

2023-2054

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

RESTEM, LLC,

Appellant,

– v. –

JADI CELL, LLC,

Appellee.

*On Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2021-01535*

REPLY BRIEF FOR APPELLANT

KEVIN C. HOOPER
ETHAN R. FITZPATRICK
JOSEPH J. RICHETTI
ALEXANDER D. WALDEN
BRYAN CAVE LEIGHTON PAISNER LLP
1290 Avenue of the Americas
New York, New York 10104
(212) 541-2000
kevin.hooper@bclplaw.com
ethan.fitzpatrick@bclplaw.com
joe.richetti@bclplaw.com
alexander.walden@bclplaw.com

K. LEE MARSHALL
BRYAN CAVE LEIGHTON PAISNER LLP
Three Embarcadero Center
7th Floor
San Francisco, California 94111
(415) 675-3444
klmarshall@bclplaw.com

Counsel for Appellant Restem, LLC

DECEMBER 11, 2023

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 2023-2054

Short Case Caption Restem, LLC v. Jadi Cell, LLC

Filing Party/Entity Restem, LLC

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

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

Date: 12/11/2023

Signature: /s/ Kevin C. Hooper

Name: Kevin C. Hooper

<p>1. Represented Entities. Fed. Cir. R. 47.4(a)(1).</p>	<p>2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).</p>	<p>3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).</p>
<p>Provide the full names of all entities represented by undersigned counsel in this case.</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>	<p>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.</p> <p><input checked="" type="checkbox"/> None/Not Applicable</p>
<p>Restem, LLC</p>		

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

BRYAN CAVE LEIGHTON PAISNER LLP	Kevin C. Hooper	Ethan R. Fitzpatrick
Joseph J. Richetti	Alexander D. Walden	K. Lee Marshall

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes (file separate notice; see below) No N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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

CERTIFICATE OF INTEREST

TABLE OF AUTHORITIES iv

ARGUMENT 1

A. THE BOARD’S IMPLICIT CLAIM CONSTRUCTIONS ARE LEGALLY
ERRONEOUS 1

1. The Board Erred by Implicitly Narrowing the Scope of the Claimed
Process to Require Additional Steps, Factors, and Conditions Not
Recited in the Claims 3

a. The Board’s express claim construction correctly determined that the
two-step process expressly recited in the claims produces the claimed
product 3

b. The Board’s implicit construction narrowed the scope of the claims and
is contradicted by the intrinsic record..... 4

2. The Board Erred by Applying an Implicit Construction for “an Isolated
Cell” that Disregards the Definitions in the Specification. 10

B. THE BOARD LEGALLY ERRED BY MISAPPLYING THE LAW ON
INHERENCY 15

1. Jadi Cell Misunderstands the Law on Product-By-Process Claims 15

2. The Board Erred by Finding that the Prior Art Teaches the Same
Process Recited in the Claims But Somehow Produces A Different
Product 21

C. THE BOARD’S ADDITIONAL FINDING WITH RESPECT TO CLAIM 9
IS WHOLLY UNSUPPORTED..... 27

D. CONCLUSION..... 28

CERTIFICATE OF COMPLIANCE

TABLE OF AUTHORITIES

Cases

<i>3M Innovative Properties Co. v. Avery Dennison Corp.</i> , 350 F.3d 1365 (Fed. Cir. 2003)	11, 13
<i>Amazon.com, Inc. v. Barnesandnoble.com, Inc.</i> , 239 F.3d 1343 (Fed. Cir. 2001)	10
<i>Amgen Inc. v. F. Hoffman–La Roche Ltd.</i> , 580 F.3d 1340 (Fed. Cir. 2009)	18
<i>Arbutus Biopharma Corp. v. ModernaTX, Inc.</i> , 65 F.4th 656 (Fed. Cir. 2023)	21
<i>Atl. Thermoplastics Co. v. Faytex Corp.</i> , 970 F.2d 834 (Fed. Cir. 1992)	16, 18, 22
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989).....	16
<i>Bos. Sci. Corp. v. Johnson & Johnson</i> , 647 F.3d 1353 (Fed. Cir. 2011)	23
<i>In re Downing</i> , 754 F. App'x 988 (Fed. Cir. 2018).....	16, 21, 22
<i>Genentech, Inc. v. Novo Nordisk A/S</i> , 108 F.3d 1361 (Fed. Cir. 1997)	20
<i>Greenliant Sys., Inc. v. Xicor LLC</i> , 692 F.3d 1261 (Fed. Cir. 2012)	19
<i>Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.</i> , 93 F. App'x 225 (Fed. Cir. 2004).....	8
<i>King Pharmaceuticals, Inc. v. Eon Labs, Inc.</i> , 616 F.3d 1267 (Fed. Cir. 2010)	6, 21
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995)	20

Mentor Corp. v. Coloplast, Inc.,
298 F.2d 992 (Fed. Cir. 1993)16

Optical Disc Corp. v. Del Mar Avionics,
208 F.3d 1324 (Fed. Cir. 2000)8

In re Sang-Su Lee,
277 F.3d 1338 (Fed. Cir. 2002)28

SmithKline Beecham Corp. v. Apotex Corp.,
439 F.3d 1312 (Fed. Cir. 2006)16

In re Thorpe,
777 F.2d 695 (Fed. Cir. 1985)16, 18

V-Formation, Inc. v. Benetton Group SpA,
401 F.3d 1307 (Fed. Cir. 2005)8

Vitronics Corp. v. Conceptronic, Inc.,
90 F.3d 1576 (Fed. Cir. 1996)8

In re Wohnsiedler,
315 F.2d 934 (C.C.P.A. 1963)17

Teva Pharms. USA, Inc. v. Sandoz, Inc.,
789 F.3d 1335 (Fed. Cir. 2015)8

ARGUMENT

There is no dispute the challenged claims are “product-by-process” claims that recite a two-step process for producing the claimed product, *i.e.*, an isolated cell having a specified marker pattern. Red Br., 3, 5. There is also no dispute the prior art teaches an isolated cell produced by this same two-step process. *Id.* Accordingly, the only natural conclusion is the prior art processes produce the claimed product. The Board erroneously concluded, however, that the isolated cells produced by the prior art are not necessarily the same as the claimed cells. This conclusion was founded upon two fundamental errors: (1) implicit constructions that improperly narrowed the claims, and (2) finding that *the claimed process* does not necessarily produce the claimed product. Jadi Cell’s attempts to explain away these critical errors and prop-up the Board’s decision completely miss the mark.

