&D, Ryan testified that true reticulocytes were not part of his invention. Contrary to R&D's suggestion, however, Ryan never said that the claimed integrated controls could not be made using true reticulocytes. To the extent Ryan testified about the difficulty of using true reticulocytes in controls, the district court found that his testimony "relate[d] to the commercial practicalities of use of true reticulocytes on a large scale and not to the feasibility or viability of true reticulocytes in a control." *Summary Judgment Order*, 658 F. Supp. 2d at 999. We agree with the district court that Ryan's testimony, when taken in context, merely reflected his personal preference for using analogs in integrated controls.

The district court properly concluded that one skilled in the art would have recognized that the claimed integrated controls could be made using either true reticulocytes or reticulocyte analogs. This is particularly true given the evidence that analogs are designed to mimic true reticulocytes and that use of true reticulocytes in stand-alone controls was well-known in the prior art. Given the language in the patents-in-suit, coupled with the well-known use of true reticulocytes in the prior art, a person of ordinary skill would understand the patent to include integrated controls using true reticulocytes. Accordingly, we affirm the district court's decision grant-

ing Streck's motion for summary judgment on written description.

C. Enablement

At the close of the evidence, but before the case went to the jury, the district court granted JMOL that the patents-in-suit enabled the claimed integrated hematology control using both true reticulocytes and reticulocyte analogs. When reviewing a district court's grant or denial of a motion for JMOL, this court applies the procedural law of the relevant regional circuit, here the Eighth Circuit. *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1357 (Fed. Cir. 2010). The Eighth Circuit reviews a district court's grant or denial of JMOL *de novo*, applying the same standard as the district court. *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007) (citation omitted). To grant judgment as a matter of law, the court must find that there is "no legally sufficient basis to support a jury verdict in the non-moving party's favor." *Id.* (citing Fed. R. Civ. P. 50(a)(1)). All factual inferences are drawn in favor of the non-moving party. *Id.*

Although R&D concedes that the patents-in-suit enable the use of reticulocyte analogs in an integrated control, it argues that they do not enable true reticulocyte integrated controls. First, R&D argues that the district court erred by failing to assess whether the patents-in-suit enable the novel aspect of the claimed invention: making and using true reticulocytes in an integrated control. According to R&D, the court improperly relied on prior art and knowledge of those skilled in the art to "fill in the missing disclosure as to the novel aspect of integrating true reticulocytes into whole blood controls." Appellants' Br. 43. In support of this argument, R&D points to the testimony of one of Streck's experts, James Janik, who testified that the patents-in-suit mention use

of true reticulocytes in an integrated control but do not "discuss it in any other detail." J.A. 45879:18-22. Second, R&D submits that the court erred in granting JMOL in favor of Streck because the patents-in-suit do not enable a true reticulocyte integrated control without "undue experimentation." R&D asks this court to grant its motion for JMOL, or, in the alternative, remand the enablement issue for a jury trial.

In response, Streck claims that: (1) the "novel aspect" of the patents-in-suit is "an *integrated* reticulocyte control, i.e., a single control containing both a reticulocyte component and a white blood cell component capable of exhibiting a five-part differential"; (2) the patents-in-suit enable the use of true reticulocytes in such integrated controls because true reticulocytes are "virtually indistinguishable" from analogs; (3) R&D failed in its burden to prove invalidity by clear and convincing evidence; and (4) R&D's expert testimony was conclusory and legally insufficient to preclude JMOL. Appellee's Br. 35, 37. For the reasons articulated below, we find Streck's arguments well-taken.

Enablement "is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citation omitted). To be enabling, a patent's specification must "teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Alza Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citations omitted). It is well-established, however, that a specification need not disclose what is well-known in the art. *See Hybritech*, 802 F.2d at 1384 ("[A] patent need not teach, and preferably omits, what is well known in the art."). It is true, however, that, "the rule that a specification need not disclose

what is well known in the art is merely a rule of supplementation, not a substitute for a basic enabling disclosure." *Alza*, 603 F.3d at 940-41 (quoting *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282 (Fed. Cir. 2007)).

