

**United States Court of Appeals
for the Federal Circuit**

ROCHE DIAGNOSTICS CORPORATION,
Plaintiff/Counterclaim Defendant-Appellant

BIOVERIS CORPORATION,
Counterclaim Defendant-Appellant

v.

MESO SCALE DIAGNOSTICS, LLC,
Defendant/Counterclaimant-Cross-Appellant

2021-1609, 2021-1633

Appeals from the United States District Court for the District of Delaware in No. 1:17-cv-00189-LPS, Judge Leonard P. Stark.

Decided: April 8, 2022

JAMES MCKEOWN, Foley & Lardner LLP, Milwaukee, WI, argued for plaintiff/counterclaim defendant-appellant and counterclaim defendant-appellant. Also represented by JEFFREY COSTAKOS, KIMBERLY KRISTIN DODD, ERIC MAASSEN.

JOHN HUGHES, Bartlit Beck LLP, Denver, CO, argued for defendant/counterclaimant-cross-appellant. Also

represented by NOSSON KNOBLOCH, DANIEL TAYLOR;
STEVEN DERRINGER, ANASTASIYA MAIONE, Chicago, IL.

Before NEWMAN, PROST, and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

PROST, *Circuit Judge*.

Roche Diagnostics Corporation and BioVeris Corporation (collectively, “Roche”) appeal a final judgment from the District of Delaware sustaining the jury’s verdict that Roche violated exclusive license rights belonging to Meso Scale Diagnostics, LLC (“Meso”) by directly infringing one patent claim and inducing infringement of three other patent claims. We affirm on direct infringement, reverse on induced infringement, vacate the damages award, and remand for a new trial on damages.¹ On Meso’s cross-appeal, we vacate the district court’s judgment of noninfringement with respect to three additional patents and remand.

¹ Judge Newman’s dissent would reverse on both induced infringement and direct infringement because, it argues, Meso doesn’t have a license to the asserted patent claims. Lest there be any confusion, the dissent agrees with us that the induced-infringement judgment cannot stand. The difference is in our reasoning. We reverse that judgment without reaching the question of Meso’s license rights (contrary to the dissent’s suggestion otherwise, *Dissent* at 3, 5), while the dissent would resolve that question against Meso. It is therefore only with respect to the single patent claim asserted to have been directly infringed that the dissent would reach a different result, since we conclude Meso does have license rights in that patent claim.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

3

BACKGROUND

The patents-in-suit concern immunoassays that exploit a phenomenon called electrochemiluminescence (“ECL”). Meso doesn’t own these patents. Indeed, appellant Bi-oVeris (a Roche entity) does. But Meso maintains that a prior owner, IGEN International, Inc. (“IGEN”), granted it exclusive rights to the patent claims it now asserts against Roche (which sells instruments and reagent packs for performing ECL immunoassays). We briefly recount the parties’ relevant licensing and litigation histories below.

Meso was formed in 1995 pursuant to a joint venture agreement between IGEN and Meso Scale Technologies, a company owned by Jacob Wohlstadter (son of IGEN CEO Samuel Wohlstadter). *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 503 F. Supp. 3d 156, 163 (D. Del. 2020) (“*Post-Trial Op.*”). The agreement specified a “Research Program” for Meso to perform and included a license agreement—the scope of which is contested here. *Id.* at 163–64.

Roche, too, has a licensing history with IGEN. In 1998, not long after Meso embarked on its joint venture with IGEN, Roche acquired Boehringer Mannheim GmbH (“Boehringer”), which IGEN had previously licensed in 1992 to develop, use, manufacture, and sell ECL assays and instruments in a particular field.² In doing so, Roche inherited Boehringer’s license rights, including that field restriction. *Id.* at 163.

In 2003, IGEN and Roche terminated the 1992 agreement and executed a new agreement granting Roche a non-exclusive license to IGEN’s ECL technology in the field of

² Namely, “use in hospitals (except where the performance of the Assay takes place at the side of the patient), blood banks[,] and clinical reference laboratories.” *Post-Trial Op.*, 503 F. Supp. 3d at 163 (quoting J.A. 4968).

“human patient diagnostics.” *Id.* at 164; *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, No. CV 17-189-LPS, 2019 WL 1332407, at *2 (D. Del. Mar. 21, 2019) (“*Summary Judgment Op.*”). Although this license required Roche to note this new field restriction on its product packaging, J.A. 5448–49, the license permitted sales that resulted in incidental out-of-field use and allowed such sales to continue (absent express prohibition from IGEN) so long as IGEN received 65% of the resulting revenues. J.A. 5438. As part of this transaction, Roche paid IGEN and its shareholders about \$1.4 billion, IGEN transferred its ECL patents (including those asserted here) to the newly formed BioVeris, and IGEN shareholders received shares of BioVeris stock. *Post-Trial Op.*, 503 F. Supp. 3d at 164; J.A. 4230.

Later, in 2007, a Roche affiliate acquired BioVeris (including over 100 patents) for approximately \$600 million. *Post-Trial Op.*, 503 F. Supp. 3d at 164. Roche announced this acquisition in a press release stating it would now “own the complete patent estate of the electrochemiluminescence (ECL) technology,” giving it “the opportunity to fully exploit the entire immunochemistry market” and ensuring its ability to “provide unrestricted access to all customers.” J.A. 6036. Roche also prepared a customer letter indicating that the field-restriction labels were “now obsolete” and would be “removed as soon as possible,” but that in the interim customers should “please ignore the restrictions.” J.A. 5898; *see also* J.A. 5901–06. Then Roche began selling the products without field restrictions, as it said it would. J.A. 4540.

Meso sued Roche in the Delaware Court of Chancery in 2010, alleging that Roche breached the 2003 license with IGEN by violating the field restriction. *Post-Trial Op.*, 503 F. Supp. 3d at 164. The chancery court determined that Meso was not a party to the 2003 license agreement, such that only BioVeris (as IGEN’s successor-in-interest) could enforce the field restriction. *Id.*; *see Meso Scale*

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

5

Diagnostics, LLC v. Roche Diagnostics GmbH, No. CIV.A. 5589-VCP, 2014 WL 2919333 (Del. Ch. June 25, 2014), *aff'd*, 116 A.3d 1244 (Del. 2015).

And in 2017, Roche brought this suit seeking a declaratory judgment that it doesn't infringe Meso's rights arising from the 1995 joint venture license agreement. *Summary Judgment Op.*, 2019 WL 1332407, at *1. Meso counterclaimed for patent infringement. *Id.* At summary judgment, Roche argued that Meso's 1995 license didn't convey the rights Meso asserts. The district court denied Roche's summary judgment motion and the parties tried the case to a jury. *Post-Trial Op.*, 503 F. Supp. 3d at 166. The jury found that Meso holds an exclusive license to the asserted patent claims, that Roche directly infringed claim 33 of U.S. Patent No. 6,808,939 ("the '939 patent"), that Roche induced infringement of claim 1 of U.S. Patent No. 5,935,779 ("the '779 patent") and claims 38 and 44 of U.S. Patent No. 6,165,729 ("the '729 patent"), and that Roche's infringement was willful. J.A. 3718–24. It awarded Meso \$137,250,000 in damages. *Post-Trial Op.*, 503 F. Supp. 3d at 163.

