

---

Appeal Nos. 18-2321, 18-2350

---

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

---

JANSSEN BIOTECH, INC.,  
*Plaintiff-Appellant,*

v.

CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.,  
*Defendants-Cross-Appellants.*

---

Appeal from the U.S. District Court for the District of Massachusetts,  
No. 17-cv-11008-MLW, Judge Mark L. Wolf

---

**OPENING AND RESPONSE BRIEF OF CROSS-APPELLANTS**

---

James F. Hurst  
Bryan S. Hales  
Elizabeth A. Cutri  
KIRKLAND & ELLIS LLP  
300 North LaSalle  
Chicago, Illinois 60654  
(312) 862-2200

John C. O'Quinn  
William H. Burgess  
KIRKLAND & ELLIS LLP  
655 Fifteenth Street, N.W.  
Washington, D.C. 20005  
(202) 879-5000

February 11, 2019

---

**U.S. Patent No. 7,598,083, Claim 1 (Appx177-178)**

1. A soluble composition, suitable for producing a final volume of cell culture media, wherein the composition comprises the following components in the following amounts per liter of the final volume of cell culture media:

anhydrous  $\text{CaCl}_2$ , 5-200 mg;  
anhydrous  $\text{MgCl}_2$ , 15-50 mg;  
anhydrous  $\text{MgSO}_4$ , 20-80 mg;  
 $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ , 0.05-0.50 mg;  
 $\text{Fe}(\text{NO}_3)_3 \cdot 9\text{H}_2\text{O}$ , 0.01-0.08 mg;  
 $\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$ , 0.40-1.20 mg;  
ferric ammonium citrate, 0.04-200 mg;  
KCl, 280-500 mg;  
NaCl, 5000-7500 mg;  
 $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ , 30-100 mg;  
 $\text{Na}_2\text{HPO}_4$ , 30-100 mg;  
 $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ , 0.001-0.005 mg;  
 $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ , 0.001-0.10 mg;  
 $(\text{NH}_4)_6\text{Mo}_7\text{O}_{24} \cdot 4\text{H}_2\text{O}$ , 0.001-0.005 mg;  
 $\text{MnSO}_4 \cdot \text{H}_2\text{O}$ , 0.000070-0.0080 mg;  
 $\text{NiSO}_4 \cdot 6\text{H}_2\text{O}$ , 0.000025-0.0005 mg;  
 $\text{Na}_2\text{SeO}_3$ , 0.004-0.07 mg;  
 $\text{Na}_2\text{SiO}_3 \cdot 9\text{H}_2\text{O}$ , 0.02-0.4 mg;  
 $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$ , 0.000025-0.0005 mg;  
 $\text{NH}_4\text{VO}_3$ , 0.0001-0.0025 mg;  
D-Glucose, 500-8000 mg;  
sodium pyruvate, 0.0-1000 mg;  
sodium hypoxanthine, 0.0-20.0 mg;  
glycine, 0.0-150 mg;  
L-alanine, 0.0-150 mg;  
L-arginine.HCl, 200-5000 mg;

L-asparagine. $\text{H}_2\text{O}$ , 40-250 mg;  
L-aspartic acid, 20-1000 mg;  
L-cysteine.HCl  $\text{H}_2\text{O}$ , 25.0-250 mg;  
L-cystine.2HCl, 15-150 mg;  
L-glutamic acid, 0-1000 mg;  
L-histidine.HCl. $\text{H}_2\text{O}$ , 100-500 mg;  
L-iso-leucine, 50-1000 mg;  
L-leucine, 50-1000 mg;  
L-lysine.HCl, 100-1000 mg;  
L-methionine, 50-500 mg;  
L-ornithine.HCl, 0-100 mg;  
L-phenylalanine, 25-1000 mg;  
L-proline, 0-1000 mg;  
L-serine, 50-500 mg;  
L-aurine, 0-1000 mg;  
L-threonine, 50-600 mg;  
L-tryptophan, 2-500 mg;  
L-tyrosine.2Na.2 $\text{H}_2\text{O}$ , 25-250 mg;  
L-valine, 100-1000 mg;  
d-biotin, 0.04-1.0 mg;  
D-calcium pantothenate, 0.1-5.0 mg;  
choline chloride, 1-100 mg;  
folic acid, 1-10 mg;  
i-Inositol, 10-1000 mg;  
nicotinamide, 0.5-30 mg;  
p-aminobenzoic acid, 0.1-20 mg;  
riboflavin, 0.05-5.0 mg;  
thiamine.HCl, 0.5-20 mg;  
thymidine, 0-3.0 mg;  
vitamin B<sub>12</sub>, 0.05-5.0 mg;  
linoleic acid, 0.01-2.0 mg;  
DL- $\alpha$ -lipoic acid, 0.03-1.0 mg;  
pyridoxine.HCl, 0.5-30 mg;  
putrescine.2HCl, 0.025-0.25 mg;  
and  
ethanolamine.HCl, 2-100 mg.

**CERTIFICATE OF INTEREST**

**1. The full name of every party represented by us is:**

Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

**2. The name of any real party in interest represented by us, and not identified in response to Question 3, is:**

None.

**3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:**

Celltrion Healthcare Co., Ltd. has no parent corporation. The entities that own 10% or more of Celltrion Healthcare Co., Ltd. include One Equity Partners IV, L.P., a Cayman Islands limited partnership.

Celltrion, Inc. has no parent corporation. The entities that own 10% or more of Celltrion, Inc. include Celltrion Holdings Co., Ltd., a Korean corporation.

Hospira, Inc. is an indirect, wholly-owned subsidiary of Pfizer, Inc. No publicly held entities own 10% or more stock of Hospira, Inc. Pfizer, Inc. has no parent corporation, and no publicly held corporation holds 10% or more of its stock.

**4. The names of all law firms and the partners or associates who appeared for the party now represented by us in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:**

Kirkland & Ellis LLP: Gregory B. Sanford, James H. McConnell, Leslie M. Schmidt, Ryan P. Kane, Noah S. Frank, Nikhil R. Krishnan, Saunak Desai (formerly of Kirkland), Sharre S. Lotfollahi, and Samuel Blake.

Winston & Strawn LLP: Charles B. Klein, Samuel S. Park (formerly of Winston), and Dan H. Hoang.

Burns & Levinson LLP: Dennis J. Kelly and Andrea L. Martin.

**5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal, per Fed. Cir. R. 47.4(a) and 47.5(b):**

None.

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
<b>STATEMENT OF RELATED CASES.....</b>	<b>1</b>
<b>STATEMENT OF JURISDICTION.....</b>	<b>1</b>
<b>INTRODUCTION.....</b>	<b>2</b>
<b>STATEMENT OF QUESTIONS PRESENTED .....</b>	<b>7</b>
<b>STATEMENT OF THE CASE.....</b>	<b>7</b>
<b>I.    JANSSEN’S INFRINGEMENT CLAIMS .....</b>	<b>8</b>
A.    Cell Culture Media.....	8
B.    The ’083 Patent .....	10
C.    Janssen’s Twelve-Way and Thirteen-Way DOE Infringement Theories.....	11
D.    Prior Art Media Ensnared By Janssen’s Infringement Theories.....	13
1. <i>GSK</i> .....	14
2. <i>Life Techs</i> .....	15
E.    District Court Ruling.....	17
<b>II.    OWNERSHIP OF THE ’083 PATENT .....</b>	<b>21</b>
A.    Four Co-Inventors Assigned Their Rights to “the COMPANY,” as Defined in Employment Agreements. ....	21
B.    Previous District Court Proceedings and J&J Companies’ Broad Interpretation of “COMPANY” in Other Litigations. ....	23
C.    Janssen’s Refiled Action and the District Court’s Denial of Celltrion’s Renewed Motion to Dismiss .....	25
<b>SUMMARY OF THE ARGUMENT .....</b>	<b>27</b>

<b>STANDARD OF REVIEW .....</b>	<b>30</b>
<b>ARGUMENT.....</b>	<b>31</b>
I.    JANSSEN’S APPEAL: THE COURT SHOULD AFFIRM THE JUDGMENT OF NONINFRINGEMENT DUE TO ENSNAREMENT. ....	31
A.    The District Court Properly Identified the Relevant Prior Art. ....	34
1. <i>It is not hindsight to consider the closest prior art.</i> .....	35
2. <i>Janssen improperly proposes an approach                     uniquely pertinent to “lead compound” cases.</i> .....	39
B.    The District Court Properly Determined the “Differences Between the Prior Art and the Claims at Issue.” .....	40
C.    The District Court Properly Rejected Janssen’s Sole Purported Factual Dispute Regarding Ferric Ammonium Citrate.....	42
1. <i>No motivation is required to choose from                     interchangeable options.</i> .....	44
2. <i>Janssen’s “teaching away” argument is contrary                     to law and unsupported by the record.</i> .....	47
3. <i>Janssen’s “unpredictable” argument is waived                     and contrary to the record.</i> .....	50
4. <i>Overlapping ranges are prima facie obvious.</i> .....	51
D.    Purported Secondary Considerations Do Not Create a Genuine Issue of Material Fact. ....	54
II.   CROSS-APPEAL: THE DISTRICT COURT ERRONEOUSLY RULED THAT JANSSEN WAS THE SOLE OWNER OF THE ’083 PATENT.....	57
A.    The Contracts Unambiguously Assign the Invention to Centocor, J&J, and its Subsidiaries. ....	58

B.	The District Court Erred by Rewriting Janssen’s Contracts .....	61
1.	<i>The district court erred in finding ambiguity in the definition of “COMPANY.”</i> .....	62
2.	<i>The extrinsic evidence cannot support the district court’s narrow, patent-ownership-specific reading of “COMPANY.”</i> .....	66
C.	The District Court Correctly Rejected Janssen’s Fallback “Disclaimer” Argument. ....	73
	<b>CONCLUSION</b> .....	<b>74</b>

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>259 Holdings Co. v. Union Dry Dock &amp; Repair Co.</i> , No. A-0267-06T5, 2007 WL 3274272 (N.J. Super. Ct. App. Div. Nov. 7, 2007) .....	62
<i>5907 Blvd. L.L.C. v. W. N.Y. Suites, L.L.C.</i> , No. A-3709-11T4, 2013 WL 3762695 (N.J. Super. Ct. App. Div. July 19, 2013).....	29, 62, 66
<i>Abbott Labs v. Dey, L.P.</i> , 287 F.3d 1097 (Fed. Cir. 2002) .....	53
<i>Abbott Point of Care Inc. v. Epocal, Inc.</i> , 666 F.3d 1299 (Fed. Cir. 2012) .....	6, 29, 31, 58, 61
<i>ACCO Brands Corp. v. Fellowes, Inc.</i> , 813 F.3d 1361 (Fed. Cir. 2016) .....	36, 41
<i>Advanced Video Techs. LLC v. HTC Corp.</i> , 879 F.3d 1314 (Fed. Cir. 2018) .....	57
<i>Ali v. Fed. Bureau of Prisons</i> , 552 U.S. 214 (2008).....	64
<i>Alza Corp. v. Mylan Labs., Inc.</i> , 464 F.3d 1286 (Fed. Cir. 2006) .....	38
<i>In re Applied Materials</i> , 692 F.3d 1289 (Fed. Cir. 2012) .....	52
<i>Atl. N. Airlines v. Schwimmer</i> , 96 A.2d 652 (N.J. 1953) .....	30, 66
<i>Bayer Pharma AG v. Watson Labs., Inc.</i> , 874 F.3d 1316 (Fed. Cir. 2017) .....	18, 28, 48, 49
<i>Bd. of Trs. of Stanford Univ. v. Roche Molecular Sys.</i> , 563 U.S. 776 (2011).....	57

*In re Bigio*,  
 381 F.3d 1320 (Fed. Cir. 2004) .....34, 38

*Brawer v. Brawer*,  
 747 A.2d 790 (N.J. Super. Ct. App. Div. 2000) .....67

*In re Carlson*,  
 983 F.2d 1032 (Fed. Cir. 1992) .....36

*Celsis In Vitro, Inc. v. CellzDirect, Inc.*,  
 664 F.3d 922 (Fed. Cir. 2012) .....47, 54

*Conway v. 287 Corp. Ctr. Assocs.*,  
 901 A.2d 341 (N.J. 2006) .....30, 66

*Del. Valley Floral Grp., Inc. v. Shaw Rose Nets, LLC*,  
 597 F.3d 1374 (Fed. Cir. 2010) .....51

*DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*,  
 567 F.3d 1314 (Fed. Cir. 2009) .....3, 30, 31, 32, 33

*Domanske v. Rapid-Am. Corp.*,  
 749 A.2d 399 (N.J. Super. Ct. App. Div. 2000) .....67

*Dome Patent LP v. Lee*,  
 799 F.3d 1372 (Fed. Cir. 2015) .....50

*Emogene v. UBS Warburg Real Estate Sec., Inc.*,  
 No. A-5165-13T4, 2016 WL 2618732 (N.J. Super. Ct. App. Div.  
 May 9, 2016).....31

*Ethicon Inc. v. U.S. Surg. Corp.*,  
 135 F.3d 1456 (Fed. Cir. 1998) .....57

*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,  
 535 U.S. 722 (2002).....31

*In re Fischer*,  
 62 F.2d 96 (C.C.P.A. 1932).....46

*Friskit, Inc. v. Real Networks, Inc.*,  
 306 F. App'x 610 (Fed. Cir. 2009) .....56, 57



*In re Geisler*,  
 116 F.3d 1465 (Fed. Cir. 1997) .....51, 52

*Gen. Hosp. Corp. v. Sienna Biopharm., Inc.*,  
 888 F.3d 1368 (Fed. Cir. 2018) .....53

*Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*,  
 655 F.3d 1291 (Fed. Cir. 2011) .....53

*Geo. M. Martin Co. v. All. Mach. Sys. Int’l. LLC*,  
 618 F.3d 1294 (Fed. Cir. 2010) .....55

*Graham v. John Deere Co. of Kansas City*,  
 383 U.S. 1 (1966).....4, 28, 40, 43, 55

*Grayzel v. Boston Sci. Corp.*,  
 No. A-0991-14T2, 2015 WL 9694354 (N.J. Super. Ct. App. Div.  
 Jan. 11, 2016).....58, 60

*Hagrish v. Olson*,  
 603 A.2d 108 (N.J. Super. Ct. App. Div. 1992) .....66, 67

*Hotchkiss v. Greenwood*,  
 52 U.S. 248 (1850).....43, 45

*Int’l Union, United Auto., Aerospace & Agric. Implement Workers of  
 Am., U.A.W. v. Skinner Engine Co.*,  
 188 F.3d 130 (3d Cir. 1999) .....68

*Intendis GmbH v. Glenmark Pharms. Inc., USA*,  
 822 F.3d 1355 (Fed. Cir. 2016) .....32

*Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*,  
 869 F.3d 1336 (Fed. Cir. 2017) .....56

*IpVenture v. Prostar Comput., Inc.*,  
 503 F.3d 1324 (Fed. Cir. 2007) .....73

*Israel Bio-Eng’g Project v. Amgen, Inc.*,  
 475 F.3d 1256 (Fed. Cir. 2007) .....57

*Jang v. Boston Sci. Corp.*,  
 872 F.3d 1275 (Fed. Cir. 2017) .....17, 32

*In re Janssen Biotech, Inc.*,  
880 F.3d 1315 (Fed. Cir. 2018) ..... 1

*Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*,  
2018 WL 2072723 (Fed. Cir. Jan. 23, 2018)..... 1

*Janssen Biotech, Inc., v. Hyclone Laboratories, Inc.*,  
Case No. 1:16-cv-000710-JNP-EJF (D. Utah) ..... 1

*K-2 Corp. v. Salomon S.A.*,  
191 F.3d 1356 (Fed. Cir. 1999) ..... 32

*Karl’s Sales & Serv., Inc. v. Gimbel Bros., Inc.*,  
592 A.2d 647 (N.J. Super. Ct. App. Div. 1991) ..... 58

*Kieffer v. Best Buy*,  
14 A.3d 737 (N.J. 2011) ..... 31, 66

*KSR Int’l Co. v. Teleflex Inc.*,  
550 U.S. 398 (2007)..... 4, 5, 28, 34, 36, 40, 41, 43, 45, 46, 48, 55

*Marquip, Inc. v. Fosber Am., Inc.*,  
198 F.3d 1363 (Fed. Cir. 1999) ..... 32

*Marx v. Gen. Revenue Corp.*,  
568 U.S. 371 (2013)..... 64

*Mayer v. Dev. Corp. of Am.*,  
541 F. Supp. 828 (D.N.J. 1981)..... 64

*McCormick v. Talcott*,  
61 U.S. 402 (1857)..... 32

*Merck & Co. v. Biocraft Labs., Inc.*,  
874 F.2d 804 (Fed. Cir. 1989) ..... 20, 41, 52

*Merck Sharp & Dohme Corp. v. Hospira, Inc.*,  
874 F.3d 724 (Fed. Cir. 2017) ..... 55

