Nos. 2021-1609, 2021-1633

In the 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.

Appeal from the United States District Court
for the District of Delaware, No. 1:17-cv-00189-LPS.
The Honorable **Leonard P. Stark**, Judge Presiding.

NON-CONFIDENTIAL PRINCIPAL BRIEF OF APPELLANTS ROCHE DIAGNOSTICS CORPORATION AND BIOVERIS CORPORATION

JAMES T. MCKEOWN
JEFFREY COSTAKOS
ERIC MAASSEN
KIMBERLY K. DODD
FOLEY & LARDNER LLP
777 E. Wisconsin Ave.
Milwaukee, WI 53202-5306
(414) 271-2400
jmckeown@foley.com
jcostakos@foley.com
emaassen@foley.com
kdodd@foley.com

Counsel for Appellants
Roche Diagnostics Corporation and Bioveris Corporation

COUNSEL PRESS · (866) 703-9373 PRINTED ON RECYCLED PAPER

U.S. Patent No. 5,935,779, Claim 1

A process for performing a binding assay for the detection or quantitation of an analyte of interest in a sample, comprising:

(a) forming a composition containing

(i) said sample.

(ii) an assay-performance substance comprising an electrochemiluminescent label and containing at least one substance selected from the group consisting of

(1) added analyte of interest or added analogue of said analyte;

(2) a binding partner of said analyte or a binding partner of said analogue; and

(3) a reactive component capable of binding with component (1) or (2); and

(iii) a plurality of inanimate particles capable of binding with said analyte and/or said assay performance substance;

(b) incubating said composition to form a complex containing said particles and said label compound;

(c) collecting said complex in a zone where electrochemiluminescence can be induced to occur;

(d) inducing said label compound in said complex to electrochemiluminescence by exposure to electrochemical energy; and

(e) detecting or quantitating emitted luminescence.

U.S. Patent No. 6,165,729, Claim 38

An electochemiluminescent assay method for determining the presence of or quantitating an analyte of interest, said method comprising the steps of:

(a) forming a complex comprising:

(i) said analyte;

(ii) a first specific binding partner of said analyte; and

(iii) an electrochemiluminescent label comprising a chelate of a transition metal or a rare earth metal, which chelate, when oxidized, is capable of being converted to an excited state which electrochmiluminesces, wherein said chelate is linked to said first specific binding partner;

(b) forming a composition comprising:

(i) said complex;

(ii) an amine which forms a reducing agent upon oxidation, said amine being selected from the group consisting of:

(x) aliphatic amines, aromatic amines, diamines, polyamines, and heterocyclic amines,

(y) the amines defined in subparagraph (b)(ii)(x) substituted by one or more substituents selected from the group consisting of –OH, alkyl, chloro, fluoro, bromo, iodo, $–SO_3$, aryl, –SH, –C(O) –H, –C(O) –OH, ester groups, ether groups, alkenyl, alkynyl, –C(O) –, $–N_2^+$, cyano, epoxide groups, and heterocyclic groups, and

(z) protonated salts of the amines defined in subparagraph (b))(ii)(x) and protonated salts of the substituted amines defined in subparagraph (b)(ii)(y); and

(iii) an electrolyte solution which functions as a medium in which said chelate and said amine can be oxidized;

(c) exposing said composition to electrochemical energy such that both the chelate and the amine are oxidized and an interaction between resulting oxidized products produces electrochemiluminescence, said electrochemiluminescence being related to the amount of said analyte;

(d) detecting said electrochemiluminescence and thereby determining the presence or amount of said analyte.

U.S. Patent No. 6,165,729, Claim 44

An electochemiluminescent assay method for determining the presence of or quantitating an analyte of interest, said method comprising the steps of:

(a) forming a complex comprising:

(i) said analog of said analyte;

(ii) a first specific binding partner of said analyte and said analog; and

(iii) an electrochemiluminescent label comprising a chelate of a transition metal or a rare earth metal, which chelate, when oxidized, is capable of being converted to an excited state which electrochmiluminesces, wherein said chelate is linked to said analog and said analog competes for binding with said analyte for said first specific binding partner;

(b) forming a composition comprising:

(i) said complex;

(ii) said analyte;

(iii) an amine which forms a reducing agent upon oxidation, said amine being selected from the group consisting of:

(x) aliphatic amines, aromatic amines, diamines, polyamines, and heterocyclic amines,

(y) the amines defined in subparagraph (b)(iii)(x) substituted by one or more substituents selected from the group consisting of –OH, alkyl, chloro, fluoro, bromo, iodo, $–SO_3$, aryl, –SH, –C(O) –H, –C(O) –OH, ester groups, ether groups, alkenyl, alkynyl, –C(O) –, $–N_2^+$, cyano, epoxide groups, and heterocyclic groups, and

(z) protonated salts of the amines defined in subparagraph (b)(iii)(x) and protonated salts of the substituted amines defined in subparagraph (b)(iii)(y); and

(iii) an electrolyte solution which functions as a medium in which said chelate and said amine can be oxidized;

(c) exposing said composition to electrochemical energy such that both the chelate and the amine are oxidized and an interaction between resulting oxidized products produces electrochemiluminescence, said electrochemiluminescence being related to the amount of said analyte present;

(d) detecting said electrochemiluminescence and thereby determining the presence or amount of said analyte.

U.S. Patent No. 6,808, 939 B2, Claim 33

A label material comprising a luminescent metal complex having the structure

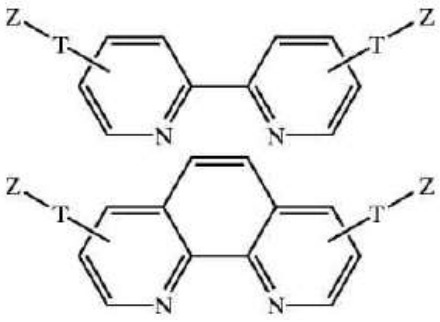
$ML^1L^2_2$

wherein

M is Os or Ru

L^1 is a substituted bipyridine or phenanthroline ligand having at least one substituent that is covalently linked to a biological material, binding reagent, enzyme substrate or other assay reagent; and

L^2 is a metal ligand selected from the group consisting of:



and

wherein

T is a linker group comprising an alkyl, alkenyl, alkynyl or phenyl linker, or a combination thereof, having, optionally, one or more chain carbons substituted by a heteroatom;

Z is $–SO_3^-$, $–SO_3H$, $–OSO_3^-$, $–OSO_3H$, $–PO_3^{2-}$, $–PO_3H^-$, $–PO_3H_2$, $–PO_3H^2$, $–OPO_3^{2-}$, $–OPO_3H^-$, $–OPO_3H_2$, $–OP(R)O_2$, $–OP(R)O_2H$, $–[NHC(NH_2)_2]^+$, or $–NHC(NH)NH_2$; and

R is alkyl.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 21-1609

Short Case Caption Roche Diagnostics Corporation v. Meso Scale Diagnostics, LLC

Filing Party/Entity Roche Diagnostics Corporation, BioVeris Corporation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 02/16/2021

Signature: /s/James T. McKeown

Name: James T. McKeown

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Roche Diagnostics Corporation		Roche Holdings, Inc., Roche Finance Ltd., Roche Holding AG
BioVeris Corporation		IGEN International, Inc., Roche Holdings, Inc., Roche Finance Ltd., Roche Holding AG

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Eric L. Maassen (Foley & Lardner LLP)	Rachel M. Blise (Foley & Lardner LLP)	Philip C. Babler (Foley & Lardner LLP)
Christopher P. Quinn (Friedlander & Gorris P.A.)	Joel Friedlander (Friedlander & Gorris P.A.)	Christopher Foulds (Friedlander & Gorris P.A.)

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages Appx62 of the Addendum reflects the district court's October 17, 2019 Memorandum Order, which was issued under seal. A redacted version of the Memorandum Order has been included in the non-confidential version of the Addendum. The material omitted on Appx62 of the non-confidential version of the Addendum redacts the name and number of products covered by claim 10 of the '607 patent. The '607 patent is not at issue on this appeal.