The district court denied Roche's post-trial motions challenging the infringement verdict and damages award. *Id.* at 169–70, 174. But it granted Roche's motion for judgment as a matter of law ("JMOL") on willfulness and denied Meso's motions to enhance damages. *Id.* at 172–74. Additionally, at Roche's request, the court rendered a non-infringement judgment with respect to three additional patents—U.S. Patent Nos. 6,451,225 ("the '225 patent"), 6,881,536 ("the '536 patent"), and 6,881,589 ("the '589 patent")—on the ground that Meso waived compulsory infringement counterclaims as to those patents. *Id.* at 170–71; *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, No. CV 17-189-LPS-CJB, 2020 WL 8409662, at *2 (D. Del. Dec. 23, 2020). Roche appeals and Meso cross-appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Roche challenges (I) the scope of Meso’s license rights, (II) the induced-infringement verdict, and (III) the damages award. On cross-appeal, Meso challenges the district court’s application of the compulsory-counterclaim rule. We review the denial of Roche’s JMOL and new-trial motions under the law of the regional circuit. *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012). The Third Circuit reviews the denial of JMOL de novo, “viewing the record in the light most favorable to the verdict winner and drawing all reasonable inferences in its favor.” *Id.* (citing *Eddy v. V.I. Water & Power Auth.*, 369 F.3d 227, 230 (3d Cir. 2004)). It reviews the denial of a new trial for abuse of discretion. *Id.* (citing *Foster v. Nat’l Fuel Gas Co.*, 316 F.3d 424, 429–30 (3d Cir. 2003)).

I. LICENSE SCOPE

First, Roche disputes the scope of Meso’s rights in “IGEN Technology”³ under the 1995 license agreement. This is the only ground on which Roche challenges the direct-infringement judgment, and it’s one of multiple grounds on which Roche challenges the induced-infringement judgment. The pertinent license provision, Section 2.1., has two prongs—A and B:

2.1. *IGEN Technology.* IGEN hereby grants to [Meso] an exclusive, worldwide, royalty-free license to practice the IGEN Technology to make, use and sell products or processes (A) developed in the course of the Research Program, or (B) utilizing or related to the Research Technologies; *provided* that IGEN shall not be required to grant [Meso] a license to any technology that is subject to exclusive licenses to third parties granted prior to the date

³ This term includes the asserted patents in this case. *Post-Trial Op.*, 503 F. Supp. 3d at 164.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

7

hereof. In the event any such exclusive license terminates, or IGEN is otherwise no longer restricted by such license from licensing such technology to [Meso], such technology shall be, and hereby is, licensed to [Meso] pursuant thereto.

J.A. 5209. Meso argues that prong A grants it rights in all the asserted patent claims—namely, '939 patent claim 33, '779 patent claim 1, and '729 patent claims 38 and 44. And it argues that prong B grants it rights in '729 patent claims 38 and 44. We assess the two prongs in turn below.

A

First we analyze prong A, Meso's right "to practice the IGEN technology to make, use and sell products or processes (A) developed in the course of the Research Program." J.A. 5209.

At summary judgment, Roche argued that this provision granted Meso "an exclusive license only to use ECL technology to make, use, or sell those *specific products and processes* that were advancements and improvements created in the Research Program." *Summary Judgment Op.*, 2019 WL 1332407, at *4 (quoting Roche's summary judgment brief). Meso, on the other hand, said this provision grants it "an exclusive right to practice [the] patent *claims*, a right which was triggered by the development during the Research Program of products and processes that are covered by those claims." *Id.* "Roche's interpretation would limit Meso's exclusive rights to the specific products and processes developed in the Research Program, while Meso's interpretation would more broadly extend Meso's exclusive rights to any product or process (whenever developed) that practices the claims of IGEN's patents." *Id.*

In assessing these arguments, the district court noted that the dispute hinged largely on the word "developed." *Id.* at *4–5. Roche, relying on the agreement's definition of

“developed product,”⁴ argued that the products “developed” in the research program were the *fruits* of that program—i.e., the products that arose out of the program. *Id.* at *4–5. Meso, for its part, argued that the ordinary meaning of “developed” is broader: “one can develop something that already exists, for instance, by improving or otherwise changing it.” *Id.* (internal quotation marks omitted). Under Meso’s reading, the agreement granted rights to patent claims as soon as Meso “developed” technology covered by them—indeed, even if Meso merely improved (i.e., further developed) preexisting technology covered by them. *Id.* The court denied summary judgment because, in its view, the parties articulated more than one reasonable interpretation. *Id.* at *5. After the jury ultimately agreed with Meso, the district court concluded that the jury chose between two reasonable views. *Post-Trial Op.*, 503 F. Supp. 3d at 166–69.

Roche makes two principal arguments on appeal regarding this provision. First, Roche relies on the provision’s plain language. “On its face,” Roche argues, “this language gave Meso the exclusive right to make, use and sell any *new* products or improvements created or invented during the Research Program.” Appellant’s Br. 23. Second, Roche relies on the parties’ course of conduct. Specifically, Roche points out that even though the agreement “specified that Meso would be the exclusive means for ‘making, using and selling products, processes and services developed in the course of the Research Program in the Diagnostic Field,’” IGEN, BioVeris, and Roche “continued to

⁴ Section 2.5.1 of the agreement provides: “a product shall be deemed to have been developed if (i) it is submitted for FDA approval, (ii) it is declared developed by the Board of Managers, or (iii) it has been developed sufficiently to be submitted for FDA approval, notwithstanding failure of [Meso] to do so.” J.A. 5116.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

9

sell” the relevant products “through 2007 without any objection by Meso.” Appellant’s Br. 26 (quoting J.A. 5111). From this, Roche reasons that “neither IGEN nor Meso understood or interpreted [prong A] to grant exclusive rights to the entirety of the patent claim.” *Id.*

Roche’s arguments have considerable heft, especially on the plain language. As we read the license agreement, we consider Roche’s interpretation a natural reading while Meso’s is a strained one. But ultimately, we need not decide between the two interpretations of “developed.” That dispute concerns only the ’779 and ’729 patents—because they predated the research program of the joint venture—and in any event we reverse the induced-infringement judgment regarding those patents for reasons independent of the license-interpretation issue, as explained in section (II) below.

The ’939 patent, by contrast, did not predate the joint venture’s research program. Rather, as the manager of that program testified at trial, “[t]he work that was done in this patent was part of the research program.” J.A. 4327. Roche didn’t dispute this fact. *See Post-Trial Op.*, 503 F. Supp. 3d at 168. Nor has Roche provided any persuasive reason why, even under its own interpretation of “developed,” the asserted ’939 patent claim wasn’t “developed in the course of the Research Program.” J.A. 5209. The most Roche offers on this score is a footnote arguing generally that “the evidence at trial was insufficient for the jury to find that Meso held exclusive rights to the entirety of the ’939 patent claim” and citing further course-of-conduct evidence. Appellant’s Br. 27 n.4. But this argument, “made in passing only in a footnote, is not sufficient under our precedents to preserve an argument for review.” *ConocoPhillips v. United States*, 501 F.3d 1374, 1381 (Fed. Cir. 2007) (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (“[A]rguments raised in footnotes are not preserved.”)). Without more, we’re unpersuaded that claim 33 of the ’939 patent is outside the

license agreement—even accepting Roche’s plain-language interpretation. Accordingly, we affirm the district court’s denial of JMOL regarding prong A with respect to ’939 patent claim 33, and we do not reach Meso’s rights under this prong with respect to the ’779 and ’729 patent claims.