A. THE BOARD’S IMPLICIT CLAIM CONSTRUCTIONS ARE LEGALLY ERRONEOUS

The Board’s decision improperly relied upon two implicit claim constructions. First, the Board distinguished the prior art from the claims by finding that the prior art did not disclose certain embodiments described in the ’176 patent specification, as well as other unspecified process “factors” and “conditions,” purportedly needed to make isolated cells with the claimed marker patterns. *See, e.g.*, Appx39 (“Majore’s process differs from at least the interior-down embodiment disclosed in the ’176 patent”); *see also* Blue Br., 32-42. The Board relied on these alleged

distinctions to determine the prior art did not anticipate the claims. Appx38-43. These alleged distinctions, however, are nowhere in the claims. By requiring the prior art to disclose these additional process requirements, the Board's analysis ***implicitly narrowed the scope of the claims***. Significantly, this implicit construction is in direct conflict with all of the intrinsic evidence, as well the Board's express claim constructions. Appx18-24. Apparently recognizing this glaring issue, Jadi Cell baldly asserts the implicit construction was a "harmless error." Red Br., 72 at n. 14. Jadi Cell also attempts to sidestep the issue entirely by portraying the added process requirements as "uncontested facts." Red Br., 47-48; *id.*, 7-8, 70-73. Not so. These added process requirements go squarely to the scope of the claims and, as Jadi Cell acknowledges (Red Br., 6-7, 35-40), formed the basis for the Board's decision that the prior art does not render the claims unpatentable (Appx36-43).

Second, the Board implicitly construed "an isolated cell" as meaning "a population of cells." Appx28; *see also* Blue Br., 46-50. In so doing, ***the Board impermissibly overrode the express definitions set forth in the specification***, which unequivocally define this term as "one or more cells" isolated from the SL. Appx96, 6:29-34. Tellingly, Jadi Cell completely ignores its own lexicography and, instead, points to certain extrinsic evidence and cherry-picked portions of the prosecution history. Red Br., 4, 46, 51-53. This is improper. The definitions in the specification control. Jadi Cell also incorrectly argues again that the Board's implicit construction

was a “harmless error.” Red Br., 4-5, 46. The Board’s erroneous implicit construction was embedded within its express construction of “expresses/does not express”—one of only two terms the Board found necessary to construe to render a judgment—and infected several other aspects of the decision.

1. The Board Erred by Implicitly Narrowing the Scope of the Claimed Process to Require Additional Steps, Factors, and Conditions Not Recited in the Claims

a. The Board’s express claim construction correctly determined that the two-step process expressly recited in the claims produces the claimed product

In its claim construction analysis, the Board correctly construed the claimed process as simply requiring the two steps recited in the claims. Blue Br., 27-30. In so doing, the Board fully considered and rejected Jadi Cell’s attempts to read-in additional steps from the specification. *Id.* For example, the Board rejected Jadi Cell’s arguments that the claims require that the SL be placed “interior side down” on the substrate (*i.e.*, the “interior-down” embodiment), finding that this was only one of multiple embodiments disclosed in the specification. Appx24; *see also id.*, 19; Red Br., 63. Indeed, as the Board noted “[a]ccording to the ‘176 patent, the target allogenic cell or stem cell population is obtained from the subepithelial layer (SL) of a mammalian umbilical cord using one of a ‘variety of techniques’ so long as the technique ‘allows such extraction without significant damage to the cells.’” Appx4 (quoting Appx97, 8:1-2, 8:34-38). Thus, the Board correctly determined the claims

broadly cover all embodiments and examples described in the specification for performing the claimed process. Appx18-24; Blue Br., 37-38; *see also* Red Br., 6.

In sum, the Board’s express constructions correctly reflect that the claimed two-step process is all that is required to produce the claimed product. ***Significantly, Jadi Cell does not dispute that the Board’s express claim constructions are correct.***

Red. Br., 51 at n. 4.

b. The Board’s implicit construction narrowed the scope of the claims and is contradicted by the intrinsic record

The Board found that the prior art teaches isolating cells according to the same two-step process recited in the claims. *See, e.g.*, Appx31-34; Blue Br. at 30-32. In so doing, the Board again rejected Patent Owner’s arguments that the claimed process required additional steps and conditions, and reiterated that the claimed process is not limited to the “interior-down” embodiment. *See, e.g.*, Appx32.

Nevertheless, the Board then determined that the prior art did not “necessarily” teach an isolated cell *having the claimed marker pattern*. *See, e.g.*, Appx43. In particular, when analyzing the marker pattern claim limitations, the Board distinguished the prior art by implicitly importing various additional steps, factors, and conditions into the claimed process. Blue Br., 32-42. Indeed, the Board even **implicitly read back in the “interior-down” embodiment:**

Majore’s process **differs from at least the interior-down embodiment disclosed in the ‘176 patent**, which Patent Owner claims is the focus of the claims at issue.”

Appx39 (emphasis added); *see also* Appx61 (same for the Phan reference). Thus, by distinguishing the prior art on this basis, the Board implicitly narrowed the scope of the claims to require this particular “interior-down” embodiment.