*Momenta Pharm., Inc. v. Teva Pharms. USA, Inc.*,  
809 F.3d 610 (Fed. Cir. 2015) ..... 30

*Morgan v. Air Brook Limousine, Inc.*,  
 510 A.2d 1197 (N.J. Super. Law. Div. 1986).....58

*In re Mouttet*,  
 686 F.3d 1322 (Fed. Cir. 2012) .....36, 41

*Nat’l Foreign Trade Council v. Natsios*,  
 181 F.3d 38 (1st Cir. 1999).....47

*Ohio Willow Wood Co. v. Alps S., LLC*,  
 735 F.3d 1333 (Fed. Cir. 2013) .....55

*In re Omeprazole Patent Litig.*,  
 483 F.3d 1364 (Fed. Cir. 2007) .....45

*Ormco Corp. v. Align Tech., Inc.*,  
 463 F.3d 1299 (Fed. Cir. 2006) .....51, 52

*Otsuka Pharm. Co. v. Sandoz, Inc.*,  
 678 F.3d 1280 (Fed. Cir. 2012) .....39

*In re Peterson*,  
 315 F.3d 1325 (Fed. Cir. 2003) .....51, 54

*Pfizer, Inc. v. Apotex, Inc.*,  
 480 F.3d 1348 (Fed. Cir. 2007) .....45, 51

*Polaris Indus., Inc. v. Arctic Cat, Inc.*,  
 882 F.3d 1056 (Fed. Cir. 2016) .....38

*Prima Tek II, L.L.C. v. A-Roo Co.*,  
 222 F.3d 1372 (Fed. Cir. 2000) .....26

*Ritchie v. Vast Res., Inc.*,  
 563 F.3d 1334 (Fed. Cir. 2009) .....43

*Rockel v. Cherry Hill Dodge*,  
 847 A.2d 621 (N.J. Super. App. Div. 2004) .....62

*Royal Food Distribs., Inc. v. Dir., Div. of Taxation*,  
 15 N.J. Tax 60 (1995) .....64

*Sage Prods., Inc. v. Devon Indus, Inc.*,  
 126 F.3d 1420 (Fed. Cir. 1997) .....51, 54

*Schor v. FMS Fin. Corp.*,  
 814 A.2d 1108 (N.J. Super. Ct. App. Div. 2002) .....62

*SmithKline Beecham Corp. v. Apotex Corp.*,  
 439 F.3d 1312 (Fed. Cir. 2006) .....47

*TMW Enters., Inc. v. Fed. Ins. Co.*,  
 619 F.3d 574 (6th Cir. 2010) .....64

*Twp. of White v. Castle Ridge Dev. Corp.*,  
 16 A.3d 399 (N.J. Super. Ct. App. Div. 2011) .....29, 60

*UCB, Inc. v. Accord Healthcare, Inc.*,  
 890 F.3d 1313 (Fed. Cir. 2018) .....4, 18, 35, 39

*Vantage Dev. Corp. v. Am. Env’t Techs. Corp.*,  
 598 A.2d 948 (N.J. Super. Law. Div. 1991).....62

*Warner-Jenkinson Co. v Hilton Davis Chem. Co.*,  
 520 U.S. 17 (1997).....31, 32, 33

*Warsaw Orthopedic, Inc. v. NuVasive, Inc.*,  
 778 F.3d 1365 (Fed. Cir. 2015) .....60

*WBIP, LLC v. Kohler Co.*,  
 829 F.3d 1317 (Fed. Cir. 2016) .....38

*Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*,  
 904 F.2d 677 (Fed. Cir. 1990) .....32, 54

*In re Winslow*,  
 365 F.2d 1017 (C.C.P.A. 1966).....27, 35

*Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*,  
 683 F.3d 1356 (Fed. Cir. 2012) .....44, 45, 56, 57

*Woodhaven Lumber & Millwork, Inc. v. Monmouth Design & Dev.  
 Co.*,  
 No. A-2914-12T3, 2014 WL 1326994 (N.J. Super. Ct. App. Div.  
 2014) .....29, 65, 73

*Wyers v. Master Lock Co.*,  
616 F.3d 1231 (Fed. Cir. 2010) .....29, 55, 57

*Yeda Research v. Mylan Pharm. Inc.*,  
906 F.3d 1031 (Fed. Cir. 2018) .....27

**Statutes**

28 U.S.C. §1295(a)(1).....2

28 U.S.C. §1338(a) .....2

28 U.S.C. §2107(a) .....2

35 U.S.C. §102.....32

35 U.S.C. §103 ..... 4, 19, 20, 28, 32, 35, 40

35 U.S.C. §261 .....57, 66, 70

35 U.S.C. §262.....60

**Rules**

Fed. Cir. Rule 32 ..... 1

Fed. R. App. P. 4(a) .....2

Fed. R. App. P. 32..... 1

**Other Authorities**

MPEP §2143 .....46

2 W. Robinson, *The Law of Patents for Useful Inventions* §939 (1890).....57

## STATEMENT OF RELATED CASES

There was one earlier interlocutory appeal from the same district court proceedings: Fed. Cir. No. 17-1120, *Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, described in Janssen’s opening brief’s Statement of Related Cases. BlueBr. x. As Janssen notes, that appeal concerned a different patent, U.S. No. 6,284,471, which is no longer part of the case and not at issue here. In a companion appeal, Fed. Cir. No. 17-1257, this Court affirmed the Patent Office’s ruling that all seven claims of the ’471 patent were invalid for obviousness-type double-patenting. Based on that ruling, the Court dismissed appeal no. 17-1120 as moot. *See In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed. Cir. 2018) (Prost, C.J., and Reyna, and Wallach, JJ.) (Appeal No. 17-1257, affirming Patent Office); *Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, 2018 WL 2072723 (Fed. Cir. Jan. 23, 2018) (Prost, C.J., and Reyna and Wallach, JJ.) (Appeal No. 17-1120, dismissing as moot).

This appeal concerns Janssen’s U.S. Patent No. 7,598,083, which Janssen is also asserting against HyClone Laboratories, Inc. in *Janssen Biotech, Inc., v. HyClone Laboratories, Inc.*, Case No. 1:16-cv-000710-JNP-EJF (D. Utah).

## STATEMENT OF JURISDICTION

The cross-appeal by Celltrion Healthcare, Celltrion, and Hospira (collectively, “Celltrion”) disputes Janssen’s standing, because not all co-owners of the ’083 patent were joined as plaintiffs. *Argument §II, infra*. Aside from that defect, the

district court had subject matter jurisdiction under 28 U.S.C. §1338(a). The court entered final judgment on July 30, 2018, and an amended final judgment on August 23, 2018. Appx20-21. Celltrion’s cross-appeal, filed August 31, 2018, was timely. 28 U.S.C. §2107(a); Fed. R. App. P. 4(a). This Court has jurisdiction under 28 U.S.C. §1295(a)(1).

## **INTRODUCTION**

This appeal is the last remnant of Janssen’s long-running campaign to hinder competition against its blockbuster drug Remicade. Janssen filed this lawsuit in 2015 to try to stop Celltrion from launching its lower-cost Inflectra, asserting six patents covering various technologies concerning biologic drugs. Less than eighteen months later, most of Janssen’s case had crumbled. The patent claiming the infliximab antibody (Remicade’s active ingredient) had been found invalid, and Janssen was forced to drop four others. That left Janssen’s ’083 patent, and only an attenuated theory of indirect infringement under the doctrine of equivalents (“DOE”).

The ’083 patent covers “cell culture media,” which is food for cells, including cells that can be used to grow biologics, such as infliximab. Claim 1 recites a cell media recipe with 52 required ingredients and specific concentration ranges for each.

The cell media field is crowded and dates back to the 1950s. Janssen’s expert acknowledged there is a “convergence of opinions on what kind of ingredients ought to be included” in a media. Appx395. In fact, one prior art reference differs from the

'083 patent media in only *two* ways, and another differs in only *five* ways. By comparison, Janssen asserts DOE infringement against media with *at least twelve* differences in concentration, ranging from 90% below the claimed minimum to 400% above the claimed maximum. Janssen calls its claimed concentration ranges mere “guidelines.”

The district court correctly recognized that by stretching its claims so far, Janssen made this case a textbook case of ensnarement. Janssen had the “burden of persuasion” on ensnarement, which is “determined by the court” “as a matter of law,” and thus generally suitable for resolution by summary judgment. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1323-24 (Fed. Cir. 2009).<sup>1</sup> After methodically reviewing the record and holding a two-day hearing, the court held in a 104-page opinion that Janssen failed to raise a material dispute of fact, and thus granted summary judgment of noninfringement.

Janssen’s main arguments on appeal are narrow and unsound legal arguments. Janssen’s repeated assertions of “hindsight” do nothing more than register its disagreement with the result, while misstating the law. Janssen criticizes the district court for “pluck[ing]” the closest prior art out of a “sea of prior art.” BlueBr. 41. But binding precedent makes clear that the skilled artisan is presumed to know *all*

---

<sup>1</sup> All quoted emphasis is added unless otherwise indicated.



pertinent prior art, and “an obviousness rejection by an examiner, or a challenge in court, *may be based on the closest prior art.*” *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1329 (Fed. Cir. 2018).

Janssen also cries “hindsight” because the court considered the differences between the claimed invention and the prior art. But that is exactly what Section 103 and *KSR* require—expressly focusing on “the *differences* between the claimed invention and the prior art.” 35 U.S.C. §103; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007). Claims are invalid when “the *differences* between them and the pertinent prior art would have been obvious to a person reasonably skilled in that art.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 37 (1966).

Janssen similarly argues that it was “hindsight” to find it obvious to substitute one form of an ingredient for another well-known, interchangeable form of that same ingredient. But *KSR* requires exactly that conclusion: the “mere substitution of one element for another known in the field” that does no “more than yield a predictable result” is obvious. *KSR*, 550 U.S. at 415-17. Indeed, for infringement purposes, Janssen argued that it was “utter[ly] trivial[,]” and “make[s] no difference from a scientific perspective,” to “replac[e] one” interchangeable ingredient “with an equivalent amount of” another. Appx3034; Appx599(¶52). Janssen’s use of known alternatives makes the recipe slightly different, but there is zero evidence it is better in any way.

Janssen ultimately alleges only a single purported fact dispute regarding prima facie obviousness: whether prior art teaches away from the use of the claimed ferric ammonium citrate as an iron source. But the district court correctly rejected that argument as a matter of law, because some prior art explicitly identified ferric ammonium citrate as a “preferred” iron source, and even Janssen’s reference (which it waived by failing to properly raise it below) merely “expresse[d] a general preference for an alternative” iron source without remotely suggesting ferric ammonium citrate “was somehow so flawed that there was no reason to” use it. *KSR*, 550 U.S. at 425-26. As a matter of law, that is not teaching away.

With respect to secondary considerations, Janssen’s “copying” argument similarly falls flat. The district court viewed the evidence in the light most favorable to Janssen, and even through that lens, held that at best Janssen raised a “close call” case of copying. Because Janssen’s claimed invention “represent[s] no more than ‘the predictable use of prior art elements according to their established functions,’” the court correctly held that Janssen’s tenuous copying allegations were “inadequate to establish nonobviousness as a matter of law.” Appx121-122.

Although the district court’s ensnarement analysis was entirely correct, it was also unnecessary. The action should have been dismissed for lack of standing based on the failure to join all co-owners of the ’083 patent. It has been the law for more

than 100 years that *all* patent owners must be joined in a complaint for infringement. Here, Janssen is the sole plaintiff, but not the sole owner.

The assignment agreements are perfectly clear. Four of the six co-inventors assigned their interests by contract to “*the COMPANY*,” explicitly defined as a group: Janssen’s predecessor “Centocor *and* JOHNSON & JOHNSON *and*” related companies. J&J family companies have taken advantage of this literal language, including in nearly a dozen other lawsuits to enforce employees’ confidentiality and non-competition obligations owed broadly to “the COMPANY.”

The district court acknowledged that “[i]nterpreted literally,” “the term ‘the COMPANY’ includes at least two entities—Janssen and J&J.” Appx150. It nonetheless concluded that the defined term “COMPANY” means “only” Janssen, “at least for the purposes of patent assignments.” Appx158. The court relied principally on “practices” within J&J about patent ownership that did not even purport to result from any interpretation of “COMPANY.”

Janssen may not like the consequences—in *this* case—of the contract language it chose. But drafter’s remorse is not a basis for deeming a contract ambiguous. “[W]hen the terms of a contract are clear, ‘it is the function of a court to enforce it as written and not to make a better contract for either of the parties.’” *Abbott Point of Care Inc. v. Epocal, Inc.*, 666 F.3d 1299, 1302 (Fed. Cir. 2012). Janssen chose an explicit, clear definition of “the COMPANY.” That definition

should have led straightforwardly to dismissal here, under age-old, black-and-white rules governing patent ownership and standing.

Standing and contract interpretation are questions of law. As a matter of law, the Court should hold Janssen to its choices and dismiss the action for lack of standing. Alternatively, the judgment of non-infringement should be affirmed.

### **STATEMENT OF QUESTIONS PRESENTED**

1. Whether the district court's judgment of noninfringement of claim 1 based on ensnarement should be affirmed where the prior art media (a) admittedly use every required ingredient, either in an identical chemical form or a well-known alternative form, and (b) disclose a concentration range for each ingredient that overlaps with the hypothetical claimed ranges.

2. Whether the district court erroneously ruled that Janssen has standing to assert the '083 patent despite not joining all co-owners, including, for instance, Johnson & Johnson, when the assignment agreements state plainly that the owners include Janssen "*and* JOHNSON & JOHNSON *and*" related companies.

### **STATEMENT OF THE CASE**

Janssen initially sued Celltrion in 2015 and 2016 for infringement of the '083 patent and five other patents. The actions were consolidated. Appx8364-8365; Appx9516-9521. Janssen's key patent was ruled invalid for obviousness-type double patenting, and Janssen dropped four others, leaving only the '083 patent. After

Celltrion moved to dismiss for lack of standing, Janssen voluntarily dismissed both consolidated cases and filed a new complaint. Appx9516-9521. The district court denied Celltrion's subsequent motion to dismiss for lack of standing. Appx135-168. That order is the subject of Celltrion's cross-appeal. After discovery closed, the district court granted Celltrion's motion for summary judgment of noninfringement under the doctrine of equivalents based on ensnarement. That order is the subject of Janssen's appeal.

## **I. JANSSEN'S INFRINGEMENT CLAIMS**

### **A. Cell Culture Media**

The '083 patent concerns cell media (*i.e.*, cell food), which provides nutrients necessary to maintain and grow cells. BlueBr. 7; Appx674(1:19-20); Appx173(1:50-64).

Scientists have been making cell media for decades. Appx417-418(¶¶70-75); Appx539-540(¶66); Appx906(¶21 Resp.). In 1955, Harry Eagle determined the essential "food" categories required to grow cells: "amino acids or proteins, an energy source such as glucose or other carbohydrates, elements such as iron, lipids or fats, vitamins, and other well-known factors." Appx417(¶70); Appx539(¶63). Those "same categories of ingredients that Eagle identified" decades ago "remain the same basic nutrient groups used" "to this day." Appx539(¶65).

Scientists have also known for decades that there are often alternative ways to deliver each of the same essential nutrients. For example, either “L-histidine•HCl•H<sub>2</sub>O” or “L-histidine free base” can provide the amino acid “L-histidine.” Appx908(¶26 Resp.). Janssen admits that such alternative ingredients providing “the same active component” are “interchangeable.” *Id.*; Appx386(59:9-12). Indeed, Janssen relied on that interchangeability for infringement purposes, contending that it would be “utter[ly] trivial[,]” and “make no difference from a scientific perspective,” to “replac[e] one [interchangeable ingredient] with an equivalent amount of” another. Appx3034; Appx599(¶52); *see also* Appx386(59:9-12); Appx2697(11:8-14); Appx908(¶¶25-26 Resp.).

A disadvantage of early cell media was that they contained components with an unknown chemical makeup, *i.e.*, “undefined” components. Animal-derived components, such as bovine serum, for example, were “undefined,” and media using those components risked inconsistency between batches or contamination (“viral contamination” or “contamination by other small, potentially life-threatening molecules”). Appx430-431(¶¶99-101); Appx173(1:17-24).

In the early 1990s, scientists responded by developing “chemically defined” media, which replaced animal serum with known ingredients so they “knew exactly what was included in the formulation.” Appx430(¶99); Appx432(¶104). By 2004, there were many available serum-free and/or chemically-defined media, including

commercial products and the two prior art references at issue here: GSK and Life Techs. Appx731; Appx672; *see also* Appx603-616; Appx910(¶29 Resp.).