B

The parties also dispute the scope of Meso’s rights under prong B “to practice the IGEN technology to make, use and sell products or processes . . . (B) utilizing or related to the Research Technologies.” J.A. 5209.

This language was also contested at summary judgment. Roche argued that a co-reactant called tripropylamine (“TPA”) isn’t within the term “Research Technologies”—a category defined by the agreement to include “agent[s] to extend the electric potential of an electrode in the direction perpendicular to its surface.” *Summary Judgment Op.*, 2019 WL 1332407, at *6. The district court saw this as a genuine factual dispute, denying Roche’s summary judgment motion. *Id.*

As with prong A, the jury agreed with Meso and the district court denied JMOL—“viewing the evidence in the light most favorable to Meso and giving it the advantage of every fair and reasonable inference.” *Post-Trial Op.*, 503 F. Supp. 3d at 169. Along the way, the court noted that by the time of trial there was “no dispute that TPA comes within the definition of Research Technologies,” although this wasn’t known at the time of the agreement. *Id.* at 168. Indeed, “it was not until 1999—four years after the 1995 License was executed—that the scientific field came to understand that TPA reactions could occur away from the electrode surface.” *Id.* Roche argued, therefore, that “a reasonable jury could not have found that the parties intended for TPA to qualify as an agent that extends the electric potential of an electrode in a direction perpendicular to its surface,” even though it undisputedly does. *Id.* (internal quotation marks omitted). In sustaining the jury’s verdict,

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

11

the district court noted Jacob Wohlstadter’s testimony that “the purpose behind the phrase ‘agents to extend’ . . . was to capture the ‘airspace above the electrode surface’ . . . and that this was not meant to be limited to any specific compound or chemical.” *Id.* (quoting J.A. 4216). Again, the district court “presume[d] that the jury drew these reasonable inferences, and all others permitted by the record, in Meso’s favor,” ultimately deciding “[t]here was sufficient evidence to allow a reasonable jury to find that TPA is within the definition of Research Technologies.” *Id.* at 168–69. And on appeal, the parties analyze the intent underlying prong B at two different levels of generality—with Roche asking whether prong B was meant to cover TPA in particular (answering no) and Meso asking whether prong B was meant more generally to cover the “airspace above the electrode surface” (answering yes).

While the jury sided with Meso on both prongs, the district court made clear its view that “Roche’s interpretation of the operative contracts was entirely reasonable.” *Post-Trial Op.*, 503 F. Supp. 3d at 173. Ultimately, as with prong A, we need not determine whether the district court was right to sustain the jury’s verdict that prong B confers on Meso the rights necessary to assert that Roche induced infringement of ’729 patent claims 38 and 44. Again, even assuming Meso possesses those rights, we nonetheless reverse the induced-infringement judgment for the reasons articulated below.

II. INDUCED INFRINGEMENT

As prefigured above, we reverse the district court’s judgment that Roche induced infringement of the asserted ’779 and ’729 patent claims. Our decision in that regard rests on two independent grounds: (A) absence of intent, and (B) absence of an inducing act that could support

liability during the damages period set forth in 35 U.S.C. § 286.⁵

A

“Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). “A defendant is liable for ‘induced infringement under § 271(b)’ if the defendant took certain affirmative acts to bring about the commission by others of acts of infringement and had ‘knowledge that the induced acts constitute patent infringement.’” *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1286 (Fed. Cir. 2020) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765–66 (2011)). “The intent element requires ‘knowledge that the induced acts constitute patent infringement,’ which can be established by a proper finding of ‘willful blindness.’” *Id.* (quoting *Global-Tech*, 563 U.S. at 766–71).

Willful blindness, in turn, is characterized by “two basic requirements: (1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.” *Global-Tech*, 563 U.S. at 769. Willful blindness is a standard of “limited scope that surpasses recklessness and negligence.” *Id.* The intent standard for inducement, therefore, “focuses on, and can be met by proof of, the defendant’s subjective state of mind, whether actual knowledge or the subjective beliefs (coupled with action to avoid learning more) that characterizes willful blindness.” *TecSec*, 978 F.3d at 1286.

Here, Roche argues that the district court in denying JMOL “incorrectly applied a negligence standard rather than requiring specific intent for inducement.” Appellant’s

⁵ Because we reverse on these grounds, we need not reach Roche’s patent-exhaustion defense.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

13

Br. 37. In support, Roche points to the court’s statement that “[t]he specific intent required for induced infringement is that the alleged infringer *knew or should have known* his actions would induce actual infringement.” *Post-Trial Op.*, 503 F. Supp. 3d at 169. We agree with Roche that this misstates the governing intent standard. While it’s true that we previously applied a “knew or should have known” formulation, we’ve since made clear that, “to the extent our prior case law allowed the finding of induced infringement based on recklessness or negligence, such case law is inconsistent with *Global-Tech* and no longer good law.” *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1366 (Fed. Cir. 2013), *vacated in part on other grounds*, 575 U.S. 632 (2015). In *Commil*, for example, we concluded that a jury instruction indistinguishable from the district court’s statement here—“that Cisco knew or should have known that its actions would induce actual infringement”—incorrectly stated “a negligence standard.” *Id.* Under the proper standard, the jury’s inducement conclusion is unsupported. As explained below, the district court’s findings regarding willfulness and enhancement compel the conclusion in this particular case that Roche lacked the requisite intent for inducement under the proper standard.

The district court granted Roche’s JMOL motion regarding willfulness by concluding that “at no time did Roche have a subjective intent to infringe (or induce infringement of) Meso’s patent rights.”⁶ *Post-Trial Op.*, 503 F. Supp. 3d at 173. This, the district court explained, “follows logically” from “Roche’s reasonable interpretation of the contract provisions,” under which “Roche had no liability to Meso for patent infringement.” *Id.* And “[w]hile the jury sided with Meso” on the license language, the court

⁶ Meso did not cross-appeal the district court’s willfulness decision. Cross-Appellant’s Br. 42 n.11.

noted, “the jury could have alternatively—and reasonably—sided with Roche.” *Id.* Although the district court recognized that “Roche’s burden . . . to set aside the jury’s willfulness finding [was] a heavy one,” it concluded nevertheless that Roche “met its burden under the unusual circumstances presented here.” *Id.* at 172 (cleaned up). Further, in the portion of its decision declining to enhance damages, the district court noted “[t]he evidence demonstrates that Roche had a good faith belief in its reasonable interpretation of the relevant contract provisions,” and it also relied on Roche’s “good faith, reasonable belief that the [BioVeris] acquisition meant the elimination of field-of-use restrictions—and, hence, no possibility of patent liability.” *Id.* at 179–80.

In some respects, the intent standard for inducement is akin to the one for willfulness, as both rest on the subjective intent of the accused infringer. *TecSec*, 978 F.3d at 1286–87 (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016)). Here, the jury’s verdict of inducement couldn’t have survived JMOL under the proper intent standard because it contradicts the court’s express findings regarding Roche’s subjective belief that it wasn’t infringing or inducing infringement. Taken together, these findings mean that Roche couldn’t have acted with knowledge that the acts it brought about “constitute[d] patent infringement” and couldn’t have taken “deliberate actions to avoid confirming a high probability of wrongdoing” as required for willful blindness. *Global-Tech*, 563 U.S. at 765–66, 769.