Similarly, the Board implicitly narrowed the claimed process by reading in additional unspecified factors and conditions not even described in the specification. *See, e.g.*, Appx40-43; Blue Br., 32-42. Again, by relying on these additional “factors” and “conditions” to distinguish the prior art, the Board implicitly narrowed the scope of the claims to require additional process limitations. This was plainly improper.

Leaving aside the internal inconsistency with the Board’s own express constructions, these implicit constructions are directly at odds with the express claim language and the specification’s broad disclosure of the two-step process used to obtain the claimed isolated cells with the specified marker patterns. *Supra*, 3-4; Appx20-24. Indeed, the specification makes clear that any number of variations to the two claimed process steps may be used to obtain the claimed isolated cell, provided that it is derived from SL tissue. Blue Br., 43-44, 54-55. For example, the ’176 patent explains that the SL “can be cultured in any media capable of producing explants therefrom” (Appx94, 2:21-22) using “any substrate capable of deriving explants” (Appx94, 2:29-30), and using “various culturing conditions” (Appx94, 2:4-42), including *e.g.*, normoxic/hypoxic conditions (Appx94, 2:45-47; Appx98, 9:65-10:2), with/without use of enzymes (Appx94, 2:47-52), culturing for

any period of time sufficient to produce primary cultures (Appx98, 9:16-18), with or without animal components (Appx97, 7:25-28), and employing one or more of various growth factors (Appx98, 10:7-12).

Significantly, the Board's determination that the prior art did not anticipate the claims was based entirely on this implicit construction. Appx36-43. Thus, the Board's implicit claim construction and ultimate patentability determination should be reversed.

Jadi Cell baldly asserts that: “[e]ven if the Board imported limitations into the process steps, that importation would constitute harmless error.”¹ Red Br., 72, n. 14. Nothing could be further from the truth. These implicitly added process limitations **formed the basis for the Board's determination that the prior art did not teach the claimed isolated cell.** *See, e.g.*, Appx40-43. Jadi Cell acknowledges as much. Red Br., 7-8, 47-48. For example, the Board explicitly “differentiated” the claims from the prior art on the basis that the prior art did not teach the “interior-down” embodiment. *See, e.g.*, Appx39. Tellingly, Jadi Cell does not even address that the Board improperly read back in this “interior-down” embodiment, let alone explain how such an implicit narrowing of the claim could possibly be “harmless.”

¹ Jadi Cell's *sole* explanation for this assertion is the claimed process is irrelevant in *product-by-process* claims. Red Br., 72, n. 14. As discussed below, far from being irrelevant, when the claimed process is known in the prior art, both the claimed product and the claimed process for making it are unpatentable. *See, e.g., King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1276 (Fed. Cir. 2010); *infra*, 15-27.

Jadi Cell also attempts to prop up the Board’s decision by arguing that these added process steps, factors, and conditions “are not ‘limitations’ read into the claims”; but, “[r]ather they are facts” that the Board relied upon to “explain[] why the process steps of the challenged claims would not necessarily produce the claimed cell.” *Id.*, 48. ² Red Br., 7-8; *see also id.*, 47-48, 70-71. This too is incorrect.

The Board’s implicit constructions are precisely that—claim constructions—which clearly narrowed the two process steps expressly recited in the claims. Again, it is indisputable that the Board “differentiated” the prior art on the basis that it does not teach the “interior-down” embodiment. *See, e.g.*, Appx39. In other words, the Board implicitly construed the claims as requiring the additional steps associated with that particular embodiment described in the specification. Likewise, the Board further distinguished the prior art processes from the claims on the basis that they do not include other unspecified factors and conditions. Appx40-43. Thus, Jadi Cell’s assertions that “the Board did not implicitly read limitations into the claims” lacks merit. Red Br., 70. Indeed, if none of these additional steps, factors, and conditions are limitations required by the claims, there is no basis whatsoever for the Board’s determination that the prior art does not teach the claimed isolated cell. For example,

² Jadi Cell even asserts, on one occasion, that these are “uncontested facts.” (Red Br., 48.) This is simply not true. Restem’s position has always been that the claimed process only requires the two steps recited in the claims, and the claimed process produces the claimed product, *i.e.*, an isolated cell with the specified marker patterns.

if the claims do not require the “interior-down” embodiment, then the Board’s “differentiation” of the prior art on that basis would be improper and inapposite. Tellingly, Jadi Cell provides no response to this glaring issue.

In short, the additional process steps, factors, and conditions are not “facts”—they go squarely to the scope of the claims. Put simply, this is a claim construction issue—not a fact question. Jadi Cell’s efforts to reframe these additional implicit claim requirements as “facts” is a blatant improper attempt to avoid the *de novo* standard of review. *See, e.g., Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.*, 93 F. App’x 225, 230 (Fed. Cir. 2004) (reviewing a court’s implicit claim construction *de novo*); *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334 & n.4 (Fed. Cir. 2000) (same). Significantly, beyond arguing that they are merely “facts,” Jadi Cell offers no arguments—let alone evidence—to support the Board’s implicit constructions.³

³ In arguing the added factors and conditions are merely “facts”, Jadi Cell points to the Board’s discussion of certain expert testimony and other extrinsic evidence. (Red Br., at 47-48, 70-73 (citing Appx40-43).) None of this extrinsic evidence can override the intrinsic record, which makes clear that the two-step process expressly recited in the claim is all that is required to produce the claimed product. *See, e.g., V-Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1310–11 (Fed. Cir. 2005); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996); *see also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1342 (Fed. Cir. 2015) (a party “cannot transform legal analysis about the meaning or significance of the intrinsic evidence into a factual question simply by having an expert testify on it.”)