### **B. The '083 Patent**

Like many prior art media, the '083 patent discloses “chemically defined” media. Appx173(1:13-14); Appx169(Title). Janssen only asserts Claim 1 (reprinted on the inside-front cover of this brief). It recites a cell media formulation with 52 required ingredients, each within a specified concentration range. Appx177-178. For 9 other ingredients, the claim recites zero as the minimum concentration, making them optional. *Id.*

All 52 required ingredients are well-known, conventional media components. Janssen’s expert admitted that 49 were “commonly used in cell culture medium prior to 2004” (the earliest priority date), and that the other three were used “in a minority of culture media formulations.” Appx649-650(57:6-19, 58:9-17).

The '083 patent’s claimed concentration ranges were also known. Prior art media used concentration ranges that overlap with the claimed ranges. Appx126-134. And Janssen’s expert testified that the claimed ranges were mere “guidelines” within a “broad plateau of interchangeable concentrations”—in fact, “*extremely* broad,” as much as “2500 times, sometimes it’s six times” the claimed range. Appx389-390(82:20-83:3); Appx380(11:15-22).

Janssen nevertheless asserted the '083 patent's media was inventive because it is "optimized for biopharmaceutical production" to "sustain high cell growth and viability." BlueBr. 8. Janssen did not, however, present evidence comparing the claimed media to either GSK or Life Techs. And Janssen does not even use (and has never used) the '083 patent's media to make any commercial product. Appx1973(47:14-16); Appx2540. Janssen and at least two competitors make infliximab without using the claimed media. Appx9528(¶10 Resp.).

**C. Janssen's Twelve-Way and Thirteen-Way DOE Infringement Theories**

Janssen asserts infringement against two media that Celltrion purchases from a third-party vendor, HyClone.<sup>2</sup> They are combinations, in different proportions, of two off-the-shelf HyClone products called ADCF-Mab and Cell Boost 5. Appx109. HyClone designed ADCF-Mab long before Janssen developed its claimed media. Appx2539. Cell Boost 5 is a "supplement" that provides additional nutrients to a base medium. Appx1736(31:10-16); Appx109.

Both accused media contain 88 ingredients, 29 of which are not recited in Claim 1. Appx1863. Janssen asserts those additional ingredients are irrelevant because Claim 1 is a "comprising" claim. Appx3369.

---

<sup>2</sup> Janssen refers to the accused products as "CGM" and "CPM."



Janssen does not allege literal infringement, because neither of the accused media match the claimed concentrations for the claimed ingredients. One has twelve differences and the other thirteen differences. Appx598. The differences are as high as 400% above the claimed ranges' maximum and as low as 10% of its minimum.

**Table 1. Literal Differences Between Claim 1 and the Celltrion Media**

<b>'083 Patent Claim 1</b>		<b>CGM</b>	<b>CPM</b>
<b>Ingredient</b>	<b>Amount (per liter)</b>	<b>Amount (per liter)</b>	<b>Amount (per liter)</b>
NaCl	5000-7500 mg	literally within range	4556.83 mg
NaH <sub>2</sub> PO <sub>4</sub> •H <sub>2</sub> O	30-100 mg	227.17 mg	262.97 mg
Na <sub>2</sub> HPO <sub>4</sub>	30-100 mg	374.15 mg	432.64 mg
CuSO <sub>4</sub> •5H <sub>2</sub> O	0.001-0.005 mg	0.000536727 mg	0.00062087 mg
CoCl <sub>2</sub> •6H <sub>2</sub> O	0.001-0.10 mg	0.000369 mg	0.00043 mg
(NH <sub>4</sub> ) <sub>6</sub> Mo <sub>7</sub> O <sub>24</sub> •4H <sub>2</sub> O	0.001-0.005 mg	0.000964 mg	literally within range
NiSO <sub>4</sub> •6H <sub>2</sub> O	0.000025-0.0005 mg	0.00094471 mg	0.00109275 mg
SnCl <sub>2</sub> •2H <sub>2</sub> O	0.000025-0.0005 mg	0.000008 mg	0.00001 mg
NH <sub>4</sub> VO <sub>3</sub>	0.0001-0.0025 mg	0.000046 mg	0.00005 mg
L-arginine•HCl	200-5000 mg	63.34 mg	73.27 mg
L-asparagine•H <sub>2</sub> O	40-250 mg	3.22 mg	3.72 mg
L-histidine•HCl•H <sub>2</sub> O	100-500 mg	13.52 mg	15.64 mg
L-methionine	50-500 mg	37.57 mg	43.43 mg
L-valine	100-1000 mg	90.56 mg	literally within range

See Appx598; Appx904(¶19 Resp.).

Janssen nevertheless asserted infringement under the DOE, partly based on arguments about the ease of swapping interchangeable ingredients. *E.g.*, Appx587(¶60). Janssen asserted, for example, that replacing “magnesium sulfate”

with “magnesium chloride” would make no difference because both supply magnesium, Appx3033-3034, and that  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$  and  $\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$  are interchangeable because both supply copper (Cu). *See* Appx587(¶¶59-60); *see also*, *e.g.*, Appx386(59:9-12); Appx380(11:8-14); Appx590-592(¶¶73-74, 77); Appx599(¶52).

Janssen also argued that the differences in concentration ranges were insubstantial because the claimed ranges are not “critical.” Appx375(166:5-19). According to Janssen, the concentration of each ingredient must simply be high enough to grow cells, but not so much as to be toxic, which is why there is “a broad plateau of interchangeable concentrations.” Appx380-381(11:15-12:1).

#### **D. Prior Art Media Ensnared By Janssen’s Infringement Theories**

Under Janssen’s DOE infringement theory, a hypothetical claim literally encompassing the accused products would be expanded 12 and 13 ways from claim 1. Appx61-62. Celltrion contended that Janssen’s theory was barred as a matter of law because such hypothetical claims would ensnare the prior art, namely: “**GSK**,” a published GlaxoSmithKline patent application filed March 2004 (Appx731-780); and “**Life Techs**,” a published Life Technologies patent application filed in 1998. (Appx672-729); Appx912(¶33 Resp.); Appx915(¶38 Resp.). Neither was before the Patent Office during the ’083 patent’s prosecution. Appx912(¶34 Resp.); Appx915(¶39 Resp.).

1. GSK

GSK discloses a 96-ingredient medium, which includes 50 of the hypothetical claim's 52 required ingredients, in the same chemical form and within the same concentration range. Appx752-755; Appx912-913(¶35 Resp.); Appx126-129; Appx660-661(269:14-270:8). GSK discloses the other two ingredients (vanadium and chelated iron) in interchangeable chemical forms, and also within the same concentration range.

Active Ingredient	Claim 1 Recites	GSK Discloses
<b>vanadium</b>	NH <sub>4</sub> VO <sub>3</sub> (ammonium metavanadate)	NaVO <sub>3</sub> (sodium metavanadate)
<b>chelated iron</b>	ferric ammonium citrate	ferric fructose

Appx67-70; Appx914(¶37 Resp.). Thus, while claim 1 differs in 12 or 13 ways from the accused media, the hypothetical claim differs in only 2 ways from GSK. Janssen presented no evidence that those two differences improved the media in any way.

Long before 2004, skilled artisans knew sodium metavanadate (recited in Claim 1) and ammonium metavanadate (disclosed in GSK) were interchangeable sources of vanadium, readily swapped even for “convenience.” Appx784(Table 1 n.a); Appx917-918(¶42 Resp.). “Janssen does not dispute that the different salt forms of trace metals in GSK (vanadium)... are interchangeable with the salt forms of those metals found in the hypothetical claim.” BlueBr. 50 n.5.

Likewise, long before 2004, skilled artisans knew that ferric ammonium citrate (recited in claim 1) and ferric fructose (disclosed in GSK) both provided cells with chelated iron. To grow, cells need iron, which is delivered in natural serum by a protein called transferrin. Appx96. Janssen’s expert admitted that in 2004 both ferric ammonium citrate and ferric fructose were known “iron chelates” with the “same overall function of delivering iron to the cells.” Appx1977(154:23-155:8; 155:16-20); *accord e.g.*, Appx937(¶¶49-50); Appx920-921(¶¶47, 49 Resp.); Appx520(¶ 243); Appx530-532(¶¶256-257).

Prior art discloses that ferric ammonium citrate “can completely replace transferrin,” Appx815, and that “chelated salts such as ferric citrate and *ferric ammonium citrate are preferred.*” Appx806(18:28-31); Appx920(¶47 Resp.). Skilled artisans also knew that the sources of chelated iron are finite and predictable. Appx365-366(¶¶46-52); Appx1949(¶ 34), Appx1957-1958(¶¶49-50 Resp.).

## 2. Life Techs

Life Techs discloses an 88-ingredient medium, which includes 47 of the 52 required ingredients in the same chemical form as the hypothetical claim, and all but one within the claimed concentration range. Appx61; Appx131-134. The one concentration difference is for putrescine.2HCl, which Life Techs discloses within 0.015 mg/L of the claimed concentration—a concentration difference Janssen never argued was nonobvious. *Argument §I.C.4, infra*; Appx131-134; Appx687-691;

Appx915(¶40 Resp.), Appx926(¶59 Resp.). For infringement, Janssen argues that larger differences than 0.015 mg/L are “equivalent.” Appx598.

For all five ingredients that differ, Life Techs uses known alternative sources for the same active ingredient:

<b>Active Ingredient</b>	<b>Claim 1 Recites</b>	<b>Life Techs Discloses</b>
vanadium	$\text{NH}_4\text{VO}_3$ (ammonium metavanadate)	$\text{NaVO}_3$ (sodium metavanadate)
chelated iron	ferric ammonium citrate	ferric citrate
manganese	$\text{MnSO}_4 \cdot \text{H}_2\text{O}$	$\text{MnCl}_2 \cdot 4\text{H}_2\text{O}$
selenium	$\text{Na}_2\text{SeO}_3$	$\text{H}_2\text{SeO}_3$
Tin	$\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$	$\text{SnCl}_2$

Appx130-134; BlueBr. 50 n.5; Appx520(¶243). Thus, while claim 1 differs in 12 or 13 ways from the accused media, the hypothetical claim differs in only 5 ways from Life Techs (not counting the one slight concentration difference, because Janssen never disputed it was obvious). Again, Janssen offered no evidence that those five differences improved the media in any way.

On the contrary, Janssen concedes “that the different salt forms of trace metals in... Life Techs (manganese, selenium, tin and vanadium) are interchangeable with the salt forms of those metals found in the hypothetical claim.” BlueBr. 50 n.5; Appx69-70. Janssen only disputes the interchangeability of the sources of chelated iron—LifeTech’s ferric citrate and the claimed ferric ammonium citrate. But just like ferric ammonium citrate and ferric fructose, by 2004, ferric citrate was a well-

known iron chelator used as replacement for transferrin. Appx67-69; Appx806(18:28-31); Appx815; Appx810. In fact, ferric ammonium citrate and ferric citrate become the same compound in water. Appx3566-3567(¶¶168, 170), Appx691(18:12).

### **E. District Court Ruling**

After discovery, Celltrion moved for summary judgment of non-infringement based on ensnarement. For its ensnarement analysis, the district court first formulated hypothetical claims covering the accused products. Appx126-134. The court next conducted a conventional obviousness analysis comparing the hypothetical claims to the prior art. *Janssen* bore the burden to prove “its theory of infringement does not ensnare the prior art.” Appx29(citing *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017)). After briefing and a two-day hearing, the district court issued an exhaustive opinion holding that, as a matter of law, *Janssen* could not meet its burden. Appx124.

The court found that both hypothetical claims—neither of which *Janssen* disputes—would be obvious over two independent, single-reference obviousness theories, one based on GSK and the other on Life Techs.

*Janssen* agreed that GSK and Life Techs are the closest prior art, but argued that the court should not consider either without some additional “motivation.” The court rejected that argument, noting that “an obviousness challenge ‘may be based

on the closest prior art.” Appx48(quoting *UCB*, 890 F.3d 1328-29). The court also found that to the extent any “motivation” was required, several were indisputable, including a “need for media free of serum.” Appx64-65; *see also* Appx49-50(n.4).

The court then considered the differences between the prior art and the hypothetical claim—two for GSK and five for Life Techs—and concluded they were insignificant, Appx80, just as Janssen had characterized such differences when asserting infringement. Appx3034. The court explained that GSK and Life Techs “contain alternative, previously-known ingredients that were known to provide the same active components as the claimed ingredients,” Appx61-62 & Appx67-68, and that Janssen had admitted as much for all ingredients except ferric ammonium citrate. Appx69-70.

For ferric ammonium citrate, the court noted that it is undisputed that ferric fructose (GSK) and ferric citrate (Life Techs) supply chelated iron as a transferrin replacement, just like ferric ammonium citrate. Appx86. The court also rejected as irrelevant Janssen’s argument that the prior art taught that ferric ammonium citrate—for certain kinds of cells—was not “preferable” based on its “performance.” Appx97-99. Even if true, that is not “teaching away” as a matter of law, *id.* (citing *Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1327 (Fed. Cir. 2017)), especially where other prior art underscored that ferric ammonium citrate “was a workable option.” Appx102.

Janssen alternatively argued that “it is impermissible hindsight for the court to focus on the differences between GSK or Life Techs and the hypothetical media.” Appx62. The court disagreed, noting that Section 103 “expressly focuses the court on ‘the differences between the claimed invention and the prior art.’” Appx62-63.

Even so, the court spent fifteen pages analyzing numerous motivations a POSA would have to substitute any known interchangeable ingredients, Appx80-94, including (1) “cost or convenience,” (2) “design incentives” and “market forces,” (3) suggestions in GSK and Life Techs to “vary[] the sources of active trace elements” to “produce effective, animal-free media compositions,” and (4) the “normal desire” to “improve upon what is already known,” such as to “achieve greater [cell] growth.” Appx82-84, Appx86, Appx88-90.

As to overlapping concentration ranges, the court likewise found the hypothetical claims’ ranges obvious because GSK’s and Life Techs’ ranges “partially overlap with the concentration ranges in the hypothetical claims” with only one slight exception. Appx61. The overlap (or in one instance, near overlap) created a “prima facie case of obviousness.” Appx74. Janssen did not rebut the prima facie case because it did not show that any claimed range is “critical.” Appx74-75, Appx77. In fact, its experts testified “that the hypothetically claimed ranges are *not* ‘precise’ or ‘critical.’” Appx78; *see also* Appx900-901.



The court also rejected Janssen's suggestion to consider only the prior art's "preferred" concentrations, Appx72-73(n.8), because "unpreferred embodiments" in GSK "must be considered" as well. *Id.* (quoting *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989)).

The only secondary consideration Janssen raised below was purported "copying." Appx105. Janssen argued that the two accused HyClone media were copies of Janssen's MET 1.5 medium (an embodiment of the '083 patent), and that Janssen had given HyClone the MET 1.5 formula in 2004. *Id.*

Drawing all inferences in Janssen's favor, the court noted that copying was at best a "close question." Appx110. It noted, for instance, that HyClone's purported copy had 29 extra ingredients (including chemically undefined ingredients) and not a single concentration in that purported copy matched MET 1.5. Appx111-112. The court also noted that any alleged similarity was "not surprising," Appx110-111, given Janssen's expert concession that there is "a convergence of opinions on what kind of ingredients ought to be included in" a cell medium. Appx395(88:16-20); Appx664-665(273:22-274:22).

But giving Janssen the benefit of reasonable inferences, the Court held that "a reasonable factfinder could conclude that HyClone copied MET 1.5." Appx112-113. Nonetheless, the court found Janssen's evidence was "insufficient to establish that

the hypothetical claim was nonobvious,” due to the “strong case of obviousness based on the other *Graham* factors.” Appx113; Appx121.

## II. OWNERSHIP OF THE '083 PATENT

### A. Four Co-Inventors Assigned Their Rights to “the COMPANY,” as Defined in Employment Agreements.

The '083 patent has six named inventors. Appx169. At the relevant time, all were employed by Centocor, which J&J acquired in 1999 and is now known as Janssen. Appx9400. Two inventors assigned their rights to Centocor. Appx146(n.3). The other four, however, all signed nearly identical employment agreements between 2001 and 2003 assigning their inventions to “the COMPANY:”

I assign and agree to assign my entire right, title and interest therein [to inventions] *to the COMPANY*.

Appx9407(¶1); Appx9409(¶1); Appx9413(¶1); Appx9417(¶1). Each agreement broadly defines “COMPANY” to include the whole family of J&J companies (bracketed numbers added):

The COMPANY *means* [1] CENTOCOR *and* [2] JOHNSON & JOHNSON *and* [3] any of their successors or assigns, purchasers, acquirers, *and* [4] any of their existing and future subsidiaries, divisions or affiliates, including any such subsidiary, division or affiliate of Johnson & Johnson to which I may be transferred or by which I may be employed in the future. Affiliates of the COMPANY are any corporation, entity or organization at least 50% owned by the COMPANY, by Johnson & Johnson or by any subsidiary of Johnson & Johnson.”

Appx9407; Appx9409, Appx9413, Appx9417.