The district court’s JMOL analysis did not apply the proper intent standard—resulting in an inducement determination irreconcilable with its willfulness and enhancement decisions. In the end, we agree with Roche that “[t]he same analysis that led the district court to grant JMOL on willfulness should have led to a JMOL on inducement” under the proper standard. Appellant’s Reply Br. 2. Thus, we reverse the induced-infringement judgment.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

15

B

Roche also argues that Meso didn't prove it committed inducing acts within the patent-damages limitations period. That period is set forth as follows: "Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." 35 U.S.C. § 286. Here, that damages period began in April 2011. *Post-Trial Op.*, 503 F. Supp. 3d at 169. On this point, too, we agree with Roche.

To be clear, Roche's argument isn't that the alleged *infringement* occurred outside the six-year period. Rather, it's that the alleged *acts of inducement* did. In so arguing, Roche relies on *Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo Co.*, 754 F.2d 345 (Fed. Cir. 1985). In that case, Nippon was accused of "inducing infringement" by supplying a catalyst to another company that directly infringed a patented process. *Id.* at 347. Writing for the court, Judge Rich explained that the "determinate fact" was that "all of the acts of Nippon complained of took place and were over and done with" more than six years before the infringement suit began. *Id.* Therefore, since "[n]o act of Nippon within the six years prior to suit [was] complained of," it followed that "no recovery against Nippon [could] be had." *Id.* at 348. Likewise here, Roche's allegedly inducing acts occurred before the damages period. Specifically, Roche's press release, customer letter, and decision to stop affixing field-restriction labels occurred solely in 2007, well before the damages period. J.A. 6036–38; J.A. 5898; J.A. 5901–06.⁷

⁷ Like in *Standard Oil*, our analysis on this point assumes "for the sake of argument" that these acts would have sufficed for inducement had they occurred during the damages period. 754 F.2d at 348.

In sustaining the jury’s verdict, the district court didn’t conclude that Roche committed affirmative acts of inducement during the damages period. Rather, despite acknowledging that “Meso was required to prove that Roche’s alleged acts of inducement occurred during the relevant limitations period,” *Post-Trial Op.*, 503 F. Supp. 3d at 169 (citing *Standard Oil*, 754 F.2d at 348), the court posited that acts occurring *before* the damages period could support a finding of inducement if they “continue[d] to have an impact and cause[d] third parties to use the products-at-issue outside’ of the licensed patient-diagnostics field after April 2011.” *Id.* (alterations in original) (quoting J.A. 3688). Then, the court reasoned, “[t]he jury could have reasonably found that Roche’s announcement to its customers following its 2007 acquisition of BioVeris that there was no longer any restriction on how and where its ECL products could be used” satisfies this standard. *Id.*

The district court did not cite any points of authority for this “continuing-impact” standard, and neither does Meso.⁸ Further, this proposition is (at a minimum) in significant tension with the reasoning of *Standard Oil*—which rejected a similar argument, i.e., that neither induced nor contributory infringement “can exist until there is a direct infringement.” 754 F.2d at 348. That line of reasoning, we observed, “is like saying that the laying of an egg takes place when the egg hatches or that a sale takes place when the buyer uses the purchased product.” *Id.* To

⁸ Instead, the district court simply adopted this standard “[i]n the context of resolving jury instruction disputes.” *Post-Trial Op.*, 503 F. Supp. 3d at 169; *see* J.A. 4648 (Meso’s counsel arguing that “it is critical that the jury be told that . . . [for] inducement, they can consider Roche’s statements and actions from before April 2011 and the effect that those had on customers['] use of the products after April 2011”).

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

17

the contrary, we explained: “If Nippon’s acts ever gave rise to a liability, the liability arose *as of the time the acts were committed*, not at some future date determined by the acts of others.” *Id.* Under a straightforward application of *Standard Oil*, Roche’s press release, customer letter, and removal of field restrictions cannot support the jury’s induced-infringement verdict because the evidence indicates—and Meso doesn’t dispute—that none of these acts occurred within the damages period.

Meso argues also that Roche did indeed commit inducing acts during the damages period because Roche “sold the products without restrictive labels throughout the damages period.” Cross-Appellant’s Br. 36. But sales without restrictive labels are not acts of inducement where, as here, the products have both in-field (non-infringing) and out-of-field (infringing) applications. *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (“The sale of a lawful product by lawful means, with the knowledge that an unaffiliated[] third party may infringe, cannot, in and of itself, constitute inducement of infringement.” (cleaned up)); *see generally id.* at 630–32. Even Meso appears to acknowledge this. Cross-Appellant’s Br. 37 (recognizing that “Roche’s thousands of post-2011 infringing sales may not be acts of inducement *on their own*”). Indeed, Meso confirmed at oral argument that using Roche’s immunoassay instruments necessarily practices the ’779 and ’729 patent claims and that whether a use fell “outside the field restriction” turned on “the use to which the running of the machine was going to be put.” Oral Arg. at 21:30–22:33, No 21-1609, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=21-1609_11022021.mp3.

Last, even if *Standard Oil* doesn’t foreclose the district court’s “continuing-impact” standard, we reach the same conclusion because Meso didn’t provide evidence of causation between the allegedly inducing acts (before the damages period) and the direct infringement (within the

damages period). Specifically, Meso put forward no evidence that any customers purchasing Roche’s products during the damages period received the 2007 communication and, in reliance on it, used the products out-of-field. And merely assuming that there were such customers is especially speculative here, in view of Roche’s significant sales growth during that timeframe. J.A. 4658–59. For similar reasons, Meso’s argument that Roche induced infringement because it “never withdrew” its 2007 guidance also fails, at least because Meso didn’t show that this omission caused customers to infringe. *See* Cross-Appellant’s Br. 36. Even under the district court’s “continuing-impact” principle, therefore, the jury’s verdict cannot stand.

III. DAMAGES

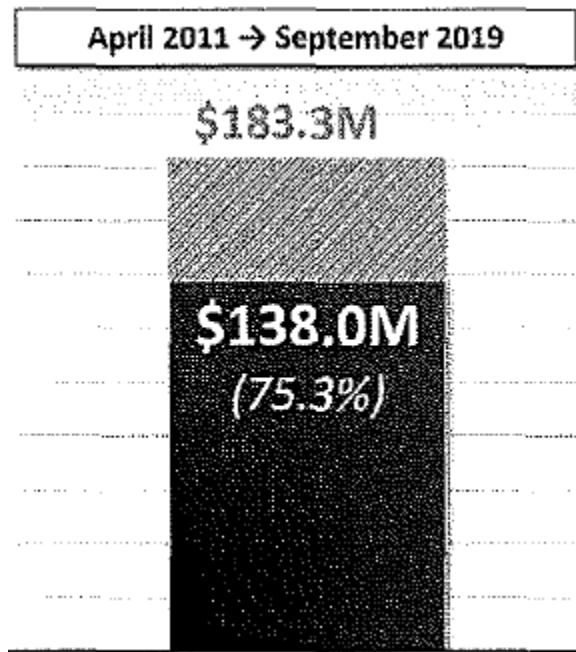
Roche also challenges the district court’s denial of its motion for a new trial on damages. Given our decision to reverse the induced-infringement judgment, we vacate the damages award and remand for a new trial on damages. *See Omega Pats., LLC v. CalAmp Corp.*, 920 F.3d 1337, 1350 (Fed. Cir. 2019) (“[T]he ‘normal rule would require a new trial as to damages’ when the jury renders a single verdict on damages and liability as to a subset of asserted claims [that] has been set aside on appeal.”) (quoting *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1310 (Fed. Cir. 2007)). Additionally, given the circumstances presented here—which we recount briefly below—the parties and the district court should proceed on remand with careful attention to the apportionment requirement set forth in our caselaw.