TABLE OF AUTHORITIES

Page(s)

Cases

Rules and Statutes

STATEMENT OF RELATED CASES

No appeal in or from the same proceeding was previously before this or another appellate court; a cross appeal (Case No. 21-1633) was filed in this case. Plaintiff-Appellant Roche Diagnostics Corporation and Counterclaim Defendant-Appellant BioVeris Corporation ("BioVeris") are unaware of any other pending case in this Court or in any other court that will directly affect or be affected by this Court's decision in the pending appeal.

JURISDICTIONAL STATEMENT

Roche Diagnostics Corporation and BioVeris appeal the December 23, 2020 final judgment of patent infringement and damages entered by the United States District Court for the District of Delaware. Appx115. The district court had jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because it was a civil action arising under the patent laws of the United States. The district court also had jurisdiction over the action pursuant to 28 U.S.C. § 1332.

Roche Diagnostics Corporation and BioVeris filed their notice of appeal on January 19, 2021. Appx5108. Meso Scale Diagnostics, LLC ("Meso") filed its notice of cross-appeal on February 2, 2021. Appx5108. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) as it is an appeal from a judgment in a civil action for patent infringement.

INTRODUCTION

The $137,250,000 infringement judgment in this case should be reversed or, at a minimum, vacated. Not only did the damages award exactly match Meso's request for a legally impermissible disgorgement of all of Roche's alleged profits, but the judgment is based on a flawed and implausible interpretation of Meso's 1995 patent license. 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.

Beyond Meso's unsustainable license interpretation, Meso failed to offer proof that, during the limitations period, Roche induced customers to use Roche instruments and reagents outside the Field authorized under Roche's license with IGEN. Meso instead claimed that Roche conduct occurring long before the limitations period induced infringement by Roche customers years later. The evidence also did not permit a jury finding that Roche had the requisite knowledge of or willful blindness toward the operative patent rights. When overturning the jury finding of willfulness, the district court held that Roche had a reasonable basis to believe that its products were not covered by Meso's license rights. The district court

should have applied that same reasoning to vacate the jury finding of induced infringement.

Patent exhaustion likewise bars Meso's claims that Roche induced infringement by customers who acquired Roche instruments and reagents for permitted uses (which Meso does not complain about) but who also acquired reagents for use outside Roche's authorized Field. These so-called "dual use" customers represented the vast majority of the royalty base. Because a customer cannot use the instruments without infringing the three method patent claims at issue in this litigation, the initial acquisition of instruments by those customers for permitted uses exhausted any license rights of Meso to the patented methods.

The damages award and ongoing royalty likewise cannot be sustained. Meso's expert failed to apportion damages to include only the value of the infringing features and to exclude value attributable to patents that Meso dropped from the case on the eve of trial, to other applicable patents in the broader patent portfolio, and to non-infringing Roche technology. Even apart from the failure to apportion, the damages award should be reversed because, as the district court acknowledged, the award of $137,250,000 is exactly Meso's estimate of Roche's profits, an impermissible measure of damages. The district court speculated about ways the jury might have reached its award. None is supported by the record.

STATEMENT OF THE ISSUES

1. Whether the verdict finding that Meso held exclusive rights to everything covered by the patent claims should be reversed because (i) the language of the 1995 License says nothing about transferring to Meso exclusive rights to all uses of the patent claims, and (ii) there was no evidence to permit the jury to find that the parties mutually intended Meso's construction;

2. Whether the induced infringement verdict on the '729 and '779 method patent claims fails because Roche committed no affirmative act of inducement within the limitations period that caused direct infringement by a Roche customer;

3. Whether the induced infringement verdict on the '729 and '779 method patent claims cannot stand because the district court applied an erroneous "should have known"—rather than "willful blindness"—standard for specific intent even while recognizing that the language in the 1995 License was ambiguous and that Roche reasonably believed it had the rights needed to sell its products;

4. Whether any patent rights Meso owns were exhausted when Roche's customers acquired Roche's instruments to practice the patent claims in the Field authorized by Roche's 2003 license from IGEN, thus insulating the customers' post-acquisition use of those same instruments out of Field from assertions of patent infringement; and

5. Whether the damages award should be vacated because Meso failed to provide any evidence to apportion which part of the total value of the Roche products was attributable to the three patents at issue rather than to other technology and attributes of the final products and because the verdict was based on an impermissible disgorgement of profits rather than a reasonable royalty.

STATEMENT OF THE CASE

I. Roche Immunoassays and ECL Detection Technology.

Immunoassays are tests that use antibodies or antigens to detect and measure the presence of a target molecule (which in clinical applications can indicate HIV, preeclampsia, hepatitis, etc.) in a biological sample (blood or other bodily fluid). Appx4206 (267:7-17), Appx4311 (503:1-9), Appx4658 (1410:24-1411:12). Roche's immunoassays, which are used predominantly by doctors to diagnose and treat patients (Appx4513 (992:3-23)), are performed on large instruments that are loaded with reagent packs. Reagent packs contain antibodies and other reagents necessary to run a particular test. Roche's customers (hospitals, regional labs, etc.) have one or more instruments on-site and receive reagent packs on an ongoing basis. *See* Appx4445-4446 (872:20-876:25), Appx4658 (1412:5-17).

Electrochemiluminescence, or ECL, refers to a chemical phenomenon that emits light as the result of electrically oxidizing an amine that then reacts with a metallic label. Relevant here, ECL can serve as the detection method for an

immunoassay to detect and measure an analyte of interest when a metallic label (a ruthenium conjugate complex) is attached to an antibody that binds to the analyte. Appx4443 (864:8-865:10).

II. Roche First Licenses and Later Acquires Ownership of IGEN's ECL Patent Portfolio.

By the early 1990s, IGEN had acquired patents to ECL technology and had begun developing its own ECL instrument and reagents and licensing its ECL technology to other entities. Appx4224 (366:14-17), Appx4446 (877:12-16). Among the patents held by IGEN were the predecessors of the '729 and '779 patents in this lawsuit, including patents directed to the use of tripropylamine ("TPA") and microparticles (sometimes called beads) in an ECL reaction. In 1992, IGEN granted a license to Roche's predecessor, Boehringer Mannheim.[1] Appx4446 (877:12-16). In 1994, Roche demonstrated its first ECL-related instrument. Appx4447 (880:12-19).

Both the Roche instrument and the earlier launched IGEN instrument used the same technology to generate the ECL reaction: a flow cell (where the ECL reaction

[1] For ease of reference, "Roche" includes defendant Roche Diagnostics Corporation as well as Roche Diagnostics GmbH and Boehringer Mannheim GmbH (with the last, the original 1992 licensee of two of the patents at issue, later acquired by Roche). Of the three, only Roche Diagnostics Corporation is a party to this lawsuit and its sales were the basis for damages.

occurs), paramagnetic microparticles, ruthenium labels and TPA. *See* Appx4231-4232 (367:9-368:12), Appx4333 (593:3-596:1). A flow cell is displayed below:

Appx8399, Photo of Ex. D471. The Roche instruments incubate a sample with the reagents for a particular test, draw the mixture into a flow cell, and then apply an electric charge to trigger an ECL reaction. Appx4333 (593:5-594:13), Appx4444 (868:11-869:16). The instrument measures the amount of light emitted and reports the test result. Appx4446 (876:18-25). Next the instrument flushes a cleaning reagent through the flow cell and repeats the process with the reagents needed to conduct the next immunoassay. Appx4446 (876:3-5).

Roche has added new tests and features over the years and now offers approximately 100 FDA approved immunoassays, all of which use that same flow cell ECL technology. Appx4442 (862:8-12), Appx4444 (871:9-15). Meso now claims it controls critical components of this ECL technology (the use of microparticles and TPA), which Roche has continuously used since 1994 (the year before Meso existed).