Jadi Cell’s assertions regarding the “notice policy” of patent law further highlight the impropriety of the Board’s implicit constructions. Red Br., 72-73. As Jadi Cell acknowledges, this policy requires that the public be given fair notice regarding the scope of the claimed invention. *Id.* Here, however, the Board’s implicit interpretations lead to significant ambiguity. Blue Br., 44-46. The public is left guessing whether the claims require the isolated cells to be produced in accordance with the “interior-down” embodiment (based on the Board’s implicit construction) or would still infringe even if they do not (under the Board’s express construction). Even more problematic is the Board’s reliance upon unspecified factors and conditions as part of the claimed process that purportedly *may or may not* result in the marker patterns. Indeed, it is not even clear what such factors or conditions would be required in order to infringe the claims.

Jadi Cell’s assertions that the Board’s implicit interpretations somehow prejudice Jadi Cell—not the public—also miss the mark. Red Br., 72-73. Jadi Cell argues the Board did not implicitly add any limitations to the claims and, therefore, Jadi Cell would not be required to prove any additional elements to demonstrate infringement. (*Id.*, 7-8, 47-48, 73.) This is precisely the problem. Under Jadi Cell’s logic, the prior art does not render the claims unpatentable because it does not teach these additional process steps, factors, and conditions. But, at the same time, Jadi Cell asserts those additional process requirements are not part of the claim and,

therefore, it may demonstrate infringement without any of those additional requirements. This is not permitted. *See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (“A patent may not, like a ‘nose of wax,’ be twisted one way to avoid anticipation and another to find infringement.”).

In sum, the Board’s implicit construction narrowing the claims to require additional process steps, factors, and conditions is contradicted by all the intrinsic evidence and should be reversed.⁴ Consistent with the Board’s express claim constructions, the claims should be construed as simply requiring the expressly recited two-step process to produce the claimed isolated cells.

2. The Board Erred by Applying an Implicit Construction for “an Isolated Cell” that Disregards the Definitions in the Specification.

At Institution, the Board construed “an isolated cell” as meaning “one or more cells isolated from the subepithelial layer of a mammalian umbilical cord.” Appx383 (emphasis added). This was consistent with the definitions set forth in the specification *and Jadi Cell’s proposed construction prior to Institution*. Appx382-

⁴ Jadi Cell also incorrectly asserts that the Board’s implicit construction was “not a new ground of rejection, nor was it even a surprise to Restem.” Red Br., 72. Jadi Cell does not contest, however, that neither the Board, nor the parties, previously construed the claims as requiring any unspecified factors and conditions. *Id.*; *see also* Blue Br., 46. Jadi Cell’s assertion that Restem was required to request another paper or rehearing is also wrong on the law. *See, e.g., In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1377 (Fed. Cir. 2016).

383. As the Board correctly found, the specification includes a “Definitions” section, which explicitly states that:

Reference to “**a cell**” **includes one or more of such cells** [and] [a]s used herein, the term “**isolated cell**” **refers to a cell** that has been isolated from the subepithelial layer of a mammalian umbilical cord.

Appx96, 6:29-34 (emphasis added); *see also* Appx383. This lexicography mandates that “an isolated cell,” means “**one or more cells** that have been isolated from the subepithelial layer of a mammalian umbilical cord.” *See, e.g., 3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003).

Following Institution, Jadi Cell changed course and argued the “isolated cell” should be construed as a population (*i.e.*, plurality) of cells.⁵ Appx484-486. In its FWD, although the Board declined to expressly construe the term (Appx17-18), it implicitly construed “an isolated cell” as meaning “a cell population” when expressly construing the terms “expresses”/“does not express” (Appx28). The Board’s implicit construction erroneously ignores the unequivocal lexicography in the specification and should be reversed. Blue Br., 47-50.

Jadi Cell does not dispute that the Board implicitly construed “an isolated cell” to mean “a cell population,” but asserts this is consistent with the intrinsic and extrinsic evidence. Red Br., 46, 53. In so doing, **Jadi Cell does not even mention—**

⁵ Contrary to Jadi Cell’s assertions (Red. Br., 51 at n. 5), Jadi Cell’s original proposed construction for this term simply required “one or more cells isolated from the subepithelial layer of a mammalian umbilical cord.” Appx382 (emphasis added).

much less address—the express lexicography in the specification. *Id.*, 46, 51-53.

Jadi Cell’s silence speaks volumes.

Jadi Cell’s cherry-picked portions of the prosecution history as allegedly supporting that the Examiner “understood the Claimed Cells referred to a population of cells” are both misleading and misplaced. Red Br., 53 at n.7; *see also id.*, 31-32, 51-53. During prosecution the Examiner referred to the claimed isolated cells in various ways, including as one or more cells. *See, e.g.*, Appx952 (“applicant’s invention is interpreted as an isolated umbilical cord cell with a certain expression profile.”) More importantly, Jadi Cell does not (nor can it) explain how *an Examiner’s* occasional reference to a “population of cells” could possibly override the express lexicography in the specification.

Jadi Cell’s reference to a “population ranging from 500,000 to 1,000,000” from the ‘176 patent (Red. Br., 52, n.6) is also misleading and misplaced. The “populations” of cells Jadi Cell refers to are the doses of cells for medical therapy (Appx99, 11:51-53) or the expansion of cells after being isolated (Appx100, 14:1-3). This has nothing to do with the number of cells having markers produced by the claimed process, much less alter the definition of “an isolated cell.”

Jadi Cell’s reliance on certain extrinsic evidence, including expert testimony, as purportedly demonstrating a POSITA would have understood the term to be a “literary device” and would have ordinarily analyzed “populations” of cells is

equally unavailing. Red Br., 52-53; *see also id.*, 31-35, 45-46. Even if true, such extrinsic evidence is completely irrelevant in view of the express definitions in the patent. *See, e.g., 3M Innovative Properties*, 350 F.3d at 1371. Indeed, Jadi Cell chose to define the terms “a cell” and “isolated cell.” Appx96, 6:29-34. Jadi Cell cannot now run away from those express definitions.