“[T]he COMPANY” was purposely defined broadly, partly to preserve confidentiality, which was the primary focus of the agreements. All four agreements are titled “Employee Secrecy Agreement” or “Employee Secrecy, Non-Competition and Non-Solicitation Agreement.” *Id.* The employees’ obligations to preserve confidential information and refrain from competing are owed to “the COMPANY”—*i.e.*, the full J&J corporate family.

In each agreement, the employees “recognize that CONFIDENTIAL INFORMATION is of great value to the COMPANY,” the “disclosure” of which “will cause immediate irreparable injury to the COMPANY.” Appx9408(¶5); Appx9410(¶5); Appx9414(¶5); Appx9418(¶5). Employees also promise not to “render services” to any “CONFLICTING ORGANIZATION” during their employment and “for a period of eighteen (18) months” thereafter, nor to “any other organization or person” that could “use CONFIDENTIAL INFORMATION to the detriment of the COMPANY.” Appx9410(¶6); Appx9414(¶6); Appx9418(¶6).

Broad confidentiality protection for “the COMPANY” is essential, at least because confidential information is routinely shared among employees of various family companies, such as marketing, finance, and legal personnel who provide support functions to multiple J&J companies. J&J subsidiary JJRT, for example, works with all “J&J operating companies, performing the research and development work necessary to bring products through FDA or other required regulatory

approval.” Appx159; Appx8790. Janssen acknowledges that its “employees may learn” confidential information “from other J&J companies,” and that it “has an interest in protecting” that information. Appx5863-5864.

**B. Previous District Court Proceedings and J&J Companies’ Broad Interpretation of “COMPANY” in Other Litigations.**

Janssen initially sued Celltrion in 2015 and 2016 for infringement of the ’083 patent. Janssen apparently realized it had a standing problem shortly after filing the first action. A few months after filing, all six inventors executed two rounds of “assignments” of the ’083 patent to Janssen. Appx9402; Appx9471-9507. Four inventors had assigned their rights to “the COMPANY” years earlier, however, and thus had nothing to assign in 2015. Appx9407(¶1); Appx9409(¶1); Appx9413(¶1); Appx9417(¶1).

Celltrion raised the standing issue as soon as it realized that Janssen was not the ’083 patent’s sole owner. After briefing and a hearing, the district court concluded there was “a serious question” about standing, Appx8445(79:1-2), *accord* Appx139, and postponed trial for further proceedings on the issue. Appx8469-8470; Appx139.

Those proceedings included discovery that revealed that J&J and its subsidiaries, in at least eleven litigations, had broadly interpreted “COMPANY” according to its plain meaning. Appx7354-7363 (citing Appx9099-9100; Appx9032; Appx9299; Appx9360; Appx8972; Appx8868; Appx8930; Appx8941; Appx8817-

8818; Appx8783; Appx8788; Appx8837; Appx8842; Appx9387). In one case, J&J and subsidiary Cordis sued to enforce an employment agreement with a nearly identical definition of “COMPANY,” and contended that under the invention assignment provision, the “*plaintiffs*”—*i.e.*, both J&J and Cordis, though only Cordis employed the defendant—“own all inventions, patentable or not, developed by [defendant] while at plaintiffs.” Appx8962-8963; Appx8984; Appx8972. In another case, two of Janssen’s sister companies contended that “[*t*]he term ‘*COMPANY*’ is defined to include *not only* DePuy Spine *but also* ‘JOHNSON & JOHNSON *and* any of their successors or assigns, purchasers, acquirers, *and* any of their existing and future subsidiaries, divisions or affiliates,’” Appx8788—*i.e.*, the same way Celltrion interprets “COMPANY” in this case.

Discovery also revealed that in approximately 2008 or 2009, J&J changed its form employment agreement to retain the broad definition of “COMPANY” for confidentiality-related provisions, but to use the narrower term “EMPLOYER” for invention-assignment provisions. Appx6552-6556; Appx6582-6589; Appx8678(23:3-12); Appx8687-8688(152:18-153:23); Appx8709-8710(182:5-183:6); Appx8714(198:7-14).

Celltrion moved to dismiss. In response, Janssen made yet another attempt to address its standing problem. Appx8508-8510. Janssen and J&J executed a “disclaimer,” asserting that “Janssen is the sole owner of the ‘083 patent,” and that

“J&J represents that none of its ... existing and future subsidiaries, divisions, and affiliates, other than Janssen,” “has or will assert any ownership rights to the ’083 patent.” Appx8509. The document did not indicate that J&J had authority to bind all of these various separate corporate entities, nor did it purport to deal with former subsidiaries previously within “the COMPANY” but no longer part of the J&J family at the time of the disclaimer.

Before the district court ruled, Janssen voluntarily dismissed both of its then-pending cases and filed a new complaint. Appx9516-9520. It argued that Janssen had standing for the *new* complaint because “Johnson & Johnson disclaimed any ownership interest in the ’083 patent” *before* Janssen filed it. Appx8644.

**C. Janssen’s Refiled Action and the District Court’s Denial of Celltrion’s Renewed Motion to Dismiss**

After Janssen filed its new lawsuit, Celltrion again moved to dismiss for lack of standing. The parties’ dispute turned on the meaning of “COMPANY.” Janssen contended that term could mean different things, depending on the circumstances:

[T]he agreements apply to ‘any’ one or more J&J company, as applicable, depending on the terms of the particular contract provision at issue and the facts of a given case.

Appx7376. Although it is a defined term, Janssen maintained that “COMPANY” had a broad meaning for confidentiality provisions, but a narrow one for “the assignment provision”: only the “entity that employed the inventor when he or she ‘conceived or made’ the invention—in this case Centocor.” Appx148-149.

The court denied Celltrion’s motion to dismiss, ruling that “at least for the purposes of patent assignments,” “COMPANY” means “only Centocor and its successor Janssen.” Appx158. The court found “ambigu[ity]” in the agreements, opening the door to extrinsic evidence, Appx149, which the court relied on to arrive at a ruling it acknowledged was “in tension with the literal definition of ‘the COMPANY.’” Appx160.

The court credited Janssen’s extrinsic evidence about its internal “practices” and “custom(s),” including a J&J database associating individual patents with the inventor’s employer. Appx153–155. And although J&J changed its forms in 2008 or 2009 to assign patents to the inventor’s “EMPLOYER” rather than the “COMPANY,” the district court treated that change as supporting—rather than refuting—its reading of the 2001–2003 contracts. *Id.*

“In the interest of completeness,” the court considered Janssen’s fallback argument that its 2017 “disclaimer” with J&J was an “independent basis to find that it has standing as the sole owner of the ’083 Patent.” Appx167. As the court noted, “[t]he Federal Circuit has never held that co-owners of a patent are not required to be joined as plaintiffs if they disclaim their interest in the patent.” Appx167. On the contrary, as Celltrion argued, “[s]tanding to sue for infringement depends entirely on the putative plaintiff’s proprietary interest in the patent, not on any contractual arrangements” about “who may sue and who will be bound by judgments.” *Prima*

*Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1381 (Fed. Cir. 2000). Janssen also made no effort to establish that J&J had the authority to bind all of its subsidiaries with the “disclaimer,” particularly those who gained patent ownership in 2001-2003, but were no longer part of the J&J family by the time of the “disclaimer.” Appx7341-7349; Appx7579-7590.

### SUMMARY OF THE ARGUMENT

**Ensnarement.** The Court should affirm summary judgment of non-infringement based on ensnarement. The hypothetical claims differ from GSK by only 2 known substitutions and from Life Techs by only 5 known substitutions—entirely trivial differences that Janssen has never even asserted improved the prior art media in any way whatsoever.

To attempt to salvage its case, Janssen repeatedly cries “hindsight.” It calls the district court’s reliance on GSK and Life Techs “hindsight,” but this Court has repeatedly found that there is “no ‘hindsight reconstruction’” in the “selection and application of... very pertinent art,” *In re Winslow*, 365 F.2d 1017, 1020 (C.C.P.A. 1966), or in “starting” an obviousness “analysis with... the closest prior art reference.” *Yeda Research v. Mylan Pharm. Inc.*, 906 F.3d 1031, 1044 (Fed. Cir. 2018). Janssen’s argument that courts should consider only art qualifying as a preferred “stating point” would effectively authorize patents on routine modifications to any other relevant prior art. That is not sensible.



Janssen also cries “hindsight” because the district court examined the differences between the prior art and the claimed invention. But §103 and *Graham* expressly require courts to focus on those “differences.” *Graham*, 383 U.S. at 37. In doing so, the district court considered the claimed medium as a whole, finding under *KSR* that the medium perfectly matched GSK and Life Techs, save for simple substitutions of one known ingredient for another with predictable results.

As to Janssen’s argument that overlapping concentration ranges do not create a prima facie case of obviousness, Janssen ignores long-standing precedent. Janssen identified nothing critical about the claimed ranges, such that the normal rule should not apply. To the contrary, Janssen argued the ranges are not critical.

Janssen only argues one dispute of fact regarding the prima facie obviousness of the hypothetical claim: whether a preference expressed in one prior art reference constitutes teaching away from the use of ferric ammonium citrate. Janssen’s argument is waived. And, regardless, Janssen’s argument fails as a matter of law because while the court construed the evidence in Janssen’s favor, merely expressing a preference is not teaching away. *Bayer Pharma*, 874 F.3d at 1327-28.

Finally, contrary to Janssen’s contention, the district court viewed alleged evidence of copying in the light most favorable to Janssen, and indeed found a dispute of fact on that issue. But the district court properly concluded that copying, especially a weak case like Janssen’s, is insufficient to overcome the strong case for

obviousness as a matter of law. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

**Standing.** Where fewer than all co-owners of a patent are joined, a suit must be dismissed for lack of standing. Janssen is the sole plaintiff, but not the sole owner of the '083 patent. Four inventors executed employment agreements assigning their inventions to “the COMPANY,” a term unambiguously defined as Janssen “*and* Johnson & Johnson *and*” their related companies.

Where the language of a contract “is plain and capable of legal construction, the language alone must determine the agreement’s force and effect.” *Twp. of White v. Castle Ridge Dev. Corp.*, 16 A.3d 399, 403 (N.J. Super. Ct. App. Div. 2011). Courts do not “make a better contract for either of the parties.” *Abbott Point of Care*, 666 F.3d at 1302. J&J and its family companies are thus co-owners of the '083 patent.

In concluding otherwise, the district court made two legal errors, either of which is sufficient to reverse and dismiss. First, it found ambiguity where there is none. Under controlling New Jersey law, a contract is ambiguous only if “susceptible to at least two reasonable alternative interpretations, or when it contains conflicting terms,” (*Woodhaven Lumber & Millwork, Inc. v. Monmouth Design & Dev. Co.*, No. A-2914-12T3, 2014 WL 1326994, at \*6 (N.J. Super. Ct. App. Div. 2014), such as when “literal compliance with [the two] provisions [is] impossible.” *5907 Blvd.*

*L.L.C. v. W. N.Y. Suites, L.L.C.*, No. A-3709-11T4, 2013 WL 3762695, at \*5 (N.J. Super. Ct. App. Div. July 19, 2013). The district court identified no “reasonable alternative interpretation” consistent with the actual text of the definition of “COMPANY.” Nor did it identify any “conflicting terms” making “literal compliance” “impossible.” The only sensible reading is the plain reading, which J&J companies had relied upon in at least eleven other litigations.

Second, even if there was ambiguity, “[t]he admission of evidence of extrinsic facts is not for the purpose of changing the writing.” *Conway v. 287 Corp. Ctr. Assocs.*, 901 A.2d 341, 347 (N.J. 2006); *Atl. N. Airlines v. Schwimmer*, 96 A.2d 652, 656 (N.J. 1953). But the court rewrote the definition of “COMPANY” based on extrinsic evidence regarding Janssen’s “practices” and how it “customarily treats patent rights.” Appx153-154. At the same time, it rejected evidence of Janssen’s conduct in other litigations involving the same or similar employment agreements and the defined term “COMPANY,” which contradicted Janssen’s arguments in this case. The case should have been dismissed.

### **STANDARD OF REVIEW**

The district court’s summary judgment rulings of noninfringement are reviewed de novo. *Momenta Pharm., Inc. v. Teva Pharms. USA, Inc.*, 809 F.3d 610, 614-15 (Fed. Cir. 2015). Ensnarement is question of law implicating underlying questions of fact. *DePuy Spine*, 567 F.3d at 1323-24. Janssen has the “burden of

persuasion” to establish “that the asserted scope of equivalency would not ensnare the prior art.” *Id.*

This Court “reviews standing to sue for patent infringement without deference.” *Abbott Point of Care*, 666 F.3d at 1302. Janssen “has the burden to show necessary ownership rights to support standing to sue.” *Id.* Under governing New Jersey law, the “interpretation of a contract is subject to de novo review by an appellate court.” *Kieffer v. Best Buy*, 14 A.3d 737, 742 (N.J. 2011). Appellate courts give “no special deference to the trial court’s interpretation and look at the contract with fresh eyes.” *Emogene v. UBS Warburg Real Estate Sec., Inc.*, No. A-5165-13T4, 2016 WL 2618732, at \*4 (N.J. Super. Ct. App. Div. May 9, 2016).

## ARGUMENT

### **I. JANSSEN’S APPEAL: THE COURT SHOULD AFFIRM THE JUDGMENT OF NONINFRINGEMENT DUE TO ENSNAREMENT.**

Janssen asserts infringement only under the DOE, asking the Court to overlook 12 or 13 differences between claim 1 and the accused products. Janssen’s 12/13-way DOE theory is ambitious by any measure. The DOE is “premised on language’s inability to capture the essence of innovation.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002). But the Supreme Court has cautioned that “when applied broadly,” it “conflicts with the definitional and public-notice functions” of patent claims. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

To prevent abuse, courts must enforce legal limits on the DOE. *Id.* at 39 n.8. Ensnarement is one such longstanding constraint on the DOE that avoids conflict with the definitional and public-notice functions of claims. *See McCormick v. Talcott*, 61 U.S. 402, 405 (1857). The DOE does not exist to “give a patentee something which he could not have lawfully obtained from the PTO had he tried.” *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683-86 (Fed. Cir. 1990). Thus, a “doctrine of equivalents theory cannot be asserted if it will encompass or ‘ensnare’ the prior art.” *Jang*, 872 F.3d at 1275.

Analyzing ensnarement involves “construct[ing] a hypothetical claim that literally covers the accused device.” *DePuy Spine*, 567 F.3d at 1323 (quoting *Intendis GmbH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1363 (Fed. Cir. 2016)). “[I]f such a claim would be unpatentable under 35 U.S.C. §§102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law.” *Id.* at 1325. Although the ensnarement analysis applies invalidity principles, *the patentee* bears the burden “to prove that the range of equivalents which it seeks **would not ensnare** the prior art.” *Marquip, Inc. v. Fosber Am., Inc.*, 198 F.3d 1363, 1368 (Fed. Cir. 1999); *see also Jang*, 872 F.3d 1275 at 1287; *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1366 (Fed. Cir. 1999). It is not the defendant’s burden to prove otherwise, much less by clear and convincing evidence. Ensnarement is “determined

by the court” “as a matter of law.” *DePuy Spine*, 567 F.3d at 1323 (internally quoting *Warner-Jenkinson*, 520 U.S. at 39 n.8).

The district court’s exhaustive analysis correctly applied familiar legal standards and held that hypothetical claims literally embodying Janssen’s infringement theory would be obvious over either GSK or Life Techs, independently. Appx124. On appeal, Janssen tries to flip the burden and attach the “hindsight” label to nearly every aspect of the district court’s reasoning that went against Janssen. In Janssen’s view, it was “hindsight” to consider the closest prior art, “hindsight” to focus on the differences between the prior art and hypothetical claims, and “hindsight” to ask whether those differences were sufficient to avoid obviousness.

The shoe does not fit. The district court was explicitly careful to avoid hindsight. Janssen asserts that the court admitted using hindsight. BlueBr. 44-45. But Janssen is misreading a sentence where the court was saying the exact opposite—that it was *not* an “impermissible use of hindsight” to apply the “Supreme Court’s analysis in *KSR*” by analyzing “the differences between the claimed composition and a composition in the prior art that was directed to the same problem.” Appx62-63; *see also* Appx65.

Ultimately, Janssen is attempting to manufacture “legal requirements” that do not exist, and that would defy the Supreme Court’s mandate that obviousness be

determined not through some “rigid” “formula[ic]” analysis, but through an “expansive,” “flexible,” and “common sense” analysis. *KSR*, 550 U.S. at 415–421. What Janssen labels as “hindsight” is the court doing precisely what precedent instructs and Janssen contorting the court’s words to argue otherwise. Janssen’s factual arguments concerning teaching away, unexpected results, and alleged “copying” are no better. All are waived, factually and legally unsupported, or both. This Court should affirm.

**A. The District Court Properly Identified the Relevant Prior Art.**

Janssen argues that a “skilled artisan would not have selected” GSK or Life Techs “as a starting point for developing a new cell culture medium,” and thus “[t]he district court used hindsight to select the GSK and Life Techs references” for its obviousness analysis. BlueBr. 24, 38; *see id.* at 41.