Today Roche owns both IGEN and BioVeris (and their ECL patent portfolio). Appx4554 (1155:5-25). In July 2003, as part of a litigation settlement, Roche paid IGEN and its shareholders about $1.4 billion for the 2003 License to the ECL technology. Appx4515 (998:23-999:5), Appx4576 (1243:6-14). As part of that transaction, IGEN transferred its patent portfolio and operations to the newly-formed BioVeris. Appx4778 (1680:25-1681:6). The 2003 License defined Roche's field of use, the 2003 Field, in terms of diagnosing and treating patients. Appx5429, §1.7. That license also required Roche to make payments to BioVeris if Roche allowed its customers to use its immunoassay products outside that 2003 Field. Appx5429, §2.5(b); Appx4515-4516 (1000:24-1001:8).

In April 2007, Roche agreed to purchase BioVeris for about $600 million, thereby obtaining ownership of BioVeris's ECL patents and eliminating the obligation to pay BioVeris for any use outside the 2003 Field. Appx4419 (769:21-770:13), Appx4435-4436 (835:22-836:4), Appx4516 (1001:9-1002:10). Roche was assured by BioVeris officers and directors (including Samuel Wohlstadter, the former CEO of IGEN and the father of Meso's CEO Jacob Wohlstadter) that BioVeris held the ECL license rights Roche needed to sell Roche's flow-cell based ECL products outside the 2003 Field. Appx4516-4517 (1004:12-1006:17), Appx4534 (1073:5-20). Roche also received a representation and warranty from BioVeris that BioVeris' filings with the Securities & Exchange Commission were

accurate and complete. Appx8079, §3.6(a), Appx4558-4559 (1171:20-1173:18). Shortly after the 2007 transaction closed, and consistent with its goals in acquiring BioVeris, Roche informed its then-current customers that they were no longer limited to using Roche's ECL instruments solely in the 2003 Field. Appx4657 (1406:10-16).

III. Meso's 1995 License and Joint Venture with IGEN.

While IGEN and Roche were introducing their ECL flow cell immunoassay systems, Jacob Wohlstadter ("Wohlstadter") was an immunology graduate student. Appx4206 (266:6-9, 267:7-17), Appx4446 (877:12-16). His lab work included placing different chemical spots in the wells of microtiter ("multi-array") plates so that a researcher could test for several molecules in a single well. Appx4206-4207 (266:23-267:17, 269:4-271:9), Appx4322 (547:18-548:2). Wohlstadter proposed to IGEN that he be allowed to try to combine IGEN's ECL technology with this multi-array technology. Appx4215 (300:14-301:19). In November 1995, IGEN (by then a publicly traded company) and Meso Scale Technologies (an entity owned by Wohlstadter) formed Meso as a joint venture and executed the 1995 License and the Joint Venture Agreement ("JVA"). Appx5111, Appx5207, Appx4211 (285:16-23), Appx4778 (1680:21-24).

Section 2.1 of the 1995 License granted Meso exclusive rights to practice IGEN's ECL 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." Appx5207, §2.1. The JVA created the IGEN-funded Research Program, which began in early 1996. Appx4209 (277:14-15), Appx4235 (381:18-24). Section 4.1 of the JVA specified that Meso would be the exclusive means for making, using, and selling products and processes developed in the course of the Research Program. Appx5111, §4.1. IGEN could not make or sell any such products. Section 4.1 further prohibited IGEN from developing, manufacturing or selling any products that used or related to defined Research Technologies. *Id.*; Appx4242-4243 (410:23-415:2).

Meso first sold commercial ECL products in late 2001. Appx4309 (496:18-20). Those products used multi-array technology rather than a flow cell and had very different applications than Roche's tests. *Id.*; Appx4214 (296:3-5), Appx4321 (546:17-25). A Meso multi-array plate is shown below:

Appx8400, Photo of Ex. D472. Besides using a completely different platform than

Roche, Meso used a "radically different way of doing the [ECL] measurements." Appx4243-4244 (415:24-417:5) In 2001, Wohlstadter represented to a federal district court that Meso products used ECL "in a manner dramatically different" from that used by IGEN and Roche. Appx4243-4244 (417:7-419:5), Appx6776, ¶5. Throughout the 1995-2004 time period, IGEN continued to sell its flow cell-based ECL instruments with no objection by Meso under the 1995 License or Section 4.1 of the JVA. Appx4243 (412:9-415:10).

IV. Meso's Claim of Exclusive Patent Rights.

In this litigation, Meso contends that Section 2.1 of the 1995 License caused all rights under the three patents at issue and, indeed, to much more of IGEN's patent portfolio,[2] to transfer to Meso in the late 1990s. Wohlstadter now asserts that the officers and directors of BioVeris (including his father) lied to Roche in 2007, apparently to entice Roche to acquire BioVeris without compensating Meso. Appx4303 (471:2-472:18), Appx5800. Wohlstadter told Roche in July 2007, after the BioVeris acquisition closed, that he believed that Meso held broader IP rights than Roche thought, but at that point he did not claim or assert the "entire patent claim" license theory that Meso offered at trial. Appx4228-4229 (355:4-356:23), Appx4518 (1011:2-1012:15), Appx4559 (1174:19-1176:21).

[2] As described below, until shortly before trial Meso contended that Meso held exclusive rights to at least 42 patent claims from ten IGEN patents.

Meso now contends that Section 2.1 of the 1995 License granted Meso exclusive rights to all aspects of entire patent claims so that any third-party use (even by IGEN) violated the exclusive rights held by Meso. *See* Appx4243 (412:9-413:19, 414:3-14). For example, claim 1 of IGEN's '779 patent (which was filed in 1994) covered the use of microparticles in an ECL reaction. Appx157. Meso contends that because some later work in the IGEN-funded Research Program involved research on a different type of microparticle, the use of microparticles in an ECL reaction was "developed in the course of the Research Program" and the exclusive rights to all of claim 1 of the '779 patent transferred from IGEN to Meso under Section 2.1 of the 1995 License. Appx4237 (390:12-391:9). Under Meso's interpretation, it did not matter that IGEN and Roche had been using pre-existing microparticle technology for years and that the Meso research cited at trial involved a different type of microparticle than the type used by IGEN and Roche. Appx4325-4326 (562:9-563:16, 565:23-566:10), Appx4337 (609:24-610:18). Under Meso's new interpretation, as soon as Meso's Research Program did anything related to the use of *any* microparticles in an ECL reaction, *all subsequent* IGEN sales of products covered by claim 1 of the '779 patent violated Meso's exclusive license rights. *See* Appx4327 (390:12-391:9), Appx4243 (412:16-413:19, 414:10-14).

IGEN's principal business was licensing ECL technology and developing ECL products. Appx4207-4208 (271:19-272:10). The IGEN ECL patent portfolio

included more than 100 patents and, according to IGEN's president, represented the company's "crown jewels." Appx4231 (365:1-5), Appx4771 (1652:4-10). Although Meso now asserts that all rights to a patent claim would transfer to Meso as work was undertaken in the Research Program, no one at IGEN or Meso attempted to track what work in the Research Program related to any of the claims within the patent portfolio. Appx4338-4339 (614:13-615:16), Appx4650-4652 (1378:3-1379:25, 1381:20-1383:13, 1387:8-1388:8). Both James Wilbur, a Meso executive who managed the Research Program, and George Sigal, now the chief scientist at Meso but previously the IGEN employee responsible for managing patents, confirmed that they knew of no one who even attempted to track such information. *Id.* Under Meso's theory, then, the "crown jewels" purportedly transferred from publicly-traded IGEN to Meso with no one paying attention. IGEN would have been left with essentially no meaningful assets. Appx4545 (1117:6-1119:10); *see also* Appx6618, Appx6631.

In February 2004, both the Research Program and the IGEN-Meso joint venture ended. Appx4239 (397:9-19), Appx4298 (451:11-16), Appx4409 (729:16-730:12). Meso then submitted a list of patents to which it claimed rights due to work performed in the Research Program. Appx7380-7391. This list contained no mention of Meso holding exclusive rights to any of the IGEN patents at issue in this lawsuit. *Id.* After February 2004, IGEN's successor BioVeris and Roche continued making

and selling their ECL instruments and reagents using the flow cell technology. Appx4333-4334 (593:5-595:2), Appx4549 (1133:18-1135:21), Appx4704 (1594:23-1597:18). After the joint venture terminated, independent appraisals yielded a fair market value of about $10 million for the IGEN/BioVeris 31% ownership interest in the Meso joint venture. Appx4299-4300 (462:11-465:13), Appx4547 (1126:11-1128:16).