Before trial, the district court precluded Meso’s damages expert from offering his reasonable-royalty opinion due to various errors in that opinion. *Post-Trial Op.*, 503 F. Supp. 3d at 174. For that reason, “the jury did not hear a reasonable royalty *rate* opinion” from Meso’s expert. *Id.* The expert “was permitted to testify about a royalty *base*,” however, “which he calculated to be between

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

19

\$170 million and \$183 million.” *Id.* And, in the context of analyzing the *Georgia-Pacific* factors,⁹ “he was further permitted to present his estimate of the profit margin Roche earned on these sales,” which “he opined was roughly 75% during the relevant damages period.” *Id.* (internal quotation marks omitted). The expert illustrated this testimony with the following graphic:



Id. at 175. And later, during closing arguments, “Meso’s counsel told the jury: ‘we believe that what is right is that Meso . . . should get the profits, the profits on the \$183 million that Roche made in our lane [that is, out-of-field sales].’” *Id.* at 175 (alterations in original) (quoting J.A. 4816).

⁹ See *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), *modified sub nom. Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971).

In denying Roche’s post-trial motions, the district court noted that, although “the verdict sheet did not ask the jury to disclose the royalty rate or base it found,” “[t]he jury’s damages award of \$137,250,000 can be arrived at (exactly) by multiplying \$183 million by 75%.” *Id.* at 175–76. The district court also expressed that “Roche present[ed] powerful challenges to the jury award.” *Id.* at 175. For instance, Roche argued that the jury’s award reflected “no apportionment for the value attributable to the infringing features of the product,” and that “the jury’s award amounts to a disgorgement of all of Roche’s profits, as expressly invited by Meso’s counsel, which is not permitted by patent law.” *Id.* (internal quotation marks omitted). Ultimately, however, the district court concluded the jury’s “presumed findings . . . are supported by sufficient evidence,” so it upheld the damages verdict. *Id.* at 176.

As possible support for the jury’s verdict, the district court noted testimony that “the asserted claims ‘cover core aspects of ECL technology,’ around which Roche could not design . . . , and that Roche expected to make (and in fact did make) significant conveyed sales.” *Id.* It then expressed that, “[o]n this reasonable view of the evidence,” Meso’s expert’s “estimations of the royalty base and Roche’s profits were conservative; in fact, an appropriate royalty base could have been *higher* than \$183 million.” *Id.* The court also indicated that the “jury could have further credited evidence showing Roche’s ECL business regularly outperformed Roche’s estimates, which again would support a higher royalty base,” and it noted that “in the 2003 [l]icense—which was executed right around the time of the hypothetical negotiation—Roche had agreed to a 65% royalty rate for out-of-field sales.” *Id.* “Taking all this into account,” the district court concluded, “the jury could have arrived at its damages award by multiplying the 65% royalty rate negotiated for in the 2003 License times a royalty base of approximately \$211 million, which is a base supported by sufficient evidence, once conveyed sales and

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

21

[Meso’s expert’s] arguably[]conservative royalty base assumptions are considered.” *Id.*

In response to Roche’s characterization of the damages award as the product of “speculation or guesswork,” the court stated that “[r]easonable minds could differ on this point” and ultimately concluded that “the slightly better view of the record is that the damages award was not based only on speculation or guesswork.” *Id.* at 178. And on Roche’s apportionment challenge, the district court reasoned that “the jury was presented sufficient evidence from which it could have reasonably determined (1) the asserted claims were essential to practice ECL technology, (2) ECL technology was the key driver of demand for Roche’s accused products sold out-of-field,” and “thus, (3) a high reasonable royalty award was appropriate.” *Id.* at 177.

On appeal, Roche again challenges the \$137,250,000 damages award, which it says “awarded 100% of the profits from all infringing sales based on infringement of three patents (out of the 100+ patents) applicable to ECL technology.” Appellant’s Br. 45–46. As we have previously explained, “where a royalty is at issue, [n]o matter what the form of the royalty, a patentee must take care to seek only those damages attributable to the infringing features.” *Omega Pats., LLC v. CalAmp Corp.*, 13 F.4th 1361, 1376 (Fed. Cir. 2021) (alteration in original) (quoting *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014)). “Consequently, to be admissible, all expert damages opinions must separate the value of the allegedly infringing features from the value of all other features.” *Commonwealth Sci. & Indus. Rsch. Org. v. Cisco Sys., Inc.*, 809 F.3d 1295, 1301 (Fed. Cir. 2015) (citing *VirnetX*, 767 F.3d at 1329). And, particularly relevant to the district court’s license-based rationale, while “a damages theory that is dependent on a comparable license (or a comparable negotiation) may in some cases have built-in apportionment,” the license “must be sufficiently comparable in that principles of apportionment were effectively baked into the

purportedly comparable license.” *Omega*, 13 F.4th at 1377 (cleaned up).

In *Omega*, for instance, we noted that “each of . . . eighteen proffered licenses involve[d] numerous patents, in contrast to a hypothetical negotiation for a single-patent license,” and we concluded that “Omega did not present to the jury a basis in fact to associate the royalty rates used in prior licenses to the particular hypothetical negotiation at issue.” 13 F.4th at 1380–81 (cleaned up). Similarly here, we take Roche’s apportionment argument to be that Meso hasn’t demonstrated the requisite comparability between the 2003 license (to the 100+ BioVeris patents) and the hypothetical negotiation undergirding the jury’s reasonable-royalty award. At least for this reason, Roche’s challenge to the jury’s verdict is indeed “powerful.” *Post-Trial Op.*, 503 F. Supp. 3d at 175. That said, we need not decide whether the district court erred in assessing the sufficiency of the evidence on apportionment, as the parties agree that reversing on induced infringement but not direct infringement would require a new damages trial. Oral Arg. at 8:26–9:29, 31:08–32:10. Accordingly, we vacate the damages award and remand for a new trial on damages.

IV. CROSS-APPEAL

In its cross-appeal, Meso challenges the district court’s noninfringement judgment as to the ’536, ’589, and ’225 patents. We vacate that judgment, which resulted from a misapplication of the compulsory-counterclaim rule. *See* Fed. R. Civ. P. 13.

The district court rendered a judgment of noninfringement with respect to these three patents because, although they were listed in Roche’s declaratory-judgment complaint, Meso did not counterclaim for infringement of these patents. *Post-Trial Op.*, 503 F. Supp. 3d at 170. The district court reasoned that, because patent-infringement counterclaims are compulsory in an action for declaration of non-infringement of those patents, Roche was entitled to

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

23

a judgment of noninfringement. *Id.* Meso’s argument on cross-appeal is twofold: (1) the compulsory-counterclaim rule bars claims in future actions but does not authorize rendering judgment in the same action, and (2) in any event, Roche’s complaint was so generic and nonspecific that it did not trigger the compulsory-counterclaim rule as to these patents. Cross-Appellant’s Br. 67–73.