Presumably recognizing this critical flaw, Jadi Cell asserts, in the alternative, that the Board’s implicit construction of “an isolated cell” was “harmless error.” Red Br., 46, 54-55. This assertion falls flat. The “isolated cell” *is the claimed product* in these product-by-process claims. And, the Board relied upon its implicit construction of “an isolated cell” as part of its construction of “express”/“does not express,” which the Board decided was one of only two claim terms that needed to be construed to render a judgment. Appx17-18.

Moreover, the Board stated that “evidence of expression or non-expression patterns as recited in the Challenged Claims can be used to identify and distinguish the isolated **cell population** from other **cell populations**.” Appx28. Thus, the Board made clear that it was looking for populations of cells in its analysis of the prior art, when it should have been looking for “one or more” cells. This is especially problematic here, given the Board’s holding was based solely on finding the prior art did not teach an isolated cell expressing/not expressing the specified markers. *See, e.g., Appx36-43*. Indeed, under the Board’s implicit claim construction, this

would require an entire “cell population” to express/not express the specified marker pattern. Conversely, when properly construed, the claims plainly cover a single cell⁶ with the specified marker pattern. Thus, it is indisputable that this implicit claim construction impacted the Board’s ultimate judgment.

The Board’s erroneous construction also infected several other aspects of its analysis concerning the prior art. As one example, the Board explained that “[w]e are persuaded in this regard by Dr. Burger’s testimony that Majore’s **isolated cell population** did not differentiate under standard *in vitro* conditions despite that the ISCT criteria for MSCs require these conditions.” Appx42 (emphasis added). This statement is in reference to an ongoing dispute between the parties regarding the efficiency (*i.e.*, the percentage) of Majore’s cells that were capable of differentiating to osteoblasts. There was no dispute that some of Majore’s cells did, in fact, differentiate to osteoblasts (albeit at low efficiency). *See, e.g.*, Appx231; Appx504-505; Appx578-579. Thus, had the Board properly reviewed Majore for “one or more” cells—rather than cell populations—that differentiate, the Board would not have credited Dr. Burger’s testimony on this issue.

In short, Jadi Cell’s assertions that the Board’s erroneous implicit construction of “an isolated cell” was “harmless” lack merit. Accordingly, the Board’s implicit

⁶ Jadi Cell mischaracterizes Restem’s position as arguing that “the ‘176 Patent defines ‘an isolated cell’ to mean a single cell.” Red Br., 45. The claims cover both a single cell and also “more” than one cell with the specified marker pattern.

construction should be reversed and, at a minimum, the Board's decision should be remanded for reconsideration in light of the proper construction for "an isolated cell" based on the express lexicography in the specification.

B. THE BOARD LEGALLY ERRED BY MISAPPLYING THE LAW ON INHERENCY

There is no dispute that the Board found the prior art teaches the same two-step process for producing an isolated cell as recited in the product-by-process claims. Red Br., 3, 5. Thus, by definition, these same prior art processes necessarily produce the same product as the claimed process, *i.e.*, an isolated cell with the specified marker patterns. Nonetheless, the Board determined the prior art does not inherently teach the claimed product because Restem did not sufficiently prove that the prior art processes produce those isolated cells. Blue Br., 6-7, 50-59. In other words, the Board effectively required Restem to prove that *the claimed process, in fact, produces the claimed product*. This was not Restem's burden.

Jadi Cell's attempts to reconcile this glaring defect in the Board's decision boils down to two arguments. First, Jadi Cell incorrectly asserts it is improper to consider the claimed process for an invalidity analysis. *See, e.g.*, Red Br., 5-6, 46-47, 55-56. Second, Jadi Cell asserts the two-step process recited in the claims (and taught by the prior art) does not necessarily produce the claimed product. *See, e.g.*, Red Br., 47-48, 62-68. Jadi Cell's assertions lack merit.

1. Jadi Cell Misunderstands the Law on Product-By-Process Claims

“Product-by-process claims [are] an exception to the general rule requiring claims to define products in terms of structural characteristics.” *Atl. Thermoplastics Co., et al. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir. 1992); *see also id.* at 838-847 (detailing the history of product-by-process claims); *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). In such claims, **it is the process that defines the claimed product.** *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n., 109 (1989) (a product-by-process claim is “one in which the product is defined at least in part in terms of the method or process by which it is made.”); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006); *Atl. Thermoplastics*, 970 F.2d at 845 (collecting cases confirming “the process limitations define the product.”); *In re Thorpe*, 777 F.2d at 697 (“product-by-process claims are limited by and defined by the process”); *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 997 (Fed. Cir. 1993) (“product-by-process claims recite how a product is made”).

Thus, it is axiomatic that the process recited in a product-by-process claim produces the claimed product. Indeed, as this Court has repeatedly recognized, where the process does not produce the product, the claim is indefinite. *See, e.g., In re Downing*, 754 F. App'x 988, 995 (Fed. Cir. 2018) (“We agree with the Director that the claims are indefinite because the claim reciting a product by process does not recite the steps for making the claimed product.”); *Atl. Thermoplastics*, 970 F.2d

at 845 (“if the process limitations of a product-by-process claim did not adequately define the invention, an applicant would fail to satisfy section 112”); *In re Wohnsiedler*, 315 F.2d 934, 937 (C.C.P.A. 1963) (affirming indefiniteness because the product-by-process claims “lack certainty as to the product which will, in fact, be produced by the recited process steps”).

Here, there is no dispute that the prior art teaches the claimed process for making the “isolated cell,” as expressly construed by the Board.⁷ Red Br., 3, 5; Appx29-34; Appx39. Thus, the inescapable conclusion is that these same prior art processes naturally result in the claimed isolated cell. Blue Br., 56-59. Put simply, the same process produces the same product. Accordingly, the Board’s conclusion that the same process in the prior art somehow does not necessarily result in the same product was incorrect. Appx39-43.