The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). Whether undue experimentation is required "is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Alza*, 603 F.3d at 940 (citing *Wands*, 858 F.2d at 737). In *Wands*, this court set forth the following factors to consider when determining whether a disclosure requires undue experimentation:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737. "[I]t is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

"Enablement is a matter of law that we review without deference; however, this Court reviews the factual underpinnings of enablement for substantial evidence." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (quotations and citation omitted). Because patents are presumed valid, lack of

enablement must be shown by clear and convincing evidence. *Alza,* 603 F.3d at 940 (citing *Auto. Techs.*, 501 F.3d at 1281).

R&D relies on *Automotive Technologies* for the proposition that, "when the patentee broadly claims two distinct species, it must enable both." Appellants' Br. 43. *Automotive Technologies* involved a side-impact crash sensor for an automobile airbag, and the district court construed the claims to include both mechanical and electronic side-impact sensors. One of the defendants moved for summary judgment that the claims covering an electronic sensor were invalid for lack of enablement. *Auto. Techs.*, 501 F.3d at 1279-80. The district court granted the motion on grounds that the specification failed to provide adequate detail to teach a person of skill in the art to make an electronic sensor without undue experimentation. *Id.* at 1280.

On appeal, this court found that the electronic sensors were novel for side-impact crash sensing and agreed with the district court that the patentee had not disclosed sufficient detail to make a side-impact electronic sensor. *Id.* at 1283-84. In reaching this conclusion, we reviewed the specification and noted that, although it detailed mechanical side-impact sensors, there was only one short paragraph and one figure showing an electronic sensor. *Id.* at 1282. We explained that "[e]lectronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor compared with the well-enabled mechanical side impact sensor that is fully discussed in the specification." *Id.* at 1285. We disagreed with the patentee's argument that the knowledge of one skilled in the art could supply the missing information regarding how the electronic sensor operates, and reiterated that the specification, not the knowledge of those skilled in the art, "must supply the

novel aspects of an invention" to satisfy the enablement requirement. *Id.* at 1283 (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

Although R&D argues that "Streck presented no evidence that the preparation and stabilization methods used for true reticulocyte stand-alone controls would work with integrated reticulocyte controls," the burden was on R&D to show invalidity by clear and convincing evidence. *See* Appellants' Br. 47. The question here is whether there was a legitimate issue of fact regarding enablement – i.e., regarding whether the specification contains sufficient information to enable a person skilled in the art to make integrated hematology controls using either true reticulocytes or reticulocyte analogs. After full review of the record, we agree with the district court that, considering its burden at trial, R&D failed to submit sufficient evidence from which a jury could reasonably conclude that one skilled in the art could not have followed Streck's specification to substitute true reticulocytes for Ryan's reticulocyte analog in the claimed control.

Unlike the situation in *Automotive Technologies*, where the electronic sensors differed in structure and operation from mechanical sensors, here, there was unrebutted evidence that true reticulocytes and Ryan's reticulocyte analogs "work in exactly the same way in a hematology control, and are virtually indistinguishable, even to one skilled in the art." Appellee's Br. 39. Indeed, the patents-in-suit incorporate by reference Ryan's prior patent for a stand-alone control using reticulocyte analogs: U.S. Patent No. 5,432,089 ("the '089 Patent"). *See* '668 Patent col.3 ll.16-23. The '089 Patent describes how reticulocyte analogs are made and explains that the "synthetic reticulocytes which are used in the reference control of the invention exhibit a reticulocyte continuum and distribution that is similar to that of normal human

reticulocytes." '089 Patent col.8 ll.35-43. As such, the specification, and the '089 Patent incorporated by reference therein, support Streck's position that true reticulocytes and reticulocyte analogs work in the same way in a hematology control.