From 1995 until June 2007 (when Roche acquired BioVeris), Meso never objected to IGEN's sales (through February 2004), BioVeris's sales (from February 2004 through June 2007), or Roche's out-of-Field sales of ECL instruments and assays that used the IGEN ECL technology to conduct an ECL reaction in a flow cell. Appx4296-4298 (443:11-444:1, 449:1-5, 451:11-453:25), Appx4457 (922:1-8), Appx4457-4458 (923:1-924:14), Appx4549 (1135:11-21), Appx4541 (1103:22-1104:5), Appx4544 (1115:19-25). 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. Appx4296-4298 (443:11-444:1). Roche paid nothing to Meso in connection with the 2003 License and Meso had no right to any future payments that Roche would make to BioVeris if Roche customers used Roche instruments or reagents outside the 2003 Field. Appx4515-4516 (998:20-999:5, 1000:24-1001:8), Appx4518 (1012:7-22), Appx4570 (1219:10-23).

V. Litigation History.

In June 2010, Meso sued Roche in the Delaware Court of Chancery claiming that Roche's sale of products used by customers outside the 2003 Field breached the 2003 License. The Court of Chancery denied that claim and held that Meso was not a party to the 2003 License. *Meso Scale 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).

Meso then threatened patent litigation, prompting Roche to file this declaratory judgment action. Appx245. Meso counterclaimed, alleging that Roche ECL products used outside the 2003 Field violated Meso's exclusive rights to ten patents (42 patent claims) of the IGEN patent portfolio. Appx1023. The district court denied Roche's motion for summary judgment as to the scope of Meso's 1995 License on the ground that the language in the 1995 License was ambiguous. Appx34. The case proceeded to trial.

Shortly before trial, the district court granted Roche's *Daubert* motion to exclude the royalty opinions offered by Quentin Mimms (Meso's damages expert) because Mimms reached his damage estimate of $139 million by using a "hold up" valuation theory and by failing to apportion what part of the total product value was attributable to just the patents at issue. Appx66-67. Meso then abandoned seven of the ten patents (38 of the 42 patent claims at issue) and sought to have Mimms testify

that the damages on the four remaining patent claims was essentially the same amount Mimms estimated for all 42 patent claims. Appx8567 (17:2-20). The district court denied Meso's motion for reconsideration and Meso proceeded to trial on the four patent claims at issue on this appeal. Appx8573 (23:1), Appx4053 (40:11-42:4).

Precluded on *Daubert* grounds from offering an opinion on a reasonable royalty (Appx65-67), Mimms testified at trial that total sales for products used outside the 2003 Field were $183.3 million. Appx4414 (751:6-14), Appx4421 (777:3-25). Mimms also testified, ostensibly in the context of the *Georgia-Pacific* factors, that Roche earned a profit margin of approximately 75%. Appx4420-4421 (775:14-776:8). In closing argument, Meso's counsel specifically urged the jury to award damages in the amount equal to Roche's profits, *i.e.*, 75% of the $183 million total out-of-field sales. Appx4815-4816 (1830:19-22, 1832:21-23).

The jury returned a verdict finding that Meso holds an exclusive license to the entirety of claim 33 of the '939 patent, claim 1 of the '729 patent, and claims 38 and 44 of the '779 patent. Appx3725. The jury also found that Roche induced customers to use Roche products outside the 2003 Field in violation of Meso's exclusive rights to the '729 and '779 patents and that Roche directly infringed the '939 patent by sales of products to customers that used the products outside the 2003 Field. *Id.* The jury also found that Roche willfully infringed one or more of the claims. *Id.* The jury

awarded damages of $137,250,000, an amount equal to a 75% profit on Mimms' estimate of total out-of-field sales. *Id.*

During trial, Roche moved for judgment as a matter of law on several issues. Appx4797 (1756:25-1761:23). Roche renewed its motions following trial, sought a new trial under Rule 59, and sought an order and judgment as to certain claims abandoned by Meso. Appx3743. On November 30, 2020, the district court issued a Memorandum Opinion (Appx76) and Order (Appx113) on the parties' post-trial motions. The district court entered judgment in favor of Meso and against Roche with respect to infringement of claim 33 of the '939 patent and induced infringement of claim 1 of the '779 patent and claims 38 and 44 of the '729 patent. Appx115. The district court reversed the jury's finding of willfulness on the ground that the court had found the 1995 License language to be ambiguous and Roche had a good faith belief that its conduct did not infringe Meso's rights. Appx93. The district court also found that BioVeris breached a contractual obligation under the 1995 License to fund the litigation against Roche. Appx117.

The district court upheld the jury's damages award. It excused the lack of apportionment on the ground that Roche's successful *Daubert* challenge prevented Roche from complaining about Meso's failure to submit sufficient evidence to allow the jury to apportion. Appx102-103. Rather than acknowledge the jury's legally improper disgorgement of Roche's profits, the court relied on a new damages theory

never offered by Meso. Appx100. The court entered judgment in favor of Meso and against Roche for damages in the amount of $137,250,000 (approximately $171 million with prejudgment interest through 2020). Appx115.

SUMMARY OF THE ARGUMENT

A. Scope of the 1995 License. Roche is entitled to judgment as a matter of law ("JMOL") because the language of Section 2.1 of the 1995 License does not permit an interpretation that transferred from IGEN to Meso exclusive rights to the entirety of patent claims based on their use by Meso as part of the Research Program, Meso offered no relevant extrinsic evidence that would support its interpretation, and Meso's undisputed conduct between 1995 and 2007 refutes any suggestion that the 1995 License transferred all rights under those ECL patents to Meso.

B. Induced Infringement. Roche is entitled to JMOL or a new trial on the induced infringement claims brought under the '729 and '779 patents because Roche committed no affirmative act of inducement within the limitations period that caused direct infringement by a Roche customer. The jury should not have been permitted to rely on conduct that occurred almost four years before the start of the limitations period. In addition, the district court incorrectly applied a negligence standard of "should have known" for the specific intent requirement of an

inducement claim when the evidence would not support a finding of specific intent under the appropriate "knowledge or willful blindness" standard.

C. Exhaustion. The patent exhaustion doctrine bars Meso's inducement claims as to dual-use customers because the 2003 License to which Meso consented authorized Roche to sell instruments to customers for uses within the 2003 Field. By definition, dual-use customers used the Roche instruments at least in part for authorized uses. Once those customers acquired the Roche instruments, Meso could not claim infringement based on the instrument performing the methods of the '729 or '779 patents.

D. Damages. Roche is entitled to JMOL or a new trial on damages because (i) Meso failed to submit any evidence that would enable the jury to award damages based on the value attributable to the three patents at issue rather than on total infringing sales, (ii) the award reflects an impermissible disgorgement of profits rather than reasonable royalty damages, and (iii) the amount of damages was unsupported by substantial evidence at trial. Meso's failure to offer expert testimony sufficient to satisfy the *Daubert* standard did not excuse Meso from the need to satisfy the apportionment requirement.

ARGUMENT

I. Standards of Review.

This Court reviews the district court's denial of a motion for JMOL *de novo* and applies the same standard as the district court. *Lighting Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). "The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury could properly find a verdict for that party." *Id.* (citations and internal quotation marks omitted). The Third Circuit reviews a district court's order denying a motion for a new trial for abuse of discretion, "unless the court's denial is based on the application of a legal precept, in which case the standard of review is plenary." *Id.* at 1167.