Jadi Cell wrongly asserts that only the claimed product—not the claimed process—is relevant to the invalidity analysis of product-by-process claims. Red Br., 5-6, 55-56. Jadi Cell’s confusion appears to be centered around certain cases explaining that the “focus” of the invalidity analysis for product-by-process claims

⁷ To the extent Jadi Cell asserts the claimed process only produces the claimed product under its narrower view of the claims—but not under the Board’s “broad” express constructions—this is flawed and inapposite. Red Br., 62-64. Jadi Cell does not dispute the Board’s express constructions are proper. *Id.*, 50-51 at n. 4. Moreover, the intrinsic record makes clear that the two steps expressly recited in the claims are all that is needed to produce the claimed isolated cells with the specified marker patterns. *Supra*, 5-6, 19-20, 23.

is generally on the claimed product. *Id.*, 5, 56 (citing *Amgen Inc. v. F. Hoffman–La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009)). These cases, however, stand for the unremarkable and “longstanding rule that an old product is not patentable even if it is made by a new process.” *Amgen*, 580 F.3d at 1370. In other words, a product-by-process claim is invalid where the product is already known in the prior art, even if made by a different process. *See, e.g., id.* (“a product-by-process claim can be anticipated by a prior art product that does not adhere to the claim's process limitation.”); *Atl. Thermoplastics*, 970 F.2d at 845; *In re Thorpe*, 777 F.2d at 697.

This does not mean that that the claimed process is irrelevant to invalidity. Far from it. Where the prior art teaches the same process for making the product as the claims—*as is the undisputed case here*—this means that both the claimed product and even the claimed process for making it were already known in the art. As a result, Jadi Cell would not even be entitled to patent the process itself. *Cf., Atl. Thermoplastics*, 970 F.2d at 844 (“[a]n applicant could obtain a process patent for a new, useful, and nonobvious process, but could not claim rights to a product already in the prior art by merely adding a process limitation.”)

Contrary to Jadi Cell’s assertion, Restem did not argue that *Greenliant Sys.* stands for the proposition “that all recited process steps, no matter how broadly they are construed, will inherently anticipate the product in the product-by-process claim.” Red Br. 47. Rather, Restem cited *Greenliant* as confirming that the process of

product-by-process claims should be considered when “that process imparts distinctive structural characteristics.” *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012); Blue Br. at 51-52. Here, Jadi Cell acknowledges that the claimed process imparts allegedly distinctive structural features to the isolated cell, namely: the specified marker patterns. *See, e.g.*, Appx489 (“The Process Steps Impart Functional Differences to the Claimed Cells”); Appx490 (“the claimed process steps impart an unexpected gene marker expression to the claimed cells”); *see also* Appx907-909 (Examiner allowing the claims based on inventor’s representations that the claimed process produces cells with novel marker patterns).

Moreover, the intrinsic record makes clear that the claimed process steps are what impart these markers to the isolated cell. The claims expressly recite that the two process steps are all that is required to produce an isolated cell with the recited markers. Appx103, claim 1. The specification confirms that these recited markers are simply characteristics of the isolated cells that are produced by the expressly recited two-step process. *See, e.g.*, Appx97, 7:65-67; Appx97, 8:3-6; *supra*, 5-6. In fact, the specification unequivocally states that the key to producing cells having the recited marker pattern is **simply to derive the cells from SL tissue:**

[A]n isolated cell that is capable of self-renewal and culture expansion and is obtained from a subepithelial layer of a mammalian umbilical cord tissue is provided. Such an isolated cell expresses at least three cell markers selected from CD29, CD73, CD90, CD166, SSEA4, CD9, CD44, CD146, or CD105, and does not express at least three cell markers

selected from CD45, CD34, CD14, CD79, CD106, CD86, CD80, CD19, CD117, Stro-1, or HLA-DR.

Appx94, 1:33-41 (emphasis added); *see also* Appx98, 9:51-55 (“cells isolated from the SL tissue . . . are negative for NANOG.”). Thus, because the prior art teaches these same two process steps, the resulting product is necessarily the same, *i.e.*, an isolated cell with the specified marker pattern.⁸

Jadi Cell’s assertions that it is the specification—not the claims—that teaches a POSITA how to make or use the invention are entirely misplaced. Red Br., 64-65 (citing *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)). Jadi Cell’s arguments appear to be directed to the enablement requirement, which is not at issue on appeal nor was it in the underlying IPR. Moreover, as Jadi Cell acknowledges, “[i]t is axiomatic that the claims define the scope of the invention.” Red Br., 64; *see also id.*, 65 (citing the dissent in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 1000 (Fed. Cir. 1995)). Here, Jadi Cell chose to utilize the product-by-process claim format, and, therefore, the scope of the claimed product is defined by the process expressly recited in the claims. For such claims the specification cannot be relied upon to fill in gaps in the process because the essential

⁸ Jadi Cell asserts Restem is improperly shifting the invalidity analysis away from the claimed product. Red Br., 67-68. Not so. It is Jadi Cell who is attempting to divorce the claimed product from the claimed process in its *product-by-process* claims. This is improper. It is axiomatic that the claimed process *defines* the claimed product.

steps for making the product must be recited in the claim. *See, e.g., In re Downing*, 754 F. App'x at 995.