At trial, moreover, Ryan testified that "I would dare say hardly anyone I know could tell the difference between [analog] and standard reticulocytes." J.A. 45587:6-7. Similarly, another Streck expert, Mr. Scholl, testified that "under a microscope [analogs] are very similar to human reticulocytes." J.A. 45518:21-24. In other words, the enabling disclosure in Streck's patents for use of reticulocyte analogs is equally enabling with respect to true reticulocytes, and, importantly, R&D failed to offer evidence to the contrary.

R&D also failed to produce adequate evidence that the experimentation required to create a true reticulocyte integrated control would be unduly laborious for one of ordinary skill in the art. R&D relies primarily on its own expert, Dr. Simson, who testified that "the patents do not enable a person of ordinary skill in the art to make . . . an integrated control preparation containing naturally occurring reticulocytes." J.A. 46613:9-12. Simson further testified that "there is no real description in the patent itself enabling one to do it" and there were no examples "of how to make this material using natural occurring reticulocytes" in the patents. J.A. 46610:25-46611:5. As Streck argues, however, conclusory expert assertions do not give rise to a genuine issue of material fact. Although Simson testified that "a large amount of experimentation" would be necessary, on cross-examination he admitted, after he was presented with his own conflicting deposition testimony, that he has never been involved in developing controls. *See* J.A. 46611:19-24; 46621:13-46622:20.

Although R&D argues that Ryan and Scholl admitted that the quantity of experimentation to make and use a true reticulocyte integrated control would be high, R&D mischaracterizes this testimony. Indeed, when taken in context, most of the testimony R&D cites was referring to the difficulty that would have been experienced in attempting to combine a reticulocyte into an integrated control *prior* to Ryan's disclosure. For example, when asked about developing a control, Ryan responded that: "sometimes it's pretty hard . . . I think that usually when we have to make a control, three or four of us will work on it and it may take us anyway [sic] from one to two years. So it doesn't happen instantaneously." J.A. 45596:5-9. Ryan clarified that statement, however, when he noted that development and testing for a true reticulocyte integrated control would be "a lot less for the obvious reason that I have already gone through the process once. Going through with a different analog, with an animal analog, shouldn't be that much harder." J.A. 45714:14-17. Ryan further testified that a person skilled in the art knew that true reticulocytes could be used in controls and that he had, in fact, previously developed stand-alone controls using animal cells.

During cross-examination, when asked whether anyone at Streck ever tried to make an integrated control using a true reticulocyte, Scholl testified that, although he was not aware of any instances, "we knew that we could if we wanted to." J.A. 45539:12. Scholl then testified that "some testing" would be required to use a true reticulocyte in an integrated control but that "the same technology would be involved with either one of the two types of reticulocytes." *See* J.A. 45539:16-45540:17. Likewise, when asked whether it would be difficult to use a true human reticulocyte cell in the integrated control, Janik testified that, "[e]ven if [Ryan's patent] gave you the exact

formula you would have to test it" but "it doesn't seem like it's a huge amount of effort." J.A. 45844:6-14. And, when asked whether a person skilled in the art would have to conduct "extraordinary experimentation" rather than "just routine testing," Janik testified that:

> the reticulocyte analog that was made even looked like a real reticulocyte under the microscope . . . You can't predict everything, but, you know, if the question was would you predict that using animal retics would work pretty much as well? The answer would be yes, because they both look the same and probably act the same to some degree, but would still have to be tested with the different instruments and understand that.

J.A. 45844:21-45845:7. Finally, Streck's expert, Dr. Langley, testified as follows:

> Q. With regard to the state of the art, as you understood it as one of ordinary skill in the art in 1999, there were a number of complications that you would need to overcome in order to take a reticulocyte-only control and use it in an integrated control; isn't that correct?
>
> A. I remember giving that opinion when I was asked to analyze the other patent. Yes.
>
> * * *
>
> Q. Dr. Langley, is it correct that I asked you: In fact, on the next page of paragraph 39, you lay out a number of complications that would need to be overcome in order to take a reticulocyte-only control and use it in an integrated control, isn't that right? And you said yes, correct?
>
> A. That's what it says.