Janssen misstates the law and misunderstands the relevant inquiry. The two grounds supporting the ensnarement judgment are single-reference obviousness theories. A reference is prior art for obviousness purposes if it is “analogous to the claimed invention,” which includes “art... from the same field of endeavor, regardless of the problem addressed.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Janssen does not dispute that GSK and Life Techs each fit that description, nor could it. Both “were ‘from the same field of endeavor’ in which the inventors of

the '083 patent were working – the field of cell culture media development.” Appx63-64. That should end the inquiry.

1. It is not hindsight to consider the closest prior art.

Janssen nevertheless argues that the court should have ignored GSK and Life Techs and instead conducted the obviousness analysis based on the alleged “starting point” for media development, specifically the so-called “classical” media from decades before Janssen filed for the '083 patent. BlueBr. 18, 63. Binding precedent is to the contrary. “[A]n obviousness rejection by an examiner, or a challenge in court, *may be based on the closest prior art.*” *UCB*, 890 F.3d at 1329. Indeed, a skilled artisan is presumed to be aware of *all* pertinent prior art:

[T]he proper way to apply the 103 obviousness test to a case like this is to first picture the inventor as working in his shop with the prior art references—which he is presumed to know—hanging on the walls around him. ... Section 103 requires us to presume full knowledge by the inventor of the prior art in the field of his endeavor. We see no ‘hindsight reconstruction’ here, but only selection and application by the examiner of very pertinent art. That is his duty.

*In re Winslow*, 365 F.2d at 1020.

Far from restricting an obviousness analysis to so-called “starting point” references, this Court has affirmed invalidity findings even when the closest prior art is obscure, literally “on display for public view in remote cities in a far-away land,” requiring “a burden of discovery for one without the time, desire, or resources



to journey there in person.” *In re Carlson*, 983 F.2d 1032, 1037 (Fed. Cir. 1992), as revised on reh’g (Feb. 1, 1993).

Janssen’s proposed rule would upend a century of obviousness law and defy common sense. Patents would become available for utterly routine alterations to prior art, as long as the particular references were not preferred “starting points.” Any company could make myriad routine modifications to such references, and then patent them all by arguing the references were not preferred “starting points.” That is not sensible. It would be a license to patent routine work.

Another problem with Janssen’s approach is that the existence of one obvious solution or starting point does not foreclose or even undermine the possibility of others. *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1367 (Fed. Cir. 2016); *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012). The obviousness inquiry asks whether a claim is obvious in light of prior art, not whether it is the *most* obvious or *more* obvious than other possibilities. Thus, even if Janssen were correct that decades-old “classics” might be an attractive starting point, it does not follow that skilled scientists would consider *only* those “classics.” Janssen’s argument would artificially remove a wide range of prior art from the obviousness analysis, and would run headlong into *KSR*’s admonition that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” 550 U.S. at 421.

In any event, although Janssen argued otherwise, Appx863-864, there is no question GSK and Life Techs would be appropriate “starting points.” Appx1910. Both “were existing serum-free media capable of growing animal cells in culture with reduced contamination.” Appx49-50(n.4). Contrary to Janssen’s claim of waiver, *e.g.*, BlueBr. 25, Celltrion’s expert made exactly this point, testifying that a POSA would have a “strong motivation... to select” LifeTechs or GSK to reproduce serum-free medium. Appx3437, Appx3458; Appx1910.

Moreover, either of GSK and Life Techs was an especially appropriate “starting point” for an artisan developing media for growing the cells discussed in those references. Cell media are often optimized for specific cells because “for any particular cell you need a particular set of ingredients and a particular concentration of each of those ingredients.” Appx665-66(274:23-275:13). And because the ’083 patent is not limited to media for any specific cell line, a media for any cell line is germane to the obviousness analysis. GSK’s medium was used to grow MRC-5 cells, Appx756, and Life Techs’ was used with VERO cells. Appx700. Either the GSK or Life Techs media would be a perfect starting point for developing media for those cells or the others discussed in those references. (*E.g.*, Appx749; Appx699-700)

Janssen’s repeated references to “pluck[ing]” references from the “sea” of prior art,” BlueBr. 41, ignores not only that point but also that the two ensnarement grounds supporting the judgment are single-reference obviousness theories, not a

combination theory. Janssen’s cropped quotations from *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016), *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n.4 (Fed. Cir. 2016), and *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) concern *combining references*. They refer to “plucking” or “selecting” multiple references *for combination with each other*; none requires a reason for selecting a single reference as a “starting point.” As just explained, if the single reference is “analogous,” nothing more is required. *In re Bigio*, 381 F.3d at 1325.

*Polaris* in particular refutes Janssen’s argument. Like Janssen, the patentee there argued that “the Board’s analysis does not address why a person of skill in the art ‘looking to get the benefits of four-wheel drive would start with a dune buggy reference... as the primary reference in the first place.’” *Polaris*, 882 F.3d at 1070. *Polaris* rejected that argument because the prior art was analogous: both involving “all terrain vehicle[s] with a pair of seats for the side-by-side passengers” and addressing a “well-known feature with known benefits.” *Id.*

Pressed at oral argument, Janssen conceded: “It’s not hindsight -- setting aside the lead compound issue, it’s not hindsight to find the closest prior art.” Appx2186(159:17-19). Janssen was right then, and cannot walk back that concession on appeal.

2. Janssen improperly proposes an approach uniquely pertinent to “lead compound” cases.

In support of its “starting point” argument, Janssen tries to import “lead compound” principles, which apply to a narrow category of obviousness challenges to molecule patents. Contrary to Janssen’s argument, they are not a “specialized application of a general principle.” BlueBr. 41. Given the specific circumstances surrounding discovering useful molecules, precedent in that context discusses identifying a “starting point” or “lead compound” because there can be a “panoply of known compounds in the prior art” that look structurally similar, but have remarkably different activity. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012).

Those cases have no application here, where Janssen acknowledges that swapping interchangeable ingredients is “utter[ly] trivial[.]” Appx3034. And this Court has specifically held that “a lead compound analysis is not required” even when “analyzing obviousness of a chemical compound,” let alone other subject matter. *UCB*, 890 F.3d at 1329. The district court correctly recognized that “lead compound” concepts were not relevant here, where the claim is directed to a predictable “mixture of known ingredients,” not a new chemical compound structure.” Appx43-44(citing cases), Appx49.

Below, Janssen was more forthright in arguing for the application of “lead compound” precedents. Appx40-52. On appeal, Janssen largely avoids the words

“lead compound,” but still selectively quotes lead compound cases as if their holdings apply broadly to all cases. Even in subtler packaging, the argument remains meritless.

**B. The District Court Properly Determined the “Differences Between the Prior Art and the Claims at Issue.”**

Janssen next argues the court “used hindsight” in considering “only whether the differences between GSK and Life Techs and the hypothetical claim were obvious.” BlueBr. 44. Janssen contends “there was no reason other than hindsight to focus on the differences” between the art and the claim. *Id.*

Again, Janssen has the law wrong. Section 103 *explicitly requires* determination of whether “the *differences* between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious.” 35 U.S.C §103. So does the Supreme Court. *Graham*, 383 U.S. at 13; *accord KSR*, 550 US at 399. In *Graham*, the Supreme Court explicitly considered such “differences,” finding the claims in that case obvious “since *the differences between them and the pertinent prior art would have been obvious* to a person reasonably skilled in that art.” *Graham*, 383 U.S. at 37.

Janssen’s contention that doing as Congress and the Supreme Court instruct is hindsight is bizarre and depends on twisting the words of both the district court in this case and this Court’s precedents. Janssen contends that “the district court assumed that the *only* ingredients in GSK and Life Techs that a POSA would

consider modifying were the ones not found in the hypothetical claim,” and “without hindsight, a POSA would not know which ingredients those were.” BlueBr. 46.

The district court made no such assumption. Rather, as Janssen admits, there are countless routine ways to modify GSK and Life Techs, including the “utter[ly] trivial[.]” step of swapping interchangeable ingredients and varying concentrations within “extremely broad” plateaus. Appx3034; Appx380(11:15-22). But obviousness does not require a showing that a claim is the *most* obvious or the *only* obvious solution to a problem; only that it is obvious in light of prior art. *ACCO Brands*, 813 F.3d at 1367; *In re Mouttet*, 686 F.3d at 1334. The fact that the prior art reveals “a multitude of effective combinations does not render any particular formulation less obvious,” especially, as here, where the “claimed composition is used for the identical purpose taught by the prior art.” *Merck*, 874 F.2d at 807.

As *KSR* held, “a court must ask whether the improvement”—and here, Janssen does not even contend the disputed differences produced any improvement—“is more than the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417. The answer to that question, as the district court correctly concluded, is “no.”

Janssen similarly argues the district court’s focus on differences violates the rule that obviousness must consider the “claimed invention *as a whole*.” BlueBr. 45. But the district court explicitly acknowledged and followed the correct approach.

Appx31. It evaluated GSK and Life Techs against *all* “52 ingredients” and “concentration ranges in the hypothetical claims.” *E.g.*, Appx61-62. It then found that the claim—as a whole—would have been obvious.<sup>3</sup> *See, e.g.*, Appx124.

In any event, it is difficult to see how focusing even more intensely on the “claimed invention as a whole” could help Janssen here. GSK and LifeTechs undisputedly contain nearly all of the 52 claimed ingredients, in the claimed chemical forms and within the claimed concentrations. Focusing broadly on all 52 ingredients only underscores the impropriety of Janssen’s position that the accused products with twelve or thirteen variations from the claims are insubstantially different, but that prior art with two or five variations would not invalidate the hypothetical claims. Janssen’s infringement theory is precisely what the ensnarement doctrine is designed to prevent. The district court was correct to find that Janssen could not, as a matter of law, carry its burden given the undisputed facts.

**C. The District Court Properly Rejected Janssen’s Sole Purported Factual Dispute Regarding Ferric Ammonium Citrate.**

Janssen does not raise any dispute over how to read GSK or LifeTechs. Janssen identifies only one alleged factual dispute: whether ferric ammonium citrate

---

<sup>3</sup> Janssen argues the district court “ignored almost all of the 96 ingredients in GSK and almost all of the 88 ingredients in Life Techs.” BlueBr. 46. But as Janssen emphasizes for infringement, claim 1 is a “comprising” claim. Appx3649. The additional ingredients make no difference.

(the claimed iron chelator) is interchangeable with ferric fructose (GSK’s iron chelator) or ferric citrate (Life Techs’ iron chelator), respectively.

The foundational case on obviousness recognizes that swapping known substitutes is not generally patentable:

[T]he [alleged] novelty consisted in the substitution of the clay knob in the place of one made of metal or wood, as the case might be. And in order to appreciate still more clearly the extent of the novelty claimed, it is proper to add, that this knob of potter’s clay is not new, and therefore constitutes no part of the discovery. . . . The difference is formal, and destitute of ingenuity or invention. It may afford evidence of judgment and skill in the selection and adaptation of the materials in the manufacture of the instrument for the purposes intended, but nothing more. . . . In other words, the improvement is the work of the skillful mechanic, not that of the inventor.

*Hotchkiss v. Greenwood*, 52 U.S. 248, 265-67 (1850); *see also KSR*, 550 US at 416; *Graham*, 386 U.S. at 3-4; *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334, 1337-1338 (Fed. Cir. 2009) (collecting “substitution cases in which patentability was denied on grounds of obviousness”); *KSR*, 550 U.S. at 416 (“mere substitution” of interchangeable ingredients is obvious).

The district court correctly concluded that there was no material dispute because ferric ammonium citrate was a known substitute for ferric fructose (GSK) and ferric citrate (Life Techs)—all were undisputedly used for the same purpose in cell media long before the 2004 priority date. Appx67-69.

The district court relied on express and un rebutted teachings that “ferric ammonium citrate... can completely replace transferrin.” Appx102. Likewise, ferric



citrate can “substitute for transferrin,” Appx686, and the “only function identified for ferric fructose in GSK... is to replace transferrin and supply chelated iron.” Appx68. Indeed, by the alleged 2004 priority date, “ferric ammonium citrate [was a] *preferred*” iron chelator in media. Appx806(18:28-31); Appx815; Appx68-69. Celltrion’s vendor, HyClone, was already using ferric ammonium citrate as an iron chelator in a publicly available medium by 2001, well before its collaboration with Janssen. Appx110.

Simply put, there is no fact issue: Janssen never disputed that ferric ammonium citrate, ferric fructose and ferric citrate are alternative ingredients used for the very same purpose.

1. No motivation is required to choose from interchangeable options.

In its effort to manufacture a dispute, Janssen repeats its common refrain, claiming the court was required to find “a reason or motivation to [] replace ferric fructose (in GSK) or ferric citrate (in Life Techs) with [ferric ammonium citrate],” and that any other approach uses “hindsight.” BlueBr. 50. Yet again, Janssen has the law wrong.

Obviousness does not require a specific reason to select one of a group of known substitutes where “all that was required to obtain” the claimed “combination was to substitute one well-known [ingredient] for another” from “a finite number of identified, predictable solutions.” *Wm. Wrigley Jr. Co. v. Cadbury Adams USA*

*LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012). As the Supreme Court noted in *KSR*, finding obviousness is “more difficult” in cases where the court must “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” as opposed to cases, like this one, involving “the simple substitution of one known element for another.” *KSR*, 550 U.S. at 417-18.

In *Wrigley*, for instance, the Court affirmed obviousness where the prior art disclosed the claimed composition, except with a cooling agent that was interchangeable with the claimed cooling agent. *Id.* The Court did not require any “reason” to pick one of those interchangeable options. *Id.* The Court likewise reversed a finding of non-obviousness where there were only “53 pharmaceutically-acceptable anions” to choose from, and one of those would have resulted in the claimed compound. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1363-64 (Fed. Cir. 2007). Again, in *Pfizer*, no reason was required to choose the particular anion among the well-known options. *Id.* at 1363; *see also In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007) (affirming obviousness where one compound was “easy to substitute” for another of its kind).

*Pfizer* and *Wrigley* are consistent with more than 150 years of Supreme Court precedent—from *Hotchkiss* to *KSR*—holding that substitution of known interchangeable components is obvious. Some of this Court’s oldest precedent is directly on point: “The mere substitution of materials... in substantially the same

manner, and with the same effect, as the materials disclosed by the patent, constitutes no invention.” *In re Fischer*, 62 F.2d 96, 97 (C.C.P.A. 1932). So too is the MPEP, which instructs patent examiners that one rationale supporting a prima facie case of obviousness is the “[s]imple substitution of one known element for another to obtain predictable results.” MPEP §2143.

A POSA is motivated to select *any* one of ferric ammonium citrate, ferric fructose, or ferric citrate by their known interchangeability, simply based on a POSA’s “ordinary skill and common sense.” *KSR*, 550 U.S. at 421. Choosing among them requires no inventive inspiration—particularly where Janssen does not even assert, much less provide evidence, that ferric ammonium citrate provides *any advantage* over ferric fructose or ferric citrate in the claimed media. Rather, choosing among them is based on considerations like “cost or convenience,” Appx90, or routine efforts to “‘improve upon’ or ‘optimize’ GSK and Life Techs by substituting different salt forms to achieve greater growth with their particular cell lines.” *Id.* This is on top of the express motivations provided in the prior art, including that ferric ammonium citrate was “preferred” by 2004. Appx68-69. On this record, the only reasonable conclusion is that the choice between ferric ammonium citrate, ferric fructose, or ferric citrate is “the simple substitution of one known element for another.” *KSR*, 550 U.S. at 417-18.

2. Janssen’s “teaching away” argument is contrary to law and unsupported by the record.

Janssen also makes a “teaching away” argument based on two references, Keenan and Field. BlueBr. 53-54. This argument fails for multiple reasons.

As an initial matter, this argument is not preserved. This Court “does not consider arguments not raised below.” *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012). As the district court noted, Janssen mentioned Keenan only in a footnote. Appx94-95. “[A]rguments raised in footnotes are not preserved.” *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006); *see also Nat’l Foreign Trade Council v. Natsios*, 181 F.3d 38, 60 n.17 (1st Cir. 1999). And Janssen never mentioned Field in its briefs below. The reference is not even part of the record. Janssen first attempted to raise Field during oral argument with a demonstrative slide with selective quotations. Appx2419. When the district court noted Field was not in Janssen’s briefs, Janssen responded, “You can disregard it, Judge.” Appx2238-2240(43:3-45:24). Janssen cannot now contend that Field or Keenan is the basis of any error by the district court.