The Court reviews issues of law, including legal standards provided to the jury and the district court's interpretation and application of patent law, *de novo*. *SBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1354 (Fed. Cir. 2000); *see also Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 501 (1984) ("[A]n appellate court [ ] [has] power to correct errors of law, including those that may infect a so-called mixed finding of law and fact, or a finding of fact that is predicated on a misunderstanding of the governing rule of law."). The Court reviews "the jury's resolution of all factual disputes for substantial evidence." *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1563 (Fed. Cir.

1996). "A factual finding is supported by substantial evidence if a reasonable jury could have found in favor of the prevailing party in light of the evidence presented at trial." *SBIA*, 225 F.3d at 1354.

II. The 1995 License Did Not Transfer to Meso the Exclusive Right to Practice ECL Technology.

As the predicate for any infringement of the '729, '779 or '939 patents, Meso first needed to prove that the exclusivity granted in Section 2.1 of the 1995 License gave Meso the broad rights now asserted. But the language of the license grants an exclusive right to practice the ECL technology only to make and sell *certain products and processes* created or invented by Meso or using the Research Technologies. Nothing more. The district court should have granted summary judgment or JMOL for Roche instead of finding the license language ambiguous. Further, Meso's conduct from 1995 through 2007 belies any basis for accepting Meso's current interpretation. To the extent Wohlstadter now contends that he held his broad but undisclosed interpretation back in 1995, subjective unexpressed views cannot serve as parol evidence. Accordingly, this Court should reverse. *See Holiday Homes of St. John, Inc. v. Lockhart*, 678 F.2d 1176, 1180 (3d Cir. 1982) (overturning district court when "there [wa]s no evidence in th[e] record which could support" the interpretation adopted by the district court).

A. The Research Program License Language Did Not Grant to Meso Exclusive Rights That Blocked Roche from Continuing to Use Its Pre-Existing Flow Cell Technology.

The language of the 1995 License and the conduct of the parties did not allow a reasonable jury a sufficient basis to find that Meso holds the license rights at the core of its infringement claims. The Research Program prong of Meso's claim relies on the 1995 License grant of exclusive rights "to practice the IGEN Technology to make, use and sell products or processes . . . developed in the course of the Research Program . . . ." Appx5207, §2.1. On its face, this language gave Meso the exclusive right to make, use and sell any *new* products or improvements created or invented during the Research Program (*e.g.*, Meso's multi-array plates and Meso's Sector instruments). Yet Meso did not assert, nor could it, that it created or invented Roche's technologies covered by the broad '729 and '779 method patents (first filed in 1986 and 1994, respectively). Nor did Meso contend that it improved or caused any change to how IGEN and Roche had used TPA or microparticles since the early 1990s. *See* Appx6853, Appx4332-4334 (588:3-590:23, 592:13-596:4). In fact, Meso conceded that the technologies in the Roche products pre-dated the creation of Meso and that Meso had previously told a federal court that Meso used ECL in a manner "dramatically" and "fundamentally" different from the technology used by IGEN and Roche. Appx4231-4232 (366:13-368:9), Appx4236 (386:6-387:9), Appx4243-4244 (415:24-419:8), Appx4333 (592:24-594:6), Appx6776, ¶5.

Instead, Meso's theory is that any aspect of ECL technology evaluated or tested during the Research Program was thereby "developed in the course of the Research Program" and, as a result, all rights to the patents covering such technology transferred to Meso when such work occurred. Applying Meso's interpretation to the claimed infringement of the '729 patent, Meso's position can be summarized as:

> (1) because Meso developed its multi-array instrument that used TPA as the co-reactant, and
>
> (2) because the use of TPA as a co-reactant for ECL falls within the scope of claims 38 and 44 of the '729 patent,
>
> (3) therefore, Meso received, at the time that this work took place, a transfer from IGEN of exclusive rights to the entirety of claims 38 and 44 of the '729 patent (including the use of TPA) as to all products or methods covered by claims 38 and 44—*even the IGEN and Roche methods and products that used TPA and that pre-dated Meso's existence*.

Under this theory, Roche products using ECL methods covered by claims 38 and 44 infringed Meso's license rights. *See* Appx4317 (529:8-12, 529:24-530:5), Appx4321 (545:11-546:5). Key to Meso's infringement theory here, Meso contends that even products and processes that pre-date the existence of Meso or the Research Program (*e.g.*, IGEN and Roche flow cells) infringe Meso's rights. *See* Appx4231-4232 (366:13-368:17), Appx4235-4236 (382:9-387:21), Appx4333-4334 (592:24-596:4).

Similarly, for the '779 patent, Meso contends that because the Research Program included work with microparticles (although not the type of microparticles used in Roche and IGEN's products), Meso gained, at the time of that work,

exclusive rights to the entirety of claim 1 of the '779 patent. Appx118, Appx4235 (381:18-382:8), Appx4236-4237 (387:22-391:9), Appx4323 (556:12-21), Appx4325-4326 (561:17-562:4, 564:14-18). Again, Meso claims the use of microparticles in Roche products infringes and Meso treats as irrelevant the fact that the Roche products use a different type of microparticle and have done so since before the Research Program began.

Meso's proposed contract construction is wrong as a matter of law. The language of Section 2.1 does not state that IGEN would transfer core, pre-existing ECL technology *exclusively* to Meso merely because Meso *evaluated or tested* that technology. The 1995 License language granted Meso exclusive rights to improvements made during the Research Program but nothing in Section 2.1 indicates that Meso and only Meso would have the right to exploit the full scope of the pre-existing patent claims and to ban pre-existing ECL technologies.[3] Meso did not introduce a single document as extrinsic evidence to support its interpretation. The district court should have granted summary judgment or JMOL. *See Rhone-*

[3] Meso's interpretation also renders words of the license grant superfluous because, if the entire patent claims transferred to Meso, the license should have granted an "exclusive . . . license *to the IGEN Technology"* rather than an "exclusive . . . license *to practice the IGEN Technology to make, use and sell products or processes*" that fell within categories A and B. Appx5207, §2.1 (emphasis added).

Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co., 616 A.2d 1192, 1196 (Del. 1992) (language of a contract controls absent some ambiguity).

The undisputed course of performance also precluded a reasonable jury from accepting Meso's made-for-litigation construction. Section 4.1 of the JVA 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." Appx5111, §4.1. All of the IGEN and Roche flow cell products used both TPA and microparticles. Appx4447 (881:17-882:8, 883:10-20). Yet IGEN (later BioVeris) and Roche continued to sell the flow cell ECL products from 1995 through 2007 without any objection by Meso. Appx4243 (412:9-415:10), Appx4298 (451:7-453:25), Appx4549 (1133:14-1135:21). This conduct demonstrated conclusively that neither IGEN nor Meso understood or interpreted the Research Program prong of Section 2.1 to grant exclusive rights to the entirety of the patent claim. *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."); *Viking Pump, Inc. v. Century Indem. Co.*, 2 A.3d 76, 101 (Del. Ch. 2009) (course of performance acquiesced in without objection is given great weight in interpreting agreement). Similarly, Meso's current '939 patent infringement claim interpretation does not square with the conduct of the parties

when IGEN and Meso assigned the '939 patent to IGEN and not to Meso.[4] The pre-2007 interpretation, evidenced by the parties' conduct in that 12-year period, should control.