We agree with Meso that the best understanding of the compulsory-counterclaim rule is that it bars future claims but does not authorize rendering adverse judgment on such claims in the same action. This view is consistent with the advisory committee notes of the Federal Rules of Civil Procedure, which describe the rule as being triggered by entry of judgment in an action: “If the action *proceeds to judgment* without the interposition of a counterclaim as required by subdivision (a) of this rule, the counterclaim is barred.” Fed. R. Civ. P. 13 advisory committee’s note to 1937 rules (emphasis added). Moreover, the Supreme Court and this court have described the rule in ways that support that understanding. *Baker v. Gold Seal Liquors, Inc.*, 417 U.S. 467, 469 n.1 (1974) (“A counterclaim which is compulsory but is not brought is *thereafter* barred.” (emphasis added)); *S. Constr. Co. v. Pickard*, 371 U.S. 57, 60 (1962) (“The [compulsory-counterclaim rule] was particularly directed against one who failed to assert a counterclaim in one action and then instituted a *second action* in which that counterclaim became the basis of the complaint.” (emphasis added)); *Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc.*, 347 F.3d 935, 938 (Fed. Cir. 2003) (“[A] party that does not assert its compulsory counterclaim in the first proceeding has waived its right to bring the counterclaim and is forever barred from asserting that claim in future litigation.”); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 801 (Fed. Cir. 1999) (citing 6 Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 1417, at 129 (2d ed. 1990)

("[F]ailure to plead a compulsory counterclaim bars a party from bringing a later independent action on that claim.")).

Roche acknowledges that "the compulsory counterclaim issue typically arises when one party files a second action involving the same patent," though it asserts nonetheless that "a party seeking declaratory judgment is entitled to such an order in the original action when its opponent fails to counterclaim or present any evidence of infringement with respect to the asserted patent(s) at trial." Appellant's Reply Br. 35–36; *see also id.* at 46 (granting that "[t]he cases on which Meso relies reflect that the compulsory counterclaim rule arises most frequently in the context of one party bringing a second action"). For its part, Roche cites one case from the Eighth Circuit that allowed entry of judgment in the same action due to the failure to assert a compulsory counterclaim. But that case provides little analysis and doesn't bind this court. *See Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807, 814 (8th Cir. 2005).

Accordingly, we vacate the district court's noninfringement judgment as to these non-counterclaimed patents and remand for the district court to consider the appropriate disposition of any properly pled declaratory judgment claims of Roche as to these non-counterclaimed patents. We do not reach the question of whether Roche's complaint is too generic to trigger the compulsory-counterclaim rule. If Meso brings a future infringement action based on those patents, the district court in that action should decide in the first instance whether those claims are barred.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, we affirm the judgment of direct infringement of '939 patent claim 33, reverse the judgment of induced infringement of '779 patent claim 1 and '729 patent claims 38 and 44, vacate the damages award, and remand for a new trial on

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

25

damages. We also vacate the district court's judgment of noninfringement of the '536, '589, and '225 patents and remand for further proceedings.

**AFFIRMED-IN-PART, REVERSED-IN-PART,
VACATED-IN-PART, AND REMANDED**

COSTS

The parties shall bear their own costs.

**United States Court of Appeals
for the Federal Circuit**

ROCHE DIAGNOSTICS CORPORATION,
Plaintiff/Counterclaim Defendant-Appellant

BIOVERIS CORPORATION,
Counterclaim Defendant-Appellant

v.

MESO SCALE DIAGNOSTICS, LLC,
Defendant/Counterclaimant-Cross-Appellant

2021-1609, 2021-1633

Appeals from the United States District Court for the District of Delaware in No. 1:17-cv-00189-LPS, Judge Leonard P. Stark.

NEWMAN, *Circuit Judge*, dissenting.

I respectfully dissent. Roche cannot infringe patents it owns.

In 2007, Roche purchased the patents in suit from IGEN International, via IGEN's patent-holding company BioVeris Corporation. Meso Scale Diagnostics (MSD or Meso) does not own or have exclusive rights to these patents, and has no right to control their use in areas outside of the designated Research Program—as I shall discuss.

I focus on the three patents found infringed at trial: U.S. Patent No. 5,935,779 (“the ’779 patent”), U.S. Patent

No. 6,165,729 (“the ’729 patent”), and U.S. Patent No. 6,808,939 (“the ’939 patent”). The jury found direct infringement of the ’939 patent and induced infringement of the ’779 and ’729 patents. The majority reverses the judgment of induced infringement on statute of limitations grounds, but affirms direct infringement of the ’939 patent. However, Roche cannot infringe these patents, directly or by inducement, for Roche has owned these patents since 2007.

DISCUSSION

In 1995, IGEN and its related company Meso Scale Technologies (MST) formed a Joint Venture whereby a new company named Meso Scale Diagnostics (MSD) was formed to conduct a Research Program to develop new products and uses in the field of electrochemiluminescence. IGEN granted MSD the exclusive license under IGEN’s patents for any such new products and uses. This 1995 license is the basis of MSD’s present charge of infringement, as summarized by Roche:

Under Meso’s interpretation, IGEN International, Inc. (the original patent licensor) gave complete control of its patents to Meso—even as IGEN and its licensee Roche continued selling products with pre-existing technology covered by the patents. Only in this litigation, twenty-two years after obtaining its license, did Meso first proffer the license interpretation that it, rather than IGEN, controlled the entirety of former IGEN patent claims.

Roche Br. 3.

The record does not support MSD’s litigation argument: that in 1995 it was granted sole and exclusive rights to all of IGEN’s past and future patents on IGEN’s operations. To the contrary, IGEN continued to operate and improve its existing technology, while MSD proceeded to develop its new discoveries such as multi-array analysis.

Nonetheless, my colleagues hold that IGEN in 1995 granted MSD the exclusive rights to the IGEN patents on the IGEN products, that Roche received nothing when it bought these patents for \$599 million, and that Roche has been infringing these patents ever since. Indeed, the jury so found, and awarded MSD Roche's profits for the six-year statutory period. The jury verdict, which was sustained by the district court,¹ has no support in the evidence. The verdict is contradicted by the activity of all parties at the time of the 1995 license and the ensuing twenty-two years. See *Old Colony Tr. Co. v. City of Omaha*, 230 U.S. 100, 118 (1913) (“[T]he practical interpretation of a contract by the parties to it for any considerable period of time before it comes to be the subject of controversy is deemed of great, if not controlling, influence”). Following is a chronological outline of relevant transactions and agreements:

1.

The three patents at issue are early patents on various aspects of electrochemiluminescence biotechnology, with filing dates in 1986 (the '729 patent), 1988 (the '779 patent), and 2001 (the '939 patent). They were all assigned to IGEN International, Inc. IGEN developed this basic technology, and marketed it starting in 1994 with the brand name “Origen.”

2.

In 1992 Roche Diagnostics Corp., through its predecessor Boehringer Mannheim GmbH, acquired a non-exclusive license to IGEN's electrochemiluminescence technology for use in designated diagnostic fields. Roche developed this field of use, exhibited a new instrument in 1994, and commenced sales on receipt of FDA approval in

¹ *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 503 F. Supp. 3d 156 (D. Del. 2020) (“Post Trial Op.”).