In any event, Janssen’s arguments fail on the merits. Keenan tested seven ingredients known to supply iron, and concluded that “all the factors tested”—*including ferric ammonium citrate*—“were able to exert a concentration-dependent, growth-promoting effect on MDCK cells.” Appx811. While concluding that certain other ingredients performed better than ferric ammonium citrate, the authors

explained that their conclusion was limited to MDCK cells. They stated that “the effectiveness of any of these factors will depend not only on the cell line but also the culture system being used,” noting that ferric ammonium citrate has produced “high level of growth” in other systems. Appx811. Contrary to Janssen’s argument, this does not qualify as teaching away as a matter of law.

First, teaching away “does not focus on whether a person of ordinary skill in the art would have merely *avored* one disclosed option over another disclosed option.” *Bayer Pharma*, 874 F.3d at 1327-28. In *Bayer*, like here, an expert testified that certain “consideration[s]” would have “lead” a POSA to one solution and away from another. *Id.* The Court explained that evidence of a mere preference “does not support a finding of teaching away.” *Id.* Teaching away requires that the option was “so flawed” that no POSA would use it. *KSR*, 550 U.S. at 425-26.

Janssen argues that Kennan “tested seven iron-containing compounds,” but “only four of the seven,” not including ferric ammonium citrate, “made the cut,” and thus ferric ammonium citrate was “inferior.” BlueBr. 53-54. That is not teaching away. Janssen is *not* suggesting ferric ammonium citrate “was somehow so flawed that there was no reason to” use it. *KSR*, 550 U.S. at 425-26. Nor could it—because Keenan expressly identified ferric ammonium citrate as a source of chelated iron to serve as a “transferrin replacement[.]” Appx809; Appx811; Appx99. At most, a POSA might “prefer” something other than ferric ammonium citrate in a particular

context, but that “does not amount to a teaching away from the lesser preferred but still workable option.” *Bayer*, 874 F.3d at 1327; *id.* at 1328.

Second, Janssen overstates Keenan by arguing that ferric ammonium citrate was not a “suitable replacements for transferrin.” BlueBr. 54. Keenan, rather, discloses testing seven “simple iron compounds or iron chelators” that were all *known* options “to replace transferrin.” Appx809. Keenan found that all of them worked—but selected four compounds “for further analysis.” Keenan says *nothing* suggesting that ferric ammonium citrate is incapable of serving as a transferrin replacement. On the contrary, Janssen omits that Keenan concluded that “all” seven, including ferric ammonium citrate, had a “growth-promoting” effect. Appx811.

Janssen also ignores that Keenan’s conclusions were limited to effectiveness with MDCK cells. The authors expressly state that “the effectiveness of any of these [iron sources] will depend on” the cell line used. Appx811. As Janssen’s expert conceded, “for any particular cell you need a particular set of ingredients and a particular concentration of each of those ingredients.” Appx665-666(274:23-275:13). Janssen’s focus on Keenan’s optimization studies for a *single, specific cell line* cannot negate its statement that ferric ammonium citrate has a “growth-promoting” effect. Appx811.

Third, regardless of Janssen’s distortion of Keenan and Field, it is undisputed that *other, later* prior art “references plainly [taught] that [ferric ammonium citrate]

could be used effectively,” which means a POSA would “not have been dissuaded” from using it. *Dome Patent LP v. Lee*, 799 F.3d 1372, 1381-82 (Fed. Cir. 2015). These references, such as Polymun Scientific (2003), and HyClone’s commercial media (2001), postdate both Keenan and Field and demonstrate that POSAs embraced ferric ammonium citrate, and indeed viewed it as a “preferred” source of chelated iron as of the ’083 priority date. Appx110; Appx806(Polymun Scientific at 18:28-31).

3. Janssen’s “unpredictable” argument is waived and contrary to the record.

Janssen also argues for the first time on appeal that “biotechnology is an ‘unpredictable’ art” and therefore “the artisan would had have had no reasonable expectation of success with using ferric ammonium citrate as a transferrin replacement in creating a media capable of high volume biopharmaceutical production.” BlueBr. 55. The argument is too late, and unsupported.

As the district court observed, Defendants’ expert testified “*without contradiction in the evidence*, that a POSA would have ‘a reasonable expectation that... the outcomes would be similar to what is in the ’083 patent’ if he substituted different salt forms for various claimed ingredients” in the prior art media, including iron chelators like ferric ammonium citrate. Appx86; *see also* Appx1384(¶122). “If [Janssen] seeks to show error in a trial court’s overlooking an argument, it must first present that argument to the trial court”—“appellate courts do not consider a party's

new theories, lodged first on appeal.” *Sage Prods., Inc. v. Devon Indus, Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997); *see also Del. Valley Floral Grp., Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374, 1383 (Fed. Cir. 2010). Janssen did not dispute the reasonable expectation of success below. This argument is waived.

Even now, Janssen presents no evidence rebutting the expectation of success. It incorrectly claims Defendants’ expert testified ferric ammonium citrate is not interchangeable and does not lead to predictable results. BlueBr. 28. But the testimony Janssen cites says the opposite. Dr. Glacken testified: “[d]ifferent forms [of iron chelators] might perform differently for a given – for a given cell line, but they’re all – ***they’re all capable of delivering iron to the cells.***” Appx1112(179:25-180:6). That some options could be more successful than others is irrelevant, because “only a reasonable expectation of success, not a guarantee, is needed;” “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Pfizer*, 480 F.3d at 1364. Janssen offered no evidence negating a reasonable expectation of success.

4. Overlapping ranges are prima facie obvious.

The district court properly found a prima facie case of obviousness because the concentration ranges in GSK and Life Techs overlap with those in the hypothetical claims. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006); *In re Geisler*, 116



F.3d 1465, 1469-70 (Fed. Cir. 1997); *In re Applied Materials*, 692 F.3d 1289, 1295 (Fed. Cir. 2012).

To overcome the presumption of obviousness, Janssen had to “show that the claimed range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range,” *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997) (original emphasis, citation omitted), or show “that the prior art teaches away from the claimed range.” *Ormco*, 463 F.3d at 1311. Janssen not only made no such showing, it vociferously argued the opposite for infringement purposes—that the claimed ranges were *not* “critical,” Appx375(166:5-19), but mere “guidelines.” Appx389-390(82:20-83:3). Indeed, Janssen argued that there is “a broad plateau of interchangeable concentrations” for each ingredient—“extremely broad, 2500 times, sometimes it’s six times.” Appx380(11:15-22); Appx389-390(82:20-83:3); Appx899-900(¶¶10-11 Resp.). Janssen cannot argue the opposite for purposes of ensnarement.

As a bit of misdirection, Janssen argues seventeen of GSK’s “preferred” concentration ranges and twelve of Life Techs’ “preferred” concentration ranges do not overlap. BlueBr. 26-27, 56. That is irrelevant. “[P]referred” ranges are “not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.” *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). There is no dispute that GSK and Life Techs disclose the ranges set forth

in Exhibits 1 and 2 to the district court's order, which overlap with the hypothetical claim. Appx924-925(¶55 Resp.).

Next, Janssen argues that there is no presumption of obviousness where the "range [is] so broad as to encompass a very large number of distinct possible compositions." BlueBr. 59-69 (citing *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291 (Fed. Cir. 2011)). But, as the district court correctly held, *Genetics Institute* is inapposite. Appx76-77. That case dealt with prior art disclosing "various structures," not "a range of values," as here. *Gen. Hosp. Corp. v. Sienna Biopharm., Inc.*, 888 F.3d 1368, 1374 (Fed. Cir. 2018).

Further, Janssen argues that considering GSK and Life Techs "as a whole, the partially overlapping ranges do not create a presumption of obviousness because" of "ingredient differences" from the hypothetical claim. BlueBr. 57 (citing *Abbott Labs v. Dey, L.P.*, 287 F.3d 1097, 1106 (Fed. Cir. 2002)). But Janssen invents this rule from whole cloth. Janssen's case, *Abbott Labs v. Dey, L.P.*, says no such thing. There, the district court erred by "ignoring other limitations of the claim" which were entirely missing. *Abbott*, 287 F.3d at 1106. Here, the prior art includes every limitation, either literally or an interchangeable substitute, and the district court considered all claim limitations.

Finally, Janssen's brief includes one sentence stating that the presumption of obviousness is "inapplicable" to Life Techs' one non-overlapping range for

putrescine.2HCl. BlueBr. 57. Janssen also did not argue this below and thus waived it. *Sage*, 126 F.3d at 1426. Regardless, as Celltrion argued below, “a prima facie case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.” *Peterson*, 315 F.3d at 1329; Appx346. Here, the claimed range is 0.025-0.25 mg/L and Life Techs’ range of 0.0001-0.01 mg/L is 40% below the claimed range. Appx134. 40% is far closer than other concentrations Janssen has declared equivalent for purposes of infringement, such as where the accused product contains 90% less than the claimed amount. *Statement of the Case* §I.C, *supra*. Moreover, Janssen’s view is that any concentration is equivalent, as long as the cells grow. *Id.*; *see also Wilson Sporting Goods*, 904 F. 2d at 685 (finding ensnarement where patentee failed to prove non-overlapping range mattered for obviousness purposes).

**D. Purported Secondary Considerations Do Not Create a Genuine Issue of Material Fact.**

For secondary considerations, Janssen only alleged copying by Celltrion’s vendor, HyClone.<sup>4</sup> The district court found that “a reasonable factfinder could

---

<sup>4</sup> Janssen attempts to argue industry praise for the first time on appeal. But below, Janssen only argued copying in its briefs, thus waiving arguments about “praise.” Appx2224(29:20-25); BlueBr. 65; *Celsis*, 664 F.3d at 931. Indeed, pressed at oral argument, Janssen agreed it was “fine” that praise was “out” because Janssen did not brief it. Appx2224-2225 (29:20-30:4).

conclude that HyClone copied” one of the embodiments of the claimed invention (MET 1.5 formulation). Appx112-13. But the court also correctly found as a matter of law that even assuming copying—what it called at best a “close” issue for Janssen—would be “insufficient to overcome the strong case of obviousness based on the other *Graham* factors.” Appx121.

This Court and the Supreme Court have repeatedly held that, as a matter of law, when the claimed invention “rests upon exceedingly small” differences from the prior art, secondary considerations will not “tip the scales of patentability.” *Graham*, 383 U.S. at 36. Likewise, when the claimed invention “represent[s] no more than ‘the predictable use of prior art elements according to their established functions,’” as here, “secondary considerations are inadequate to establish nonobviousness as a matter of law.” *Wyers*, 616 F.3d at 1246 (quoting *KSR*, 550 U.S. at 417); *see also Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013) (affirming obviousness despite evidence of copying); *accord Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 731 (Fed. Cir. 2017) (same).

Among the secondary considerations, alleged “copying” is disfavored. It is, at best, “only *equivocal evidence* of non-obviousness in the absence of more compelling objective indicia of other secondary considerations.” *Geo. M. Martin Co. v. All. Mach. Sys. Int’l. LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010). It “has limited probative value” when, as here, there is an “absence of evidence of failed

development efforts by the infringer.” *Friskit, Inc. v. Real Networks, Inc.*, 306 F. App’x 610, 617 (Fed. Cir. 2009).

In this case, Janssen’s “copying” evidence is exceedingly thin and no stronger than evidence this Court and the Supreme Court have found insufficient as a matter of law to defeat obviousness. The alleged “copy” has **29 ingredients** not found in MET 1.5 without even a single matching concentration. Appx2541; Appx9522-9523. As Janssen’s expert Dr. Butler conceded, those extra 29 ingredients “could contribute *substantially* to the ability of these two media to divide and grow cells.” Appx3021(231:15-18). Janssen’s expert likewise admitted that it is not “surprising” that HyClone’s product, MET 1.5, **and** GSK **and** Life Techs have so many common ingredients, because there is a “convergence of opinions on what kind of ingredients ought to be included in” a cell culture medium. Appx395(88:16-20). Where, as here, there is a “practice of marketing very similar products,” general similarities are “not a strong indicator of nonobviousness.” *Wrigley*, 683 F.3d at 1364.

Finally, Janssen “cannot complain that the district court failed to credit its evidence regarding objective indicia”; to the contrary, “the district court accepted the facts [Janssen] asserted about... copying.” *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1347 (Fed. Cir. 2017). The court simply engaged in the *legal* analysis of whether, even assuming copying, that secondary consideration could overcome the strong prima facie case of obviousness. *Id.*

(affirming summary judgment of obviousness despite evidence of copying); *Wrigley*, 683 F.3d at 1364 (same); *Friskit*, 306 F. App'x at 617 (same).

This Court should affirm. Janssen's weak evidence of copying, even viewed in the light most favorable to Janssen, "cannot overcome a strong prima facie case of obviousness." *Wyers*, 616 F.3d at 1246.

## **II. CROSS-APPEAL: THE DISTRICT COURT ERRONEOUSLY RULED THAT JANSSEN WAS THE SOLE OWNER OF THE '083 PATENT.**

For more than 100 years, it has been the law that "[a]bsent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing" and the suit must be dismissed. *Israel Bio-Eng'g Project v. Amgen, Inc.*, 475 F.3d 1256, 1264-1265 (Fed. Cir. 2007); accord *Advanced Video Techs. LLC v. HTC Corp.*, 879 F.3d 1314, 1319 (Fed. Cir. 2018); 2 W. Robinson, *The Law of Patents for Useful Inventions* §939, at 127-128 (1890) ("In suits on a joint patent all the patentees must be made plaintiffs").

The original joint owners of the '083 patent were the six co-inventors. *See Bd. of Trs. of Stanford Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 785-86 (2011); *Ethicon Inc. v. U.S. Surg. Corp.*, 135 F.3d 1456, 1465 (Fed. Cir. 1998). Janssen thus must show that, before filing suit, Janssen—and only Janssen—acquired the rights of all six co-inventors, rights which can only be transferred in writing. *See* 35 U.S.C. §261. Janssen cannot meet this burden.

**A. The Contracts Unambiguously Assign the Invention to Centocor, J&J, and its Subsidiaries.**

In New Jersey, as elsewhere, contract interpretation must be rooted in the text of the contract. “The polestar of contract construction is to discover the intention of the parties *as revealed by the language used by them.*” *Karl’s Sales & Serv., Inc. v. Gimbel Bros., Inc.*, 592 A.2d 647, 650 (N.J. Super. Ct. App. Div. 1991). “[I]t is ‘well-settled that when the terms of a contract are clear, ‘it is the function of a court to enforce it as written and not to make a better contract for either of the parties.’” *Abbott Point of Care*, 666 F.3d at 1302.

Moreover, “where a contract repeats the same terms, such terms should be given the same meaning.” *Grayzel v. Boston Sci. Corp.*, No. A-0991-14T2, 2015 WL 9694354, at \*5 (N.J. Super. Ct. App. Div. Jan. 11, 2016). That principle applies with special force for *defined terms*, the very purpose of which is to make clear that a term means the same thing each time it is used. *Cf. Morgan v. Air Brook Limousine, Inc.*, 510 A.2d 1197, 1201 (N.J. Super. Law. Div. 1986).

Here, Janssen’s standing turns on such a defined contractual term. Each employment agreement states that “I assign and agree to assign my entire right, title and interest [in inventions] *to the COMPANY.*” Appx9407(¶1); Appx9409(¶1); Appx9413(¶1); Appx9417(¶1). The drafters took care to avoid ambiguity by specifically defining “COMPANY” as follows (bracketed numbers added):

The COMPANY *means* [1] CENTOCOR *and* [2] JOHNSON & JOHNSON *and* [3] any of their successors or assigns, purchasers, acquirers, *and* [4] any of their existing and future subsidiaries, divisions or affiliates, including any such subsidiary, division or affiliate of Johnson & Johnson to which I may be transferred or by which I may be employed in the future. Affiliates of the COMPANY are any corporation, entity or organization at least 50% owned by the COMPANY, by Johnson & Johnson or by any subsidiary of Johnson & Johnson.”

Appx9407, Appx9409, Appx9413, Appx9417.

That definition may be broad, but it is neither ambiguous, nor a scrivener’s error. It explicitly refers to Centocor, *and* Johnson & Johnson, *and* two categories of successor and affiliate companies. The district court recognized, at a minimum, that the definition of “COMPANY” “literally includes both Centocor and J&J,” Appx152, and that its Centocor-only reading was “in tension with the literal definition of ‘the COMPANY.’” Appx160. That is an understatement: The court’s interpretation results in an *expressly defined term* having different meanings in different paragraphs of the same agreement.

That these are “employee secrecy” agreements reinforces this clarity. They use “COMPANY” throughout their paragraphs on confidentiality and non-competition. As Janssen concedes, for these purposes, “COMPANY” is broad: “[w]here a person “is employed by Cent[o]cor,” for example, “[but] has access to confidential information of another J&J subsidiary,” “COMPANY” “might include that other company.” Appx8711-8713(188:24-189:19, 190:3-13).



There is not a single word in the contract that justifies—especially for a *defined* term—departure from the ordinary rule that the “same meaning” applies “where a contract repeats the same terms” multiple times. *Grayzel*, 2015 WL 9694354, at \*5. Indeed, perhaps the clearest feature of the agreements is that all of the signing employee’s obligations—safeguarding confidential information, respecting competitive interests, and conveying inventions—are owed to the same entities: “[T]he COMPANY,” which is explicitly defined in each contract, and repeated in capital letters several times on each page.