2. The Board Erred by Finding that the Prior Art Teaches the Same Process Recited in the Claims But Somehow Produces A Different Product

The Board's determination that the prior art does not inherently disclose the claimed product was based on an erroneous application of the law on inherency to these product-by-process claims. *Blue Br.*, 50-59. Specifically, the Board found that, even though Restem proved the prior art teaches the same two-step process recited in the claims for producing one or more isolated cells, Restem did not prove that the prior art processes necessarily result in the claimed isolated cell with the specified marker pattern. *Id.*; *see also* Appx40 ("although Majore's disclosed process may satisfy the process limitations under our claim construction, we find that does not establish that cells produced using Majore's process would necessarily have the same marker profile required by the claim."). Because it is undisputed that the prior art process is the same as the claimed process, the Board effectively required Restem to prove that *the claimed process* actually produces the claimed cell. *Blue Br.*, 50, 52-57. This was plainly improper because "the prior art need only meet the inherently disclosed limitation to the same extent as the patented invention." *Arbutus Biopharma Corp. v. ModernaTX, Inc.*, 65 F.4th 656, 664 (Fed. Cir. 2023); *King Pharmaceuticals*, 616 F.3d at 1276.

Incredibly, in a misguided attempt to prop up the Board’s decision, Jadi Cell now asserts that its claimed process does not necessarily result in the claimed product. Red Br., 62 (“Jadi Cell [does not agree] that the claimed process steps, construed broadly, would produce the Claimed Cells.”), 63 (“At no time did Jadi Cell ‘agree’ that following only the recited process steps as construed by Restem, would yield a population of self-renewing cells with the recited marker expression”), 64 (“Put plainly, the claims of the ‘176 Patent do not teach the POSITA how to make and use the [Claimed Cells].”); *see also* 65-68.

Jadi Cell’s new⁹ position is, quite frankly, not reasonable. Jadi Cell’s position is tantamount to arguing that its product-by-process claims are defective. *See, e.g., In re Downing*, 754 F. App’x at 995 (holding that product-by-process claims were indefinite where the claim “does not recite the steps for making the claimed product.”); *Atl. Thermoplastics*, 970 F.2d at 845. Jadi Cell chose to claim its product by reciting the process for making it. In so doing, Jadi Cell represented to the Patent Office (and the public) that the two-step process recited in the claims produces the claimed “isolated cell” with the specified marker pattern. Jadi Cell cannot now—when facing invalidating prior art—assert that the two-step process does not actually

⁹ Jadi Cell’s assertion that it consistently argued the claimed process does not produce the claimed product is simply not true. *See, e.g.,* Appx489-490. To the extent Jadi Cell is now asserting that this is the case because the Board’s express constructions are too broad, that argument falls flat. *Supra*, 17, n. 7.

produce the claimed product. In short, either (i) the process produces the claimed product (as the intrinsic record supports), in which case the prior art necessarily anticipates or renders obvious the claims, or (ii) the process does not produce the claimed product (as Jadi Cell now asserts), in which case the claims fail to satisfy the requirements for patentability.

Moreover, as demonstrated above, the intrinsic record confirms that the claimed process produces the claimed product, namely: one or more isolated cells with the specified marker patterns. *Supra*, 5-6, 19-20. In particular, both the express claim language and the specification make clear that the expressly recited two-step process—of “placing” and “culturing” the SL—is all that is required to produce the claimed product. *Id.* Tellingly, Jadi Cell fails to address this wealth of intrinsic evidence. Jadi Cell cannot ignore or contradict what it disclosed in its own specification in an attempt to overcome invalidity. *See Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

Rather, Jadi Cell merely reargues that additional steps of “removing Wharton’s Jelly” and placing the SL “interior side down” described in certain embodiments in the specification “contribute[] to” imparting the specified markers. Red Br., 63. But, those steps are nowhere to be found in the claims. In fact, as Jadi Cell acknowledges, the Board considered and expressly rejected importing those steps into the claims because they are merely one of several embodiments described in the specification.

Appx18-22; *supra*, 3-4. Beyond re-raising this flawed argument, Jadi Cell has not (and cannot) identify any particular process steps, factors, or conditions—beyond the two steps expressly recited in the claims—that are purportedly required to impart the recited marker patterns.

Jadi Cell also points to the Board’s statement that, because the express claim language encompasses different combinations of markers being expressed/not expressed, “cells prepared according to the process limitations . . . would not all have the exact same marker expression profile.” Red Br., 66 (citing Appx40); *see also* Red Br., 37, 56. This is a red herring. The fact that the claimed process may produce cells with different combinations of the specified markers is inapposite. What is key here is that *at least one isolated cell* with the marker pattern recited in the claims is, by definition, produced by the expressly recited two-step process. To the extent other cells with different marker patterns might also be produced, such cells do not impact the presence of the cell (or cells) with the recited marker pattern. Appx103, claim 1. Moreover, these claims are “comprising” claims, and, therefore do not preclude the process from producing additional isolated cells that do not have the specified marker patterns.¹⁰ *Supra*, 10-15.

¹⁰ This highlights the error in the Board’s implicit construction of “an isolated cell” as requiring a “cell population” having the specified markers. *Supra*, 10-15. In so doing, the Board effectively required the prior art to disclose that all the cells produced by performing the prior art process have the recited marker patterns. This is not required by the claims.

Jadi Cell's reliance on certain extrinsic evidence and its inventor's Rule 1.132 declaration during prosecution is equally misplaced. Red Br., 66-67; *see also id.*, 24-26. Jadi Cell conveniently omits that neither the extrinsic evidence (including expert testimony cited by it) nor the inventor declaration even contemplate "factors" and "conditions" that might affect marker expression **of the specific markers recited in the claims**. To the contrary, the extrinsic evidence was directed to comments on cell markers generally (Appx41-42; Red Br., 66) and the inventor declaration was directed to different markers (Appx3418-3424). Moreover, the data disclosed in the Rule 1.132 declaration is inapposite because it does not compare the process of the claims to the process of Majore, Phan, or Kita.¹¹

Jadi Cell also repeatedly holds up Phan's and Kita's disclosure of NANOG expression as evidence that the claimed process does not produce an isolated cell having the recited marker patterns.¹² Red Br., 61; *see also id.*, 39-40, 42. In so doing,

¹¹ Jadi Cell represented to the Board in its sur-reply that the declaration "provided data demonstrating that Majore yields cells (i.e., control cells) that are significantly different from the claimed cells" and the "[t]he control cells were isolated following the Majore protocol." Appx620. This is demonstrably false. Appx731, n. 1. Jadi Cell now re-characterizes the protocol as merely "similar to Majore." Red Br., 24. This too, is inaccurate. The "control cells" of the 1.132 declaration were obtained by a protocol that is qualitatively different than Majore's protocol. *Compare* Appx1932, right col., 2nd para. *with* Appx3420, ¶5. Thus, the 1.132 declaration is inapposite.