Neither Dr. Richard Massey, who negotiated the 1995 License for IGEN, nor other IGEN witnesses interpreted the agreement to give Meso control of entire patent claims. Appx4771-4773 (1652:11-25, 1655:17-1656:2, 1660:24-1661:21), Appx4776 (1673:2-1675:8), Appx4544 (1116:12-1117:5), Appx4354 (676:2-677:5, 678:4-12), Appx4457-4458 (923:6-924:10). Delaware law presumes that Massey and the other IGEN directors acted in good faith and in the best interests of IGEN. *Bragger v. Budacz*, Civ. A. No. 13376, 1994 WL 698609, at *5 (Del. Ch. Dec. 7, 1994). Even if Wohlstadter held an unexpressed belief, the "subjective understandings of a party to a contract which are not communicated to the other

[4] Meso contended that the Research Program work yielded the sulfonated ruthenium label or "Sulfo-TAG" described in claim 33 of the '939 patent (Appx4327-4328 (570:21-571:4)) but the evidence at trial was insufficient for the jury to find that Meso held exclusive rights to the entirety of the '939 patent claim. The inventors of the '939 patent, following Wohlstadter's direction, assigned that patent to IGEN, not Meso. Appx183, Appx4239 (396:2-397:8), Appx4650 (1378:18-1379:7). The 2001 Amendment to the 1995 License listed the proposed application for the '939 patent among those owned by IGEN. Appx5325, Appx4219-4220 (319:19-320:2). In 2004, Meso sent IGEN a cumulative summary of all patents for products or improvements "*developed in connection with the Research Program.*" *See* Appx7380, Appx4239-4240 (397:9-400:14) (emphasis added). That report lists neither the '939 patent nor "Sulfo-TAG." *Id.*

party are of no effect." *United Rentals, Inc. v. RAM Holdings, Inc.*, 937 A.2d 810, 836 n.122 (Del. Ch. 2007) (citing *Supermex Trading Co. v. Strategic Sols. Grp., Inc.*, C.A. No. 16183, 1998 WL 229530, at *3 (Del. Ch. May 1, 1998); *see also United Rentals*, 937 A.2d at 835 ("private, subjective feelings of the negotiators are irrelevant and unhelpful" in the absence of evidence that "the other party knew or should have known of such belief"); *Acierno v. Worthy Bros. Pipeline Corp.*, 693 A.2d 1066, 1070 (Del. 1997) (lower court's analysis was incorrect because it was based on subjective intent). Contrary to the district court's suggestion, nothing in the record contained more than Wohlstadter's unexpressed belief. *See* Appx84 (citing Appx4212 (Wohlstadter Tr. 289-90).

Further, all relevant evidence contradicted any such unexpressed belief. IGEN's ECL technology and patent rights were its "crown jewels" and not items IGEN would treat cavalierly. Appx4771 (1652:4-10). If either Meso or the publicly-traded IGEN believed that the Research Program work caused those valuable patents to transfer from IGEN to Meso, the parties would have tracked which claims transferred. That never happened. Appx4338 (614:13-615:16), Appx4650-4652 (1378:3-17, 1381:20-1383:13, 1387:5-1388:8). Research Summaries prepared by Meso in 2000 also identified certain technology (including microparticles (beads) and TPA) as IGEN's. Appx6681-6682, Appx6163-6166. When the JVA ended in 2004 and third party appraisers valued the IGEN/BioVeris 31% ownership interest

in Meso, BioVeris received only approximately $10 million for that interest—nothing close to what Roche paid for the 2003 License. Appx4300-4301 (462:16-465:13). Further, the IGEN and BioVeris Form 10-K and other SEC filings, verified by the officers, never suggested that IGEN no longer held rights to its patent portfolio or that its continued sales of ECL products infringed exclusive patent rights owned by Meso. *See, e.g.*, Appx6618-6624, Appx6924-6929, Appx7603-7608, Appx7785-7792, Appx4543-4544 (1110:14-1113:7).

This Court should reverse the district court as to the Research Program claims (jury verdict questions 1, 3 and 5) because Meso's entirety of the patent theory fails as a matter of law and because, even if ambiguity existed, no reasonable jury could find for Meso on this issue.

B. The Evidence Does Not Support the Jury Finding That TPA Is Within the Definition of "Research Technologies."

The Court should also vacate the jury finding that Meso held exclusive rights to claims 38 and 44 of the '729 patent because Meso's current interpretation of "Research Technologies" contradicts what the parties contemplated or could have understood when entering the 1995 License. The contemporaneous meaning at the time of the contract should control because, under Delaware law, "what a reasonable person in the position of the parties would have thought the language of a contract means" has paramount importance in contract interpretation. *See Lorillard Tobacco Co. v. Am. Legacy Found.,* 903 A.2d 728, 738-39 (Del. 2006); *see also Osborn ex*

rel. Osborn v. Kemp, 991 A.2d 1153, 1160 (Del. 2010) ("An unreasonable interpretation produces an absurd result or one that no reasonable person would have accepted when entering the contract.").

Section 1.11 of the JVA defined Research Technologies to include an "agent that extends the electric potential of an electrode in the direction perpendicular to its surface." Appx5111, §1.11.[5] In 1995, neither party knew that TPA could enable an ECL reaction to occur away from the electrode surface. Appx4240 (401:22-402:11).[6] If asked this question when the 1995 License was signed or in the years immediately following, neither IGEN nor Meso would have thought TPA fell within the definition of Research Technologies.

Meso agrees that the function of TPA in an ECL reaction never changed but asserts that experiments conducted in 1999 enabled a new understanding that ECL reactions involving TPA occur not only at the surface of the electrode but also at a slight distance above the electrode.[7] Appx4240-4241 (403:3-404:17), Appx4334

[5] Section 2.1 of the 1995 License used the term Research Technologies but the parties defined that term in Section 1.11 of the JVA. Appx5111, Appx5207.

[6] By contrast, the examples of agents that extend the electric potential found at the end of JVA Section 1.11 ("electrically conducting polymers" and "conducting micro-particles") match non-TPA concepts listed in a patent application that Wohlstadter filed in March 1995 (8 months before signing the JVA). Appx6739, Appx4241-4242 (406:19-409:16).

[7] Under Meso's theory, even a much later, third party study finding that TPA extended the electric potential of the electrode would change the respective patent

(595:13-596:4). Discarding the contemporaneous understanding from 1995, Meso wants to change the 1995 deal based on a later-discovered learning. Delaware courts have rejected expansive interpretations of contract terms that would include unanticipated future developments. *See, e.g.*, *Alexandria Coca-Cola Bottling Co., Ltd. v. Coca-Cola Co.*, 637 F. Supp. 1220, 1229 (D. Del. 1984) (rejecting expansive interpretation of a contract term that would include future product developments not known to the parties at the time of contracting); *see also Coca-Cola Bottling Co. of Shreveport v. Coca-Cola Co.*, 769 F. Supp. 671, 705 (D. Del. 1991) ("the Court resists the temptation to conform the contract to modern circumstances by adding contract terms not assented to originally"), *aff'd,* 988 F.2d 414, 428 (3d Cir. 1993).

Again, the conduct of the parties after the 1999 "discovery" is conclusive. First, before Roche acquired BioVeris in 2007, Meso never told anyone at IGEN, BioVeris, or Roche that Meso claimed exclusive rights to use TPA in an ECL reaction. Appx4296 (443:7-444:1), Appx4297 (449:1-5), Appx4300 (460:13-461:4). Even when the Meso JVA and License were amended in 2001 after contentious negotiations, this language was not edited. *See* Appx4244-4245(419:9-421:21).[8]

---

rights held between IGEN and Meso and give Meso exclusive control of the only amine used in commercial applications of ECL. *See* Appx4240 (401:6-12), Appx4447 (881:17-882:8).

[8] The 2001 amendments involved numerous changes to the documents, including to the definition of Research Technologies, but they made no change to clarify the "agent to extent the electric potential" clause. Appx5235-5236 (amending §1.11).

Second, TPA is a component for commercial ECL products and IGEN intended to (and did) continue to make, sell, and license ECL products using TPA after the 1995 License and after the 2001 amendments to the 1995 License and JVA. *See, e.g.*, Appx4769 (1646:8-24), Appx4771 (1653:1-22), Appx4457 (920:6-24). Nonetheless, Meso never tried to stop these IGEN sales of ECL products. Appx4243 (412:9-415:10), Appx4297 (449:1-5), Appx4457 (922:1-11). After the IGEN-Meso joint venture terminated in February 2004, Meso never claimed that BioVeris products using TPA violated Meso's exclusive rights under the 1995 License. *Id.*; *see also* Appx4298 (451:11-453:25), Appx4549 (1135:11-21). Nor did it make such claims as to Roche sales outside the 2003 Field. This conduct before the controversy with Roche arose "is deemed of great, if not controlling, influence." *See Old Colony Tr.*, 230 U.S. at 118. The evidence did not permit a reasonable jury to find in favor of Meso on question 6 of the verdict.