The literal terms of the contract should have been the end of the matter. When “the language is plain and capable of legal construction, the language alone must determine the agreement’s force and effect.” *White*, 16 A.3d at 403. Janssen argued below that giving “COMPANY” its plain meaning “leads to absurd and unreasonable results,” such as requiring numerous J&J subsidiaries “to join in this and other patent infringement actions,” and creating “accounting chaos.” Appx7390-7391. Group patent ownership also has benefits though, including avoiding the need for transfer or license agreements to give family companies the right to use inventions (*see* 35 U.S.C. §262), which must take place at arm’s length, for fair market value. *See, e.g., Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1377 (Fed. Cir. 2015), *vacated sub nom, Medtronic Sofamor Danek USA, Inc. v.*

*NuVasive, Inc.*, 136 S. Ct. 893 (2016), *reinstated in part*, 824 F.3d 1344 (Fed. Cir. 2016).

Of course, Janssen *now* finds the consequences of the definition it chose for “COMPANY” undesirable—for this specific case—because it lacks standing to sue on its own. But the plain language of these “employee secrecy” agreements indicates that responsible Janssen attorneys in the early 2000s struck a different balance, perhaps weighing confidentiality concerns more heavily than any patent-related considerations.

But none of that matters anyway. “[W]hen the terms of a contract are clear, ‘it is the function of a court to enforce it as written and not to make a better contract for either of the parties.’” *Abbott Point of Care*, 666 F.3d at 1302. Drafter’s remorse, driven by Janssen’s patent litigation-influenced view today, is not a legal basis for deeming a contract ambiguous. Janssen chose a simple and clear definition of “the COMPANY”—one that was written to explicitly apply to the *entire* contract in *every* provision that used that capitalized term. That straightforward definition should have resulted in dismissal here, under age-old rules governing patent ownership and standing.

#### **B. The District Court Erred by Rewriting Janssen’s Contracts**

The district court’s ruling, in effect, struck every word after “Centocor” from the definition of “COMPANY,” with the new definition changing to a *different*

company if an employee moved within the J&J family. The Court applied the new definition only for purposes of patent ownership, while still using the full, plain text for confidentiality and non-compete provisions. Appx158. This outcome rests on two legal errors, each of which requires reversal: (1) finding ambiguity in the definition of “COMPANY,” and (2) using that ambiguity to adopt an unsupportable reading of the contract.

1. The district court erred in finding ambiguity in the definition of “COMPANY.”

Ambiguity is not a broad license to rewrite contracts. New Jersey courts caution against “tortur[ing] the language of a contract to create ambiguity.” 259 *Holdings Co. v. Union Dry Dock & Repair Co.*, No. A-0267-06T5, 2007 WL 3274272, at \*3 (N.J. Super. Ct. App. Div. Nov. 7, 2007). Ambiguities are relevant to choosing between “reasonable alternative interpretations.” *Schor v. FMS Fin. Corp.*, 814 A.2d 1108, 1112 (N.J. Super. Ct. App. Div. 2002). And “[o]nly genuine interpretational difficulties engage the doctrine of ambiguities.” *Vantage Dev. Corp. v. Am. Env't Techs. Corp.*, 598 A.2d 948, 955 (N.J. Super. Law. Div. 1991).

The district court’s finding of ambiguity was premised on purported “conflict” within the employment agreements. But “conflict” exists, for example, where “literal compliance with [two] provisions is impossible,” 5907 *Blvd.*, 2013 WL 3762695, at \*5, or where language “confounds any clear understanding of the parties’ undertaking.” *Rockel v. Cherry Hill Dodge*, 847 A.2d 621, 625 (N.J. Super. Ct. App.

Div. 2004). Neither of the so-called “conflicts” the district court identified are actual conflicts or make the definition of “COMPANY” ambiguous.

**a. The definition of “Affiliates” does not create a conflict.**

The court found ambiguity in the second sentence of the COMPANY definition, which states that “affiliates of the COMPANY” are “any corporation, entity or organization at least 50% owned by the COMPANY, by Johnson & Johnson, or by any subsidiary of Johnson & Johnson.” Appx150-151. The court reasoned that “[i]f ‘the COMPANY’ included, or always included, J&J and its subsidiaries, the [affiliates] clause could have easily ended at ‘the COMPANY,’ to read ‘any corporation, entity or organization at least 50% owned by the COMPANY.’” Appx151. Thus, the court held, the principle that each term “should be given meaning so that no term is superfluous” supports that the COMPANY “does not include J&J and its subsidiaries, or always include them.” Appx150-151.

This reasoning is unsupportable. First, the language is not actually superfluous. “Affiliates,” as written, includes entities “at least 50% owned by the COMPANY, by Johnson & Johnson or by any subsidiary of Johnson & Johnson,” which extends to lower-level subsidiaries, *i.e.* subsidiaries of subsidiaries, or entities owned at least 50% *collectively* by the COMPANY, such as two J&J family entities each owning 25% of a company. Appx7570-7571. Without this language, the employment agreements would fail to protect these lower subsidiaries.

Second, even if there is some overlap, it is redundancy, not ambiguity. In contracts, redundancy is often a virtue, not a vice: repetition adds clarity and avoids loopholes. Anyone familiar with the expressions “belt-and-suspenders” or “full and complete stop” knows that lawyers “frequently say two (or more) things when one will do or say two things *as a way of emphasizing one point.*” *TMW Enters., Inc. v. Fed. Ins. Co.*, 619 F.3d 574, 578 (6th Cir. 2010); *Mayer v. Dev. Corp. of Am.*, 541 F. Supp. 828, 843 (D.N.J. 1981), *aff’d*, 688 F.2d 822 (3d Cir. 1982) (“[T]here is a distinction between superfluity and redundancy,” and language that is “merely redundant” simply “hit[s] the head of the nail harder.”); *see also Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 226 (2008) (similar); *Royal Food Distribs., Inc. v. Dir., Div. of Taxation*, 15 N.J. Tax 60, 71-73 (1995) (similar).

Ironically, the court’s special meaning for “COMPANY” makes *all 55 words* in the term’s definition, after the word “Centocor,” superfluous. *Cf. Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 385 (2013) (“[T]he canon against surplusage ... ‘assists only where a competing interpretation gives effect to every clause and word of a statute.’”).

**b. The patent assignment provision does not create a conflict.**

The second conflict the court relied on is no better. It compared the literal definition of “COMPANY” (Centocor “and” J&J “and” related companies) with the “sense” the court got from the patent assignment provision, Paragraph 1, which

refers to “inventions conceived or made by me during my employment with the COMPANY.” Appx150. According to the court, the reference to “employment” “*implies* that ‘the COMPANY’ means the inventor’s employer” and “*suggests* that the term ‘the COMPANY’ means only the inventor’s employer.” Appx152. The court held that this created a “conflict[.]” *Id.* That reasoning is unsound.

First, the court did not identify any actually “conflicting terms” in the agreements. Appx143 (citing *Woodhaven*, 2014 WL 1326994, at \*6). Rather, the court held that the actual words in the literal definition of “COMPANY” “conflict[.] with the *sense* in which the term is used” in the patent assignment provision, or what the court thought that provision “suggests” and “implies.” Appx152. That is not enough to justify rewriting a defined term.

Second, the patent assignment provision simply does not “suggest[.]” that “COMPANY” really “means only the inventor’s employer.” *Id.* The operative sentence in the assignment provision is clear: “I assign and agree to assign my entire right, title and interest [in inventions] to the COMPANY.” Appx9407(¶1); Appx9409(¶1); Appx9413(¶1); Appx9417(¶1). At most, references in that paragraph to “employment with the COMPANY” make clear that “the COMPANY” *includes* the J&J entity that directly employs the inventor. Nothing in that clause *limits* “COMPANY” to the specific direct employer, nor reveals an intent that is different than the actual words. The court’s reliance on “employment with the COMPANY”

is also unworkable because other provisions Janssen agrees confer broad protection to the entire J&J family—including non-compete provisions—use the very same phrase. *See, e.g.*, Appx9410(¶¶6-7); Appx9411(¶12); Appx9414(¶¶6-7); Appx9415(¶12); Appx9418(¶¶6-7); Appx9419(¶12).

Neither of the “conflicts” the district court identified show that “COMPANY” is susceptible to two reasonable readings or make literal compliance with the contract “impossible.” *5907 Blvd*, 2013 WL 3762695, at \*5. The district court erred in finding the contract ambiguous.

2. The extrinsic evidence cannot support the district court’s narrow, patent-ownership-specific reading of “COMPANY.”

Even where a court finds ambiguity, “[t]he judicial task is simply interpretative.” *Kieffer*, 14 A.3d at 742-43. “The admission of evidence of extrinsic facts is not for the purpose of changing the writing.” *Conway*, 901 A.2d at 347; *Atl. N. Airlines*, 96 A.2d at 656 (extrinsic evidence may not be used to “curtail[ the] terms” of an agreement.”). Keeping analysis rooted in the text is especially important with patent assignments, because only *writings* can transfer patent ownership. 35 U.S.C. §261.

Contracts are construed to carry out the parties’ mutual intent, and it is the “parties’ *objective* intent” as expressed by a contract’s plain text that “governs”—the one that each party “outwardly manifests to the other party,” not some “different, secret intention from that outwardly manifested.” *Hagrish v. Olson*, 603 A.2d 108,

110 (N.J. Super. Ct. App. Div. 1992). “Under long-settled principles, the secret, unexpressed intent of a party cannot be used to vary the terms of an agreement.” *Domanske v. Rapid-Am. Corp.*, 749 A.2d 399, 402 (N.J. Super. Ct. App. Div. 2000) (quoting *Brawer v. Brawer*, 747 A.2d 790 (N.J. Super. Ct. App. Div. 2000)).

Here, none of Janssen’s extrinsic evidence suggested the parties mutually understood “COMPANY” to mean anything other than what the contract expressly says. And certainly none supported the way the district court read it. Quite the opposite, the extrinsic evidence bearing directly on the meaning of “COMPANY”—internal correspondence, filings in other J&J family litigations, and the rewriting of the form employment agreement—revealed that Janssen not only understood the meaning of “COMPANY” to be just what it says, but took advantage of that broad meaning whenever it was helpful.

**a. Janssen’s extrinsic evidence does not support the court’s reading of “COMPANY”**

None of the extrinsic evidence cited by the district court supports the conclusion that “COMPANY” means only Centocor for “patent assignments.” Appx158. All four pieces of evidence show, at best, Janssen’s *current* preference, for purposes of this litigation, to be the sole owner of the ’083 patent. None reflect an “objective intent” “outwardly manifest[ed] to the other party” at the time of signing in 2001–2003. *Hagrish*, 603 A.2d at 110.



*First*, the court relied on a declaration from Janssen’s in-house counsel Mr. Dow stating that Janssen intended for the patent to be assigned to Centocor. Appx9399-9405. Dow, however, was not involved in drafting the employment agreements, and had never “edited or drafted employment agreements on behalf of any [J&J] company.” Appx8745-8747, Appx8748-8751(75:22-25, 76:12-77:2, 83:23-84:3, 85:17-24, 90:13-20). He never even saw the 2001–2003 agreements until shortly before he filed his declaration in 2017. Appx8748(83:9-22).

Moreover, the declaration does not discuss any specific text in the employment agreements and thus sheds no light on the meaning of their terms. Instead, it offers self-serving generalities about current-day “customs and practices of Janssen with respect to ownership of patents,” Appx9399(¶4), and opines that it would be “cumbersome” and “burdensome” for J&J to have patents owned jointly by a group of companies. Appx9404-9405(¶¶17-19).

None of this has any bearing on the contracting parties’ objective intent about the meaning of “COMPANY” when signing the agreement. Patents are not transferred by “customs and practices,” and Janssen’s view of what would be most convenient today, in this case, is not a basis to depart from the contracts’ plain meaning. *See Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am., U.A.W. v. Skinner Engine Co.*, 188 F.3d 130, 145 (3d Cir. 1999) (declining to

rely on executives’ “subjective and self-serving testimony” “as to what they believed the collective bargaining agreements required”).

*Second*, the court relied on invention disclosure forms addressed to Centocor (rather than the broader J&J family). Appx155. But those have no bearing on the meaning of “COMPANY” in the 2001-2003 contracts. An inventor has to disclose its invention to some J&J entity. The forms merely reflect a protocol of inventors *disclosing* their inventions to their direct employer, which has nothing to do with the meaning of “COMPANY” in the agreements *assigning* the inventions.

*Third*, the Court referred to the inventors’ later execution of documents purporting to assign the ’083 patent to Centocor or Janssen alone. Janssen’s multiple belated efforts to solve its standing problem—including the post-lawsuit “assignments” signed by the inventors—cut against, not for, Janssen. They were executed in 2015, more than a decade after the 2001–2003 employment agreements, thus shedding no light on drafter intent. What they do show is that Janssen knew it had a problem and scrambled after filing suit to generate evidence to support an argument of sole ownership.

Finally, the district court relied on a report Janssen retrieved from a J&J internal “patent database.” According to Janssen, the database shows that J&J associates each patent within its umbrella of families, including the ’083 patent, with an individual company or group of companies. Appx9402-9403(¶¶11-12). Again,

patent ownership is transferred by written instruments, 35 U.S.C. §261, not a company's internal recordkeeping system. And not a shred of evidence shows that anyone involved in creating that database even referred to the employment agreements, much less relied on some special meaning of the term "COMPANY." On the contrary, "clerks" populate the database simply by lifting information from "correspondence in the patent applications." Appx8775-8777(256:6-258:3).

**b. Evidence of Janssen and J&J's treatment of the agreements supports Celltrion's interpretation**

In contrast to Janssen's legally irrelevant extrinsic evidence, other extrinsic evidence bearing directly on the meaning of "COMPANY" confirms that Janssen understands the term to have the meaning written in the contract.

As detailed above, J&J family companies have repeatedly interpreted "COMPANY" broadly in lawsuits against former employees and in company correspondence. That includes at least one instance relating to the invention assignment provision, where J&J and its subsidiary Cordis (the only entity that employed the defendant) represented that they *both* "own[ed] all inventions, patentable or not, developed by [defendant] while at plaintiffs." Appx8972. Moreover, in at least ten other lawsuits, J&J family companies advanced a broad interpretation of "COMPANY" that includes more than just an employee's direct employer, under which multiple family companies joined as plaintiffs. Appx7352-7363.

Janssen's own correspondence reads "COMPANY" the same way. In letters to departing employees, Janssen reminds them of their confidentiality obligations to "the Johnson & Johnson family of companies under" agreements containing the same or similar definition of "COMPANY." Appx8990-8997; Appx 8999-9004; *see also* Appx9006-9020. Janssen could not have that view unless "COMPANY" means what the contracts literally say it means.

The statements in court filings and correspondence were the best—indeed, the only—evidence directly discussing the form employment agreements and what they mean. The district court dismissed all this evidence, however, based on another term in the agreements, "CONFIDENTIAL INFORMATION." It held that because of the breadth of that defined term, "the position of the other [J&J] companies that the Agreements protect their confidential information, as well as the [direct] employer's, is not necessarily inconsistent with Janssen's position that 'the COMPANY' means only the employer" for purposes of the patent assignment provision. Appx159.

But one thing has nothing to do with the other. Regardless of the meaning of "CONFIDENTIAL INFORMATION," the breadth of "COMPANY" is what justifies multiple companies suing to protect their contractual rights to confidentiality and non-competition. Court filings state, for example, that "COMPANY" "is defined to include *not only* [the employer] DePuy Spine," Appx8788, and that "[a]s a former employee of DePuy Spine, [the former employee]

is subject to non-competition and non-solicitation *covenants with DePuy Spine and JJRT.*” Appx8783. Moreover, it makes no sense to rely upon and leave intact one broadly defined contract term (“CONFIDENTIAL INFORMATION”) in service of drastically narrowing the meaning of another (“the COMPANY”). It also misses the critical point that the extrinsic evidence the court dismissed bears directly on the meaning of “COMPANY,” whereas the extrinsic evidence the court relied upon does not.

J&J’s 2008-2009 revision to its form employment agreement further confirms the plain, broad meaning of “COMPANY.” While maintaining their duties of confidentiality and non-competition to the “COMPANY,” employees now assign their patent rights only to their “EMPLOYER.” Appx8991-8992; Appx9044-9046; Appx8687-8688(152:18-153:23); Appx8714(198:7-14).

Janssen’s in-house attorney Martinson testified that this revision “did not change” the agreements’ “intent,” but “simply clarified the language.” Appx8709(182:5-12), Appx154. But Martinson was not involved in the original agreements. Appx8678(23:3-12); Appx8709(182:5-8). And her litigation-driven view now cannot be squared with the substantive change to the text. *See* Appx6552-6556; Appx6582-6589. In fact, the meaning of the new “EMPLOYER” term is similar to the special meaning for “COMPANY” the court adopted in this case: “Centocor Ortho Biotech Inc. or, if applicable, any other COMPANY by which you

are (or were) employed at the time an issue arises under this Agreement.” Appx153-154.