Q. And then I asked you: To overcome those, you would have to do a substantial amount of testing, correct?

A. That's --

Q. You said, "I think so, yeah."

A. That's what it says.

Q. That's what I thought.

J.A. 46013:9-46014:17. According to R&D, this testimony is evidence of Langley admitting that "there would be a number of complications to overcome in order to use a true reticulocyte stand-alone control in an integrated reticulocyte control." Appellants' Br. 54. Streck accurately responds, however, that Langley was "discussing the difficulties in combining any reticulocyte component (true or analog) into an integrated control *before* Ryan disclosed his invention." Appellee's Br. 45. Langley did not say that making an integrated control using true reticulocytes would be more difficult than making it with analogs. Nor did he testify that, after reading the patents-in-suit, a person of ordinary skill would have to conduct the same level of experimentation Ryan already completed to make the claimed invention using reticulocyte analogs.

The foregoing testimony, when taken in context, establishes that no undue experimentation would be necessary once the teachings in the patents-in-suit were known. In light of this testimony, the district court correctly concluded that there was no evidence showing that it would make any difference whether true reticulocytes or reticulocyte analogs were used in the claimed integrated control. Importantly, there was no testimony from which a jury could find that using true reticulocytes

would require "undue experimentation."[13] Because R&D failed to offer any evidence showing that one skilled in the art could not follow the patent's teachings to use a true reticulocyte in the claimed integrated control, a reasonable jury could not have found the patents invalid for lack of enablement by clear and convincing evidence.[14] As such, the district court did not err in granting Streck's JMOL with respect to enablement.

D. Priority and Evidentiary Rulings

The jury found in favor of Streck on the issue of priority. R&D filed a renewed motion for JMOL, which the court denied on grounds that the evidence adduced at trial "supports the jury's finding that R&D did not prove by clear and convincing evidence that Dr. Johnson was the first to invent an integrated reticulocyte control

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[13] In its order denying R&D's renewed motion for JMOL and motion for a new trial, the district court specifically found that "Streck presented undisputed evidence that its invention was properly enabled" and that R&D failed to show that a person skilled in the art would have to undergo "undue experimentation" "to create a control composition with other reticulocyte analogs than those described in the patent." *Denial of Renewed JMOL Order*, 2010 U.S. Dist. LEXIS 104461, at *36.

[14] While we believe the evidence clearly supports a finding of enablement, the standard of review imposed upon us by the district court's decision to take this fact-laden inquiry away from the jury is an exacting one. Despite careful application of that standard of review, we ultimately conclude that the district court's JMOL ruling should be affirmed. *See* Fed. R. Civ. P. 50(b) advisory committee's note on the 1991 amendments ("[T]he court may often wisely decline to rule on a motion for judgment as a matter of law made at the close of evidence, and it is not inappropriate for the moving party to suggest such a postponement of the ruling until after the verdict has been rendered.").

composition." *Denial of Renewed JMOL Order*, 2010 U.S. Dist. LEXIS 104461, at *32.

In Appeal No. 2011-1045, we affirmed the district court's award of priority to Streck in the § 146 action. *Streck*, 659 F.3d at 1196. It is undisputed that resolution of priority in that appeal controls the priority issues here, where R&D's burden was higher and this court's deference to the jury verdict is substantial. Specifically, in the § 146 action, R&D had to establish priority by a preponderance of the evidence whereas in this appeal, R&D had to show its priority defense by clear and convincing evidence. As such, our decision in Appeal 2011-1045 that R&D failed to establish priority by a preponderance of the evidence necessarily means that R&D could not meet the clear and convincing burden required in this case. And, because the priority defense here was decided by a jury, on appeal R&D has to show that the jury's findings were not supported by substantial evidence. In addition, as Streck argues, because the § 146 appeal involved the same parties, the same evidence, and the same priority issue presented in this appeal, R&D is barred by the doctrine of collateral estoppel from challenging this court's priority determination in Appeal No. 2011-1045.