¹² As Jadi Cell acknowledges, Majore does not disclose NANOG expression. Red Br., 61 at n. 9.

Jadi Cell asserts that “[e]very prior art reference that evaluated NANOG reported positive NANOG expression **in cultured MSCs.**” *Id.*, 61 (emphasis added). This too is incorrect. As an initial matter, Jadi Cell’s assertion reads-in an extra step of culturing the cells after isolation (*i.e.*, “cultured MSCs”). *See also id.*, 40 (referring to “cultured cells.”) But, the claims only require culturing of the SL tissue to produce the isolated cells—not further culturing the cells after isolation. Moreover, as Restem demonstrated during the IPR, Pierantozzi teaches that all cells freshly isolated according to the claimed two-step process are *expected to lack NANOG expression*. Appx239-240, Appx252-253; Appx264-265. Pierantozzi further explains that NANOG expression is known to change (*i.e.*, is “turned on”) as the isolated cells are cultured and, even then, only in some fraction of the cells.¹³ *Id.*

Thus, Phan’s and Kita’s reporting of NANOG expression in cultured cells does not change that the two-step process recited in the claims and taught by the prior art produces isolated cells that, at least initially, do not express NANOG. Simply put, the claims do not require assaying for the marker pattern at any particular time or cell passage. The specification expressly teaches, and the claims recite, that if the claimed two-step process is performed, then the claimed isolated cell is produced.

¹³ Again, the claims merely require that the claimed process produces at least one isolated cell that does not express the NANOG marker—not that every cell resulting from the process exhibits negative NANOG expression. *Supra*, 24-25.

In short, Jadi Cell's reliance on Phan's and Kita's reporting of NANOG expression is another red herring.

In sum, express claim language, the specification, and the very nature of product-by-process claims, makes clear that the two-step process recited in the claims produces the claimed isolated cells with the specified marker patterns. Thus, because there is no dispute that the prior art discloses isolating cells using this same two-step process, the prior art process must also produce one or more isolated cells with the same marker patterns. Accordingly, the Board's conclusion that, although the prior art discloses the claimed process, it does not result in the claimed product, was plainly improper.

C. THE BOARD'S ADDITIONAL FINDING WITH RESPECT TO CLAIM 9 IS WHOLLY UNSUPPORTED

Jadi cell does not address, much less dispute, that its own expert admitted that use of media "free of animal components" was well known at the priority date, that such media was taught by Majore, and that there was ample motivation to use such media. Blue Br., 59-60. Rather, Jadi Cell endorses the Board's single conclusory sentence by providing a generic summary of the law of obviousness, citing its own expert's declaration, and baldly asserting "the Board properly assessed the factual record." Red Br., 77. Jadi Cell's assertions do nothing to cure the Board's complete lack of explanation in support of its conclusion. In short, the Board did not adequately set forth its findings regarding claim 9 or explain its application of the

law thereto. *See, e.g., In re Sang-Su Lee*, 277 F.3d 1338, 1342, 1345-46 (Fed. Cir. 2002).

D. CONCLUSION

For all the foregoing reasons, and those stated in Restem's Opening Brief, the Court should reverse or, at minimum, vacate the Board's decision.

Dated: December 11, 2023

Respectfully submitted,

/s/ Kevin C. Hooper

Kevin C. Hooper
BRYAN CAVE LEIGHTON
PAISNER LLP
1290 Avenue of the Americas
New York, New York 10104
Ph: (212) 541-2000
Fax: (212) 541-4630
Email: kevin.hooper@bclplaw.com

/s/ K. Lee Marshall

K. Lee Marshall
BRYAN CAVE LEIGHTON
PAISNER LLP
Three Embarcadero Center, 7th Floor
San Francisco, CA 94111
Ph: (415) 675-3400
Fax: (415) 675-3434
Email: lee.marshall@bclplaw.com

/s/ Joseph J. Richetti

Joseph J. Richetti
BRYAN CAVE LEIGHTON
PAISNER LLP
1290 Avenue of the Americas
New York, New York 10104

Ph: (212) 541-2000
Fax: (212) 541-4630
Email: joe.richetti@bclplaw.com

/s/ Alexander Walden

Alexander Walden
BRYAN CAVE LEIGHTON
PAISNER LLP
1290 Avenue of the Americas
New York, New York 10104
Ph: (212) 541-2000
Fax: (212) 541-4630
Email: alexander.walden@bclplaw.com

/s/ Ethan R. Fitzpatrick

Ethan R. Fitzpatrick
BRYAN CAVE LEIGHTON
PAISNER LLP
1290 Avenue of the Americas
New York, New York 10104
Ph: (212) 541-2000
Fax: (212) 541-4630
Email: ethan.fitzpatrick@bclplaw.com

Attorneys for Appellant RESTEM LLC

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2023-2054

Short Case Caption: Restem, LLC v. Jadi Cell, LLC

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

- the filing has been prepared using a proportionally-spaced typeface and includes 6,968 words.
- the filing has been prepared using a monospaced typeface and includes _____ lines of text.
- the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 12/11/2023

Signature: /s/ Kevin C. Hooper

Name: Kevin C. Hooper