The Court should, therefore, reverse and order that judgment be entered in favor of Roche. Because the judgment in favor of Meso on its contract claim against BioVeris is predicated on a finding that Roche materially infringed Meso's license rights, the Court also should vacate and reverse that portion of the judgment.

The parties would not have remained silent if both understood (or even suspected) that TPA might fall within the Research Technologies definition.

III. The Jury's Induced Infringement Verdict Is Unsupported and Legally Incorrect.

Meso brought only induced infringement claims under the '729 and '779 patent methods, which required that Meso prove not only direct infringement by Roche customers but also affirmative acts of inducement by Roche within the limitations period and with the requisite intent. *See Enplas Display Device Corp. v. Seoul Semiconductors Co., Ltd.*, 909 F.3d 398, 407 (Fed. Cir. 2018) (patentee must first show "that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement") (citation omitted)). Because conduct occurring years before the limitations period cannot suffice, the jury heard no evidence sufficient to satisfy Meso's burden. Further, the district court's willfulness decision demonstrates the lack of evidence that Roche had the requisite knowledge or willful blindness required for inducement. The Court should vacate the judgment for inducement or, at a minimum, order a new trial at which the proper legal standards will apply.

A. Meso Failed to Show an Affirmative Inducing Act Within the Limitations Period Caused Infringement by Roche Customers.

A party asserting an induced infringement claim can recover only those damages caused by *acts of inducement* that *occurred* no more than six years before the filing of the complaint. *See Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo*

Co., Ltd., 754 F.2d 345, 348 (Fed. Cir. 1985) (applying § 286 to induced infringement claim under § 271); *see also SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 137 S. Ct. 954, 961 (2017) (interpreting 35 U.S.C. § 286 as establishing limitations period). Meso filed its counterclaim in April 2017, so the six-year limitations period began in April 2011. *See* Appx1023-1084.

The district court declined to follow *Standard Oil* and held that acts occurring in 2007 would suffice if that earlier conduct caused an effect after April 2011. Appx88-89. The district court then justified the jury verdict by concluding that Roche's press release and announcement to then-existing customers in 2007[9] allowed the jury to find that the 2007 conduct constituted inducement within the limitations period based on subsequent sales of ECL products to customers after April 2011. *Id.* This was error on three levels.

First, in *Standard Oil*, this Court held that "[i]f [defendant'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." (emphasis added). *Standard Oil* controls here. *See also* 35 U.S.C. § 271(b) (liability only for one who "actively

[9] Meso offered three exhibits on this point: an April 4, 2007 Roche Press Release (Appx6036-6038), a June 2007 form customer letter announcing Roche's acquisition of BioVeris (Appx5898), and a June 26, 2007 internal Roche email announcing the acquisition. Appx5899-5906. The jury heard no evidence of any specific inducing acts after 2007.

induces infringement of a patent."). Requiring that the conduct actively inducing infringement occur within six years before suit follows the general policy rationale of protecting defendants from stale claims for which memories have faded or witnesses and records no longer exist. Meso filed its counterclaim nearly ten years after the statements by Roche in 2007. That is far too late.

Second, neither Roche's 2007 decision to stop affixing field restriction labels on its ECL products nor Roche's post-April 2011 sales constitute an affirmative act of inducement. The cessation of labeling is not an affirmative act of inducement because Meso needed to show that Roche "took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *See Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015) (rejecting argument that the label on medication indicated only for prophylaxis of gout "need[ed] to contain a 'clear statement' to show that it was avoiding gout flare indication"). Nor can mere sales serve as acts of inducement, even if Roche suspected or knew that its customers would engage in both in-field and out-of-field uses of those products. *Id.* at 630 ("[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.") (quoting *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 2163, 1276 n.6 (Fed. Cir. 2004)).

Third, Meso did not demonstrate causation as to any (or all) customers, yet included all Roche sales in the royalty base for damages. To support a reasonable inference of direct infringement via circumstantial evidence, a plaintiff will show that the alleged infringer induced the infringing use contemporaneously with sale of the product. *See, e.g.*, *Convolve, Inc. v. Compaq Computer Corp.*, 527 F. App'x 910, 929 (Fed. Cir. 2013) ("evidence of specific tools, with attendant instructions, on how to use the drives in an infringing way" was sufficient circumstantial evidence of direct infringement); *see also Takeda*, 785 F.3d at 631-32 ("vague label language cannot be combined with speculation about how [customers] may act to find inducement"). But that did not happen here. Meso made no attempt to prove that Roche customers making purchases between 2011 and 2019 received the 2007 communication and then used the much-later-purchased Roche products outside the 2003 Field.[10] Roche sales grew considerably between 2007 and 2019 yet Meso did not explain how customers that first acquired Roche products after 2007 were induced to infringe by the 2007 conduct. Appx4658-4659 (1410:8-1414:21). Meso made no attempt to isolate for damage purposes which customers received a Roche communication in 2007 and which customers first purchased years later.

[10] The situation here, when the alleged inducing communication occurred four to ten years before the product sale or delivery, differs from that presented when every alleged infringing user received the product with instructions or a label that teaches the infringing use.

In sum, the Court should reverse and order judgment for Roche because the record lacks evidence sufficient for a reasonable jury to find that Roche induced infringement within the limitations period. Alternatively, the Court should order a new trial both due to a failure of proof and because the jury instruction (which allowed the jury to find inducement based solely on *effects*, rather than inducing *acts*, in the limitations period) was legally incorrect. Appx3688-3689, Appx4765 (1627:4-10), Appx4804 (1786:13-22).

B. Meso Failed to Prove That Roche Acted with the Requisite Knowledge and Specific Intent.

The district court incorrectly applied a negligence standard rather than requiring specific intent for inducement. Active inducement requires knowledge of the patent, knowledge that the induced acts will infringe, and "intent to 'bring about the desired result, which is infringement.'" *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015); *Enplas*, 909 F.3d at 407; *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). The inducement knowledge requirement "may be satisfied by a showing of actual knowledge or willful blindness." *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1372-73 (Fed. Cir. 2015). "Willful blindness is a high standard, requiring that the alleged inducer (1) subjectively believe that there is a high probability that a fact exists and (2) take deliberate actions to avoid learning of that fact." *Id.* (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 768-69 (2011)).

Here the district court applied a less rigorous "should have known" definition of intent. (*See* Appx89 ("The specific intent required for induced infringement is that the alleged infringer knew or should have known his actions would induce actual infringement . . .") (citing *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 811 (D. Del. 2017));[11] Appx56 ("[t]he specific intent element 'requires that the alleged infringer knew or ***should have known*** his actions would induce actual infringement.'" (quoting *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (original emphasis)). This Court previously rejected the "knew or should have known" standard as inconsistent with Supreme Court precedent and "no longer good law" because it permitted the jury to find induced infringement based on mere negligence where knowledge is required. *Commil*, 720 F.3d 1361, 1366-67 (Fed. Cir. 2013), *vacated in part on other grounds*, 575 U.S. 632 (2015) (finding jury instruction that used "knew or should have known" language erroneous citing the Supreme Court's articulation of the appropriate standard in *Global-Tech*); *see also Omega Patents, LLC v. CalAmp Corp.*, 920 F.3d 1337, 1349 (Fed. Cir. 2019) (liability for inducement can only exist

[11] The district court cited *Orexigen*, which does not support the application of the "knew or should have known" standard. *Orexigen*, 282 F. Supp. 3d at 811 (citing *Global-Tech*, 131 S. Ct. at 2068) ("knowledge requirement may be satisfied by showing actual knowledge or willful blindness").

if the defendant knew of the patent and also knew that the induced acts constitute patent infringement)).