1996. Trial testimony of Dr. Ofenlach-Hähnle 877:12–881:16, ECF No. 299. Roche’s sales contained a field-of-use restriction on the product label, in conformity to Roche’s license from IGEN. As testified at the trial, Roche’s license did not

include analyzing for life science research and/or development, including at any pharmaceutical company or biotechnology company, patient self testing use, drug discovery and/or drug development (including at any pharmaceutical company or biotechnology company), including clinical research or determinations in for clinical trials or in the regulatory approval process for a drug or therapy, veterinary, food, water or environmental testing or use.

Trial testimony of Robert Salsmans, IGEN Board Member, 928:7–25, ECF No. 299. This 1992 license was superseded in 2003 by another non-exclusive license from IGEN to Roche, *see post*, preserving the field-of-use restriction.

3.

On November 30, 1995, IGEN, MST, and MSD entered into a Joint Venture Agreement and License Agreement. MSD was “organized for the purpose of conducting [a program] of research and development.” Joint Venture Agreement at 1. The Joint Venture Agreement gave MSD the exclusive right to the results of the Research Program:

§ 4.1. Exclusive Vehicle. . . . MST and IGEN agree that MSD shall be their and Wohlstadter’s exclusive means of conducting the Research Program and making, using and selling products, processes and services developed in the course of the Research Program in the Diagnostic Field, and neither MST, IGEN, nor Wohlstadter shall market directly, or license others to market, products that

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

5

compete with MSD with respect to such products, processes, and services.

Joint Venture Agreement § 4.1.

The record states that MSD developed and is selling several new products, described by MSD's President as "dramatically different" from the IGEN products. Trial testimony of Jacob Wohlstadter, 418:14–419:5, ECF No. 297. The MSD products are not here at issue.

4.

Concurrently with the Joint Venture Agreement and incorporated therein by reference, on November 30, 1995 the parties executed the "IGEN/MSD License Agreement," which exclusively licensed IGEN's Technology to MSD for products and processes developed under the Research Program or related to the Research Technologies. The License Agreement defines the licensed subject matter:

§2.1. IGEN Technology. IGEN hereby grants to MSD an exclusive, worldwide, royalty-free license to practice the IGEN Technology to make, use and sell products or processes (A) developed in the course of the Research Program, or (B) utilizing or related to the Research Technologies; provided that IGEN shall not be required to grant MSD a license to any technology that is subject to exclusive licenses to third parties granted prior to the date hereof.

License Agreement § 2.1.

The issue in this appeal is whether this grant to MSD included the exclusive right to all IGEN patents and all IGEN technology that had been developed and was being sold by IGEN. The jury so found, and my colleagues agree. However, even if the license is deemed ambiguous, such an unlikely interpretation is without support. Two of the three patents, the '779 and '729 patents, were filed long

before the entry of the License Agreement. Although the majority reverses infringement as to these patents on limitations grounds, the majority errs in preserving the theory that the 1995 Agreement transferred these patents to MSD. The majority further errs in creating a novel theory of forfeiture in order to hold that the 1995 Agreement implicitly transferred the '939 patent to MSD, although it was explicitly assigned to IGEN. *See* Maj. Op. at 9.

MSD's position is that in 1995 IGEN granted MSD the sole and exclusive right and license to all IGEN past, present, and future patents—notwithstanding the explicit limitation to technology “developed in the course of the Research Program” or “utilizing or related to the Research Technologies.” MSD made no such claim at the time, or when any of the patents was issued. MSD made no such claim when IGEN sold its patent estate of over 100 patents to Roche in 2007.

Although no document or any other evidence supports the MSD position, at the trial MSD's President Jacob Wohlstadter, son of Samuel Wohlstadter the President of IGEN, told the jury that his father and the other officers and directors of IGEN made statements to Roche in 2003 and again in 2007 that were “100 percent wrong.” *See* Trial testimony of Jacob Wohlstadter 471:2–472:18, ECF No. 298:

Q. Let's look at Exhibit P-267 . . . the current restriction on freedom to operate due solely to BioVeris license limitations. You were shown this yesterday; is that correct?

A. I was.

Q. Okay. So am I correct that you consider this statement to be inaccurate; is that right?

A. I did and I do.

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

7

Q. Okay. And you think this is a false statement. Is that your position?

A. I do.

Q. And so anyone that would make this statement, if they would make this statement to Roche, they would be lying in your view; is that right?

A. Well, I'm not sure I would call it lying. I would say they're not telling the truth just because I wouldn't want to put it in these terms.

* * *

Q. And in your view, anyone that made that statement was making a false statement to Roche; is that correct?

A. I think they were making a false, inaccurate statement.

It was not disputed at the trial that, whether or not IGEN lied to Roche, IGEN and Roche lived that lie for the ensuing decade and throughout the life of the patents that IGEN sold to Roche for \$599 million, with IGEN and Roche and even MSD operating as if IGEN had the right to sell its patents to Roche in 2007. *See Sun-Times Media Grp., Inc. v. Black*, 954 A.2d 380, 398 (Del. Ch. 2008) (“When the terms of an agreement are ambiguous, ‘any course of performance accepted or acquiesced in without objection is given great weight in the interpretation of the agreement.’” (quoting Restatement (Second) of Contracts § 202)).

5.

In July 2003, IGEN and Roche entered into a successor non-exclusive license agreement, with payment to IGEN of \$1.4 billion. Roche's non-exclusive license again contained field-of-use restrictions, including a restriction to the field of “in vitro diagnostics” and restriction on the size of the machines that Roche could sell. *See* Trial testimony of Dr.

Keller 999:8–1000:15, ECF No. 300 (describing the fields of use).

MST and MSD signed a consent to the 2003 agreement. Roche explained at trial:

Q. What was the purpose of this particular consent?

A. Well, we asked for that because we didn't really have much clarity about the relationship between IGEN and Meso. We wanted to have confirmation that Meso knew about this license, the relationship, that they have not in their minds, which would interfere with the license.

Id. at 997:20–25.

Roche states, without contradiction, that “Even when asked to consent to the 2003 License from IGEN to Roche, Meso did not assert that Meso—rather than IGEN—owned all the patent rights for which Roche would pay IGEN [\$1.4 billion].” Roche Br. 15 (citing Trial testimony of Jacob Wohlstadter 443:11–444:1, 449:1–5, 451:11–453:25, ECF No. 298); Meso Br. 8.

6.

In 2003, the BioVeris Corporation was created by IGEN. As described by MSD, “As part of the 2003 transaction, IGEN transferred its intellectual property, including its ECL patents, to a new entity called BioVeris.” Meso Br. 9 (citing Trial testimony of Jacob Wohlstadter 446:12–16, ECF No. 298).

MSD filed a written consent to this transfer and license agreement:

MSD and MST hereby represent and warrant to [IGEN] and its Affiliates that each of them hereby waives any right that either of them may have to in any way restrict or limit [IGEN] and its

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

9

Affiliates' exercise of the licenses granted in the License Agreement during the Term thereof.

MSD License Consent (July 24, 2003), Appx 5456–57.

IGEN, BioVeris, and Roche continued to produce and sell the products and methods that they had developed and in accordance with the licenses and transfers that existed among them. MSD made no charge that MSD, rather than IGEN, BioVeris, or Roche, had exclusive rights to the IGEN patents.