In the alternative, R&D argues that this court should overturn the jury verdict and remand for a new trial on priority because the district court "abused its discretion and materially prejudiced R&D's priority case by committing several errors relating to the presentation of evidence." Appellants' Br. 63-64. In particular, R&D argues that the court erred when it: (1) denied R&D's motion *in limine* regarding conception and diligence; (2) failed to control the order of proof by allowing Streck "to preemptively rebut R&D's case-in-chief on invalidity"; and (3) submitted a misleading question to the jury on the verdict form. Each of these arguments relates to priority,

which, as previously discussed, is controlled by this court's prior decision in the companion appeal. Resolution of that appeal renders R&D's arguments regarding priority moot.

To the extent R&D's evidentiary challenges can be construed to relate to anything other than priority, we have considered them and find that they are without merit, particularly given the level of deference afforded to district courts with respect to motions *in limine*, and the order of proof and presentation of evidence.

E. Injunction

After the jury trial, Streck moved for a permanent injunction. The district court applied the four-factor test for injunctive relief set forth in *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006), and concluded that all four factors favored entry of an injunction. Specifically, the court ordered that R&D is prohibited from:

> making, using, offering to sell, selling, or importing into the United States, or supplying from the United States, or causing to be made, used, offered for sale, sold, imported into the United States, or supplied from the United States the infringing hematology control products presently designated CBC-XE, CBC-4K Plus Retics, and CBC-5D Plus Retics, as well as any hematology control products that are only colorably different therefrom in the context of the infringed claims, whether individually or in combination with other products or as a part of another product, and from otherwise infringing the asserted claims of [the patents-in-suit] until the expiration of the last to expire of the Patents-in-Suit.

J.A. 40047 (internal statutory citations omitted). We review the district court's decision entering an injunction, as well as the scope of the injunction, for abuse of discretion. *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010) (citation omitted).

R&D argues that the district court erroneously entered the injunction and that the injunction itself is overbroad because it prohibits R&D "from otherwise infringing the asserted claims of [the Patents-in-Suit] until the expiration of the last to expire of the Patents-in-Suit." Appellants' Br. 69. Specifically, R&D asks this court to vacate the injunction or replace it with one limited to "the adjudicated CBC-XE, CBC-4K Plus Retics, and CBC-5D Plus Retics products, and products not more than colorably different therefrom." *Id.* at 70. Streck responds that "the injunction already prohibits exactly what R&D proposes by expressly listing the three adjudicated products and extending only to products that are 'only colorably different therefrom.'" Appellee's Br. 64. We agree with Streck.

R&D does not challenge any of the court's underlying *eBay* findings. As such, R&D's sole argument on appeal relates to overbreadth. After careful consideration, we find that R&D's argument is without merit, particularly given the language in the injunction referring to the specific products at issue in this case. Mere inclusion of the phrase "from otherwise infringing the asserted claims," when taken in the context of the entire order and record on which it was entered, does not render the injunction overbroad. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1359 (Fed. Cir. 1999) (holding that, in light of the "detailed record" on which it was entered, an injunction prohibiting "any further infringement . . . of the patent" complied with the specificity requirements set

forth in Fed. R. Civ. P. 65(d)). Simply put, we read the injunction to contain the very limitations R&D now seeks.

CONCLUSION

For the foregoing reasons, and because we find that R&D's remaining arguments are without merit, we affirm the district court's judgment against R&D and its decision entering a permanent injunction in favor of Streck.

AFFIRMED