The district court's JMOL decision on willfulness demonstrates the prejudice to Roche from applying a "should have known" standard rather than the required "willful blindness." Appx4648 (1370:13-1371:25). In overturning the jury finding of willfulness, the district court noted that this case differs from the typical patent infringement case in that liability turned on the contract interpretation of the 1995 License and JVA and Roche had a good faith basis to believe that Meso's license did not cover Roche's products. *See* Appx94. The district court held that Roche's interpretation of the operative contracts was "entirely reasonable," the jury could have reasonably sided with Roche on the contract interpretation, and "at no time did Roche have a subjective intent to infringe (or induce infringement of) Meso's patent rights." Appx94-95.

Even if Roche should have known that some customers used Roche products in a manner inconsistent with the 2003 License,[12] the issue is whether Roche knew

[12] The 2003 License recognized that customers could use the Roche products outside the 2003 Field as long as Roche did not knowingly induce that use. Appx5434-5438, §§1.7(c), 2.5(b). After any such use was discovered, *and on a customer-specific basis*, IGEN/BioVeris could decide whether to tell Roche to stop such sales or to continue with a payment to BioVeris pursuant to Section 2.5 of the 2003 License. Appx5434-5435, Appx5438, Appx4556 (1161:23–1163:22). Meso had no rights or role in that mechanism. *Meso Scale Diagnostics, LLC,* 2014 WL 2919333, at *9, n.86; Appx4570 (1219:10-23).

or was willfully blind that such uses infringed Meso's rights. Just as the record lacked evidence sufficient to uphold the jury finding of willfulness,[13] so too the record is insufficient to sustain a finding of induced infringement when the proper standard for intent is applied.

The Court should vacate and reverse the verdict for induced infringement as to claims 38 and 44 of the '729 patent and claim 1 of the '779 patent or, at a minimum, order a new trial with the proper legal standards for the time and effect of an alleged inducing act and for specific intent.

IV. Exhaustion Bars Post-Sale Restrictions on Sales to Customers Who Lawfully Acquired Roche's Instruments for In-Field Use.

There can be no liability based on Roche's sales to dual-use customers—customers who used Roche's immunoassay products both within the 2003 Field and out-of-Field—because any patent rights Meso has were exhausted when the customers acquired Roche instruments for authorized in-field use. *Keurig, Inc. v.*

[13] The district court noted that, in addition to Roche holding an "entirely reasonable" interpretation of the 1995 license, Roche received assurances from BioVeris that Meso's license rights would not interfere with Roche's ability to sell the Roche products outside the 2003 Field. *See* Appx94-95. The acquisition agreement included a specific representation that the BioVeris SEC filings did not omit a material fact in their SEC filings. *See, e.g.*, Appx4517 (1006:20–1008:3), Appx4558-4559 (1171:20–1173:18), Appx8095. Those filings noted the potential for future disagreements with Meso on BioVeris's ability to expand its business but said nothing suggesting that the existing flow cell ECL products violated Meso's license rights. Appx5837, Appx95.

Sturm Foods, Inc., 732 F.3d 1370, 1373 (Fed. Cir. 2013) ("The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item.") (quoting *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008)). All the asserted method claims require use by dual-use customers of Roche instruments that those customers lawfully obtained, so those customers did not infringe Meso's patent rights when they used the instruments to perform the methods for out-of-Field tests.

The '729 and '779 method patents cover the use of TPA and microparticles in an ECL reaction. The patents claim an ECL method and do not claim a specific type of immunoassay or a particular reagent. For all Roche immunoassay products, that ECL reaction occurs in Roche's instrument. Appx4444 (868:11-869:16). The customer loads reagent packs (each type unique to a particular immunoassay) and containers of TPA into the instrument and the instrument conducts all the steps needed to mix the sample with the reagents and then initiate the ECL reaction in order to measure the output. The '729 and '779 method claims are essential to any ECL measurement made in the Roche instruments; the instruments cannot function without using TPA and microparticles and thereby infringing those method claims. Appx4240 (401:6-12), Appx4317 (528:2-529:7), Appx4443-4444 (864:22-871:19).

The 2003 License authorized Roche to provide customers with instruments and reagent packs for use within the 2003 Field and the district court failed to apply

the important distinction between so-called "single-use" and "dual-use" customers.[14] By definition, dual-use customers used the instruments for in-Field use. The 2003 License anticipated that some customers purchasing Roche products for authorized uses might also make out-of-Field use without Roche's knowledge (Appx5434-5438, §§1.7(c), 2.5(b)) and Meso claimed infringement by those dual-use customers (and induced infringement by Roche) only as to their use of the Roche products outside the 2003 Field. The issue is significant as dual-use customers accounted for approximately $156 million of the $183 million royalty base estimated by Meso's damages expert. Appx4785 (1707:7-15) (single use sales account for $26.7 million).

Under the doctrine of patent exhaustion, the sale of an item "terminates all patent rights to that item." *Quanta*, 553 U.S. at 625. "The same is true when a licensee sells a patented product. 'That licensee's sale is treated, for purposes of patent exhaustion, as if the patentee made the sale itself.'" *MiiCs & Partners Am., Inc. v. Toshiba Corp.*, 274 F. Supp. 3d 247, 253 (D. Del. 2017) (quoting *Impression Prod., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1535 (2017)). "Patent exhaustion reflects the principle that, when an item passes into commerce, it should not be shaded by a legal cloud on title as it moves through the marketplace." *Lexmark*, 137

[14] The single-use customers used the products only outside the authorized Field (Appx4785 (1707:7-20)), and Roche agrees that patent exhaustion does not apply to those sales.

S. Ct. at 1534.

The ’729 and ’779 claims are method claims for which Meso relied on alleged direct infringement by Roche customers. Appx4804 (1785:18-1786:1). But the doctrine of patent exhaustion applies because the 2003 License authorized Roche to sell instruments to those customers for use in the 2003 Field. Appx5434-5438, §§1.7(c), 2.5(b). Once a dual-use customer had the Roche instrument, it could use the instrument for any purpose—inside or outside of the 2003 Field—without infringing the ’729 and ’779 method patent claims. *Lexmark*, 137 S. Ct. at 1535 (once the product is sold, “that sale exhausts [ ] patent rights, regardless of any post-sale restrictions the patentee purports to impose”). The exhaustion doctrine therefore bars any infringement claim for the ’729 and ’779 patents based on out-of-field uses by dual-use customers. No direct infringement, no inducement claim.

Keurig controls here. Keurig brought a claim for induced infringement claiming that the defendant sold brewing cartridges that were used by the defendant’s customers in brewing devices sold by Keurig and using a patented method of brewing coffee. *Keurig*, 732 F.3d at 1371-72. The Court affirmed the district court’s summary judgment holding that Keurig’s claim was barred by exhaustion. *Id.* at 1375. Quoting *Quanta*, the Court held that the sale of the brewer (like Roche’s instruments) carried with it the right to use the patented method, which was practiced when using the brewer, even with cartridges sold by the defendant

(like Roche's reagents): "[W]here a person ha[s] purchased a patented machine of the patentee or his assignee, this purchase carrie[s] with it the right to the use of the machine so long as it [is] capable of use." *Id.* at 1374 (quoting *Quanta*, 553 U.S. at 625) (alterations in original).

So too here. The 2003 License authorized Roche to sell instruments for uses within the 2003 Field to customers who would in using the machines necessarily perform the methods claimed in the '779 and '729 patents. Appx5434-5435, §§1.7(a)-(c). As in *Keurig*, the authorized transfer of the instruments exhausted Meso's license rights so the customers' use of those instruments to also perform the patented ECL methods outside the 2003 Field cannot infringe. With no direct infringement claim against the dual-use customers, exhaustion bars any claim for inducing infringement of the '729 and '779 patents based on out-of-Field uses by those customers.

The district court decided the patent exhaustion issue and, in a one-paragraph analysis, held that patent exhaustion did not apply because Roche's unrestricted sales of the ECL products violated the 2003 License. Appx91-92. That holding conflicts with the Supreme Court's decision in *Lexmark* and this Court's decision in *Keurig*. The district court ruling failed to recognize both that Meso based its '729 and '779 liability theories on indirect infringement and that Roche's patent exhaustion argument applied to only the dual-use customers, whose acquisition of the