7.

In February 2004, the IGEN-Meso Research Program was terminated. The relevance to the present litigation is pointed out by Roche:

Meso then submitted a list of patents to which it claimed rights due to work performed in the Research Program. This list contained no mention of Meso holding exclusive rights to any of the IGEN patents at issue in this lawsuit.

Roche Br. 14 (citing Memorandum from Jacob Wohlstadter, as President and CEO of MSD, to BioVeris Corporation and Meso Scale Technologies (Feb. 13, 2004); Appx7380. *See also id.* (submitting “a cumulative Intellectual Property Position Report” to the Joint Venture). The memorandum accompanying the Report states:

[T]he attached report includes a cumulative summary of all patents, patent applications and invention disclosures that may comprise, in whole or in part, Licensed Technology and Developments, MSD Improvements and/or other discoveries, inventions, or improvements developed in connection with the Research Program.

Id. Jacob Wohlstadter's report did not list any of the three patents here at issue. *Id.* The trial testimony of Jacob Wohlstadter was in accord:

Q. Okay. And as of that time, you never identified the '939 patent as one of the patents that was within that IP position; isn't that correct?

A. No. That was a patent assigned to IGEN. . . . [T]here are certain applications that were going to be part of the MSD assigned pool of intellectual property and there were others that were assigned to IGEN, and the '939 was assigned to IGEN.

Trial testimony of Jacob Wohlstadter 399:9–400:14, ECF No. 297.

This uniform understanding cannot now be reversed by MSD's attempted revision of history. *See Viking Pump, Inc. v. Century Indem. Co.*, 2 A.3d 76, 101 (Del. Ch. 2009) (the course of performance in which a party acquiesced without objection is given great weight in interpreting agreement).

Contrary to MSD's present argument, the 2004 Report attempted to capture all intellectual property that might "comprise, in whole or in part, Licensed Technology." Memorandum from Jacob Wohlstadter as President and CEO of MSD, to BioVeris Corporation and Meso Scale Technologies (Feb. 13, 2004), Appx7380; *cf.* Meso Br. 25 n.8. The 2004 Report constitutes powerful, contemporaneous evidence that MSD did not believe that any of the patents here at issue were among "all" the patents to which MSD held an exclusive license. *See Salamone v. Gorman*, 106 A.3d 354, 374 (Del. 2014) (courts may look to "overt statements and acts of the parties" to interpret ambiguous contracts).

There was not substantial evidence by which a reasonable jury could conclude that the 1995 License Agreement or any other document afforded MSD exclusive rights to the patents here at issue. The years of acquiescence in the IGEN and BioVeris and Roche practice of the patents, and

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

11

MSD's failure to claim any right in any patent, negate MSD's present accusation and my colleagues' ruling.

The majority now disregards the undisputed evidence of MSD's acceptance of Roche's rights, because Roche mentioned that evidence in a footnote. Maj. Op. at 9 (citing *ConocoPhillips v. United States*, 501 F.3d 1374, 1381 (Fed. Cir. 2007)). In *ConocoPhillips* an argument was deemed forfeited because it consisted of "a single conclusory statement" and was "made in passing." 501 F.3d at 1381. That is not the situation here. Of course, courts should be wary of "sandbagging," as warned in *Freytag v. Comm'r*, 501 U.S. 868, 895 (1991) (Scalia, J., concurring in part). However, here Roche presented arguments supported by evidence in its opening brief, and Meso responded—both in footnotes. Roche Br. 27 n.4; Meso Br. 25 n.8. Although presented in footnotes, these arguments were fully developed. The majority's holding that Roche forfeited this issue defeats "the orderly administration of justice," instead presenting a trap for the unwary. See *Freytag*, 501 U.S. at 895 (Scalia, J., concurring in part) (quoting 9 C. Wright & A. Miller, Federal Practice and Procedure § 2472 (1971)). The judicial obligation is to seek truth and justice, even from footnotes.²

² This court's hostility to footnotes appears to be rooted in *Graphic Controls Corp. v. Utah Med. Prod., Inc.*, 149 F.3d 1382 (Fed. Cir. 1998). There, the parties attempted to evade Rule 28 of Federal Appellate Procedure by incorporating arguments from the joint appendix by reference in footnotes. *Id.* at 1385. Neither party has attempted such impropriety here. This court has also recognized that, as with all equitable doctrines, forfeiture "is 'not to be applied in a ritualistic fashion.'" *Omega Pats., LLC v. CalAmp Corp.*, 920 F.3d 1337, 1342 (Fed. Cir. 2019) (quoting 9B Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 2472 (3d ed. 2018)).

8.

IGEN, BioVeris and Roche continued to practice the IGEN technology, with no assertion by MSD that it held the exclusive rights to this technology. “From 1995 through the sale of BioVeris in 2007, IGEN (later BioVeris) and Roche kept selling ECL products with microparticles and TPA [tripropylamine] – with no objection by Meso.” Roche Reply Br. 4–5. MSD does not contradict this statement.

In April 2007 IGEN, through BioVeris, sold its entire patent portfolio to Roche for \$599 million. At the trial, Roche explained that by acquiring complete ownership of the patents under which it was operating, the field-of-use restrictions no longer existed. Roche so informed its customers:

Roche is now the owner of the complete patent estate of the electrochemiluminescence (ECL) technology deployed in the Elecsys product line which gives us the opportunity to expand our immunochemistry business from the human diagnostic field into new market segments such as life science research, life science development, patient self testing, veterinary testing, drug discovery, drug development and clinical trials.

Joint Trial Ex. 512, Appx5898; *see also* Trial testimony of Scott Griffin 1425:18–1426:2, ECF 301.

The record does not show any intervention by MSD to prevent the sale to Roche. However, the record states that after several years, MSD began threatening Roche’s customers with lawsuits for infringement – whereby Roche in 2017 brought this declaratory action.

9.

On Roche’s filing of this declaratory action, MSD counterclaimed for infringement of patents that MSD states it

ROCHE DIAGNOSTICS CORPORATION v.
MESO SCALE DIAGNOSTICS, LLC

13

exclusively licensed from IGEN in 1995 or later. MSD's position at trial was that IGEN and BioVeris had no right to sell these patents to Roche in 2007, because MSD held the exclusive patent rights. The jury agreed with MSD, and my colleagues now affirm the jury verdict. This verdict cannot be sustained, for the reasons I have discussed.³

CONCLUSION

Substantial evidence does not support the jury verdict. The plain reading of the several agreements and the testimony of witnesses for both sides was overwhelmingly in conformity with the contracts for the various transactions, including the 2007 sale of the IGEN/BioVeris patents to Roche. MSD's actions before and after the 2007 sale conformed to this understanding of the 2007 sale to Roche. From the panel majority's contrary ruling, I respectfully dissent.

³ The panel majority misunderstands my dissent. *Cf.* Maj. Op. at 2 n.1. As explained, these patents were not developed under the Research Program and were all owned by IGEN. Accordingly, Roche does not infringe because Roche owns the patents it bought from IGEN. If I have not been sufficiently clear, I repeat that the patents in this suit are all patents that Roche bought from IGEN, not patents owned or licensed exclusively to Meso. And since Roche cannot directly infringe these patents, its customers cannot indirectly infringe them.