At bottom, the district court rewrote the contracts rather than holding Janssen to the contracts as written. The rule of patent law requiring joinder of all co-owners is more than a century old, as is the rule that patent ownership rights can only be transferred in writing. Sophisticated companies like Janssen and J&J should know and understand those rules better than anyone. Janssen may regret the consequences, in this case, of contracts it signed and drafted many years ago, but it is black letter law in New Jersey, as elsewhere, that “[u]nambiguous language controls the rights and obligations of the parties, even if it was unwise in hindsight.” *Woodhaven*, 2014 WL 1326994, at \*6.

**C. The District Court Correctly Rejected Janssen’s Fallback “Disclaimer” Argument.**

Finally, the district court correctly rejected as “unmeritorious” Janssen’s last-resort argument that its 2017 “disclaimer” agreement with J&J somehow solved its standing problem. Appx167.

As the court noted, Janssen relied on an overreading of dicta in *IpVenture v. Prostar Comput., Inc.*, 503 F.3d 1324 (Fed. Cir. 2007). Appx167. *IpVenture* “involved the question of whether a contract was an assignment of a patent or an agreement to assign it.” Appx167. Neither *IpVenture* nor any other Federal Circuit

decision has held “that co-owners of a patent are not required to be joined as plaintiffs if they disclaim their interest in the patent.” *Id.*

Even apart from any interpretation of *IpVenture*, the “disclaimer” cannot be, as Janssen argued, an independent basis to give Janssen standing. Amongst several failings of the 2017 “disclaimer,” one is that some J&J subsidiaries that were part of “the COMPANY” in 2001–2003 were no longer part of the J&J family as of the time of the “disclaimer.” *See* Appx7594. These subsidiaries are co-owners of the patent today, and the “disclaimer” cannot act on their behalf to change that. As Janssen has acknowledged, “companies that were subsequently divested would retain rights in Centocor’s patents and could impede Centocor’s ability to enforce its patents by refusing to be joined.” Appx5641. The “disclaimer” did not and cannot change this. The district court properly rejected it as legally insufficient.

## CONCLUSION

This Court should reverse the denial of Celltrion’s motion to dismiss for lack of standing. Alternatively, it should affirm the grant of summary judgment of noninfringement.

February 11, 2019

Respectfully submitted,

*/s/James F. Hurst*

---

James F. Hurst  
Bryan S. Hales  
Elizabeth A. Cutri  
KIRKLAND & ELLIS LLP  
300 North LaSalle  
Chicago, Illinois 60654  
(312) 862-2200

John C. O'Quinn  
William H. Burgess  
KIRKLAND & ELLIS LLP  
655 Fifteenth Street, N.W.  
Washington, D.C. 20005  
(202) 879-5000

*Counsel for Cross-Appellants*



# **ADDENDUM**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., )  
Plaintiff, )  
 )  
v. )  
 ) C.A. No. 17-11008-MLW  
CELLTRION HEALTHCARE CO., )  
LTD., ET AL., )  
Defendants. )  
 )

MEMORANDUM AND ORDER

WOLF, D.J.

October 31, 2017

I. INTRODUCTION

Plaintiff Janssen Biotech, Inc. ("Janssen") alleges that defendants Celltrion Healthcare, Co., Ltd. and Celltrion, Inc. (together, "Celltrion"), and Hospira, Inc. ("Hospira") have infringed U.S. Patent No. 7,598,083 (the "'083 Patent"). Defendants have moved to dismiss for lack of standing. They claim that Janssen lacks standing because it is not the sole owner of the '083 Patent and the other co-owners have not joined Janssen as plaintiffs as required by Section 262 of the Patent Act, 35 U.S.C. §262. See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1467 (Fed. Cir. 1998). In particular, defendants allege that the inventors, in a series of employee secrecy agreements (the "Agreements"), assigned the rights to the '083 Patent to more than

200 other companies, including Johnson and Johnson ("J&J") and its subsidiaries and affiliates.

The court, however, finds that the Agreements assigned the patent rights to Janssen's predecessor Centocor, Inc. ("Centocor") alone. Therefore, Janssen is the sole owner of the '083 Patent and is not required to join any other party to maintain this action. Accordingly, the motion to dismiss is being denied.

## II. THE COMPLAINT AND PROCEDURAL HISTORY

### A. The Complaint

The facts as alleged in the complaint are as follows.

Janssen produces Remicade, a biologic medicine whose active ingredient is a monoclonal antibody called infliximab. See Compl. at ¶¶38. Growing the cells that produce biologic medicines like infliximab requires a composition called "cell culture media." Janssen alleges that it holds the '083 Patent. The patent claims a "soluble composition suitable for producing a final volume of cell culture media," and lists 61 ingredients in varying concentrations. Compl. Ex. A. It names as inventors David Epstein, Roger Monsell, Joseph Horowitz, Susan Lenk, Sadettin Ozturk, and Christopher Marsh. See id. Centocor, Janssen's predecessor, is named as the assignee. See id.

Celltrion produces a biosimilar to Remicade called Inflectra, which received Food and Drug Administration ("FDA") approval on April 5, 2016. See id. at ¶52. Third-party HyClone makes the cell

culture media that Celltrion uses to produce its biosimilar infliximab product. Id. at ¶7. Hospira collaborates with Celltrion to market Inflectra. See id. at ¶9. Plaintiff alleges that Celltrion infringes the '083 Patent by employing HyClone to manufacture the media under Celltrion's direction and control, and by inducing HyClone to infringe the patent.<sup>1</sup> See id. at ¶¶1, 101, 111. It alleges that Hospira is liable for Celltrion's actions as a joint venturer and induces Celltrion to infringe the patent by ordering Inflectra from it, among other things. See id. at ¶83.

#### B. Procedural History

On March 6, 2015, plaintiff initiated Civil Action No. 15-10698 (the "2015 Action") alleging, among other things, technical infringement of the '083 Patent under the Biologics Price Competition and Innovation Act.<sup>2</sup> On June 14, 2016, after obtaining

---

<sup>1</sup> A party is liable for direct infringement under 35 U.S.C. §271(a) when it "[a] acts through an agent (applying traditional agency principles) or [b] contracts with another" to do the infringing act. See Akamai v. Limelight Networks, 797 F. 3d 1020, 1022 (Fed. Cir. 2015). Induced infringement under §271(b) requires both an affirmative act that encourages infringement and specific intent: that is, "knowledge that the induced acts constitute patent infringement." Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011).

<sup>2</sup> The complaint in the 2015 Action also alleged infringement of several related patents, including U.S. Patent No. 6,284,741 (the "'471 Patent"), which relates to the infliximab antibody that is the fundamental component of Remicade. On August 19, 2016, the court granted summary judgment for defendants on the claim concerning the '471 Patent on the ground that the '471 Patent is invalid. The court subsequently entered partial judgment, authorizing plaintiffs to appeal the grant of summary judgment.

more information in discovery, plaintiffs filed a second action alleging actual infringement of the '083 Patent under the Patent Act, 35 U.S.C. §271(a) and (b). The cases were consolidated and scheduled for trial beginning on February 13, 2017.

At a January 18, 2017 scheduling conference, the parties requested that the court address certain legal issues concerning the appropriate measure of damages and plaintiffs' entitlement to a permanent injunction if defendants were found to have infringed the '083 Patent. The court subsequently ordered the parties to file memoranda addressing these issues.

In their memorandum, defendants argued for the first time that Janssen failed to join all co-owners of the '083 Patent in either action and, therefore, lacked standing. In particular, defendants argued that four of the inventors of the '083 Patent had, in their Agreements with Centocor, assigned their rights to the '083 Patent not only to Janssen's predecessor, Centocor, but also to Janssen's parent, J&J, and all of J&J's subsidiaries and affiliates (together, the "J&J Family" of companies). As explained earlier, a plaintiff's failure to join all co-owners in an action for patent infringement requires dismissal without prejudice for lack of jurisdiction. See Ethicon, 135 F.3d at 1467.

On February 8, 2017, the court heard oral argument on the

---

That appeal is pending in the United States Court of Appeals for the Federal Circuit.

issue of standing and found that the Agreements, which did not clearly assign patent rights to Janssen's predecessor Centocor, raise serious questions concerning its jurisdiction. As the parties agreed, those questions required the postponement of trial to permit the filing of a motion to dismiss for lack of jurisdiction and limited additional discovery.

On February 22, 2017, plaintiffs filed a motion to dismiss the 2015 and 2016 Actions for lack of standing due to plaintiffs' alleged failure to join all co-owners of the '083 Patent. The parties conducted limited discovery in connection with that motion. On March 6, 2016, Janssen and J&J entered into an agreement that states that Janssen is the sole owner of the '083 Patent, and that neither J&J nor any of its operating companies ever owned any interest in the '083 patent. See C.A. No. 15-10698, Docket No. 521-7. Janssen filed that agreement on March 8, 2017 with its opposition to the motion to dismiss. See id.

On June 30, 2017, before briefing concerning the motion to dismiss was complete, the parties agreed to the dismissal of all of the claims for infringement of the '083 Patent in the 2015 Action and the complete 2016 Action, each without prejudice. See C.A. No. 15-10698, Docket No. 582 at 2-3.

On May 31, 2017, Janssen filed this case. Defendants again moved to dismiss, arguing that the court lacks jurisdiction unless Janssen joins each of the more than 200 members of the J&J Family

that defendants assert are co-owners of the '083 Patent. On October 13, 2017, the court heard oral argument on the motion.

### III. LEGAL STANDARDS

#### A. Motion To Dismiss for Lack of Subject Matter Jurisdiction

The court must satisfy itself that it has subject-matter jurisdiction before the merits of this case can be decided. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94-95 (1998). When, here, "the facts relevant to the jurisdictional inquiry are not intertwined with the merits of the plaintiff's claim...the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Torres-Negron v. J & N Records, LLC, 504 F. 3d 151, 163 (1st Cir. 2007); see also DDB Techs., L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284, 1291-92 (Fed. Cir. 2008).

#### B. Standing

To establish that the court has subject matter jurisdiction, the plaintiff has the burden of proving by a preponderance of the evidence that it has standing to sue. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992).

One co-owner acting alone lacks standing and must "join as plaintiffs all co-owners" of the patent. Ethicon, 135 F.3d at 1467 (citing Waterman v. Mackenzie, 138 U.S. 252, 255 (1891)). In addition, any co-owners must ordinarily consent to join an infringement suit and cannot be joined involuntarily under Federal

Rule of Civil Procedure 19. See STC.UNM v. Intel Corp., 754 F.3d 940, 945-46 (Fed. Cir. 2014). In Ethicon, the Federal Circuit characterized this standing requirement as "a matter of substantive patent law," which gives "one co-owner...the right to impede the other co-owner's ability to sue infringers by refusing to voluntarily join in such a suit." 135 F.3d at 1468 (citing 35 U.S.C. §262). The rule protects alleged infringers from being subject to multiple lawsuits, and potentially conflicting rulings and judgments. See IpVenture, Inc. v. Prostar Computer, Inc., 503 F.3d 1324, 1325 (Fed. Cir. 2007) (citing Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 468 (1926)).

#### C. Interpretation of Patent Assignments

Patent owners may assign or transfer their ownership interests in a patent as personal property. See 35 U.S.C. §261. Section 261 provides that patents "shall be assignable in law by an instrument in writing" which may "take the form of a patent license or any other written instrument that transfers patent rights." Morrow v. Microsoft Corp., 499 F.3d 1332, 1337 n. 3 (Fed. Cir. 2007). "State law governs contractual obligations and transfers of property rights, including those relating to patents." Regents Of Univ. Of New Mexico v. Knight, 321 F.3d 1111, 1118 (Fed. Cir. 2003). "[The Federal Circuit] treats an agreement granting patent rights as a contract and interpret[s] its terms consistent with the choice of law provision in the agreement in



question." Diamond Coating Techs., LLC v. Hyundai Motor Am., 823 F.3d 615, 618 (Fed. Cir. 2016).

In this case, the relevant Agreements state that New Jersey law governs their terms. See Exhibit A to the Declaration of Kenneth Dow (Docket No. 27-1) at 3, 6, 10, and 14 of 15. In interpreting a contract under New Jersey law, the court must "discern and implement the common intention of the parties." McMahon v. City of Newark, 195 N.J. 526, 546 (2008). However, "a contracting party is bound by the apparent intention he outwardly manifests to the other contracting party. To the extent that his real, secret intention differs therefrom, it is entirely immaterial." Frangella v. Frangella, 2013 WL 4792863, at \*5 (N.J. Super. Ct. App. Div. 2013). Therefore, the court's role is to "consider what is written in the context of the circumstances at the time of drafting and to apply a rational meaning in keeping with the expressed general purpose." McMahon, 195 N.J. at 546 (emphasis added). "The quest is for the reasonably certain meaning of the language used, taken as an entirety, considering the situation of the parties, the attendant circumstances, the operative usages and practices, and the objects the parties were striving to achieve." George M. Brewster & Sion, Inc. v. Catalytic Constr. Co., 17 N.J. 20, 32 (1954); accord Manahawkin Convalescent v. O'Neill, 217 N.J. 99, 118 (2014) ("Courts enforce contracts based on the intent of the parties, the express terms of the contract,

surrounding circumstances and the underlying purpose of the contract.").

"When the terms of [a] contract are clear," the court must "enforce it as written and not...make a better contract for either of the parties," as "the parties are entitled to make their own contracts." McMahon, 195 N.J. at 545-46. A contract is not "clear" and is instead ambiguous "if its terms are susceptible to at least two reasonable alternative interpretations, or when it contains conflicting terms." Woodhaven Lumber & Millwork, Inc. v. Monmouth Design & Development Co., Inc., 2014 WL 1326994, at \*6 (N.J. Super. Ct. App. Div. 2014); 5907 Blvd. L.L.C. v. W. N.Y. Suites, L.L.C., 2013 WL 3762695, at \*4 (N.J. Super. Ct. App. Div. 2013). If the contract is ambiguous, the court must give the contracting "parties' practical construction of the contract...controlling weight in determining a contract's interpretation." Cty. of Morris v. Fauver, 153 N.J. 80, 103 (1998).

"To determine whether a contract is ambiguous," and "to discover the intention of the parties," courts may consider evidence outside the text of the contract. Frangella, 2013 WL 4792863, at \*5 (citing Conway v. 287 Corp. Ctr. Assocs., 187 N.J. 259, 268-69 (2006)). Such extrinsic evidence includes "the circumstances leading up to the formation of the contract, custom, usage, and the interpretation placed on the disputed provision by the parties' conduct." Conway, 187 N.J. at 268-69.

The use of extrinsic evidence to determine whether a contract is ambiguous, as well as to resolve ambiguity once it is found, is consistent with federal common law. See Frangella, 2013 WL 4792863 at \*5 (citing In re Teamsters Indus. Emp. Welfare Fund, 989 F.2d 132, 135 (3d Cir. 1993)). In In re Teamsters, the Third Circuit explained that under "traditional rules of contract interpretation:"

To decide whether a contract is ambiguous, we do not simply determine whether, from our point of view, the language is clear. Rather, we hear the proffer of the parties and determine if there [are] objective indicia that, from the linguistic reference point of the parties, the terms of the contract are susceptible of different meanings. Before making a finding concerning the existence or absence of ambiguity, we consider the contract language, the meanings suggested by counsel, and the extrinsic evidence offered in support of each interpretation. See also Restatement (Second) of Contracts §223 cmt. b (1981) ("There is no requirement that an agreement be ambiguous before evidence of a course of dealing can be shown, nor is it required that the course of dealing be consistent with the meaning the agreement would have apart from the course of dealing"). Extrinsic evidence may include the structure of the contract, the bargaining history, and the conduct of the parties that reflects their understanding of the contract's meaning.

989 F. 2d at 135 (citations omitted).

In Atl. N. Airlines v. Schwimmer, the New Jersey Supreme Court cautioned that even though extrinsic evidence of the parties' intent may reveal and resolve ambiguity in the contractual language, the court may not use such evidence to rewrite a contract whose terms are clear:

The admission of evidence of extrinsic facts is not for the purpose of changing the writing, but to secure light by which to measure its actual significance. Such evidence is admissible only for the purpose of interpreting the writing--not for the purpose of modifying or enlarging or curtailing its terms, but to aid in determining the meaning of what has been said. So far as the evidence tends to show, not the meaning of the writing, but an intention wholly unexpressed in the writing, it is irrelevant.

12 N.J. 293, 301 (1953); see also Cnty. Of Morris, 153 N. J. at 103 ("Where both parties to a contract have erred in the construction of that contract, courts will generally not require that the parties continue in that mistaken construction, but will instead insist on a return to the written provisions of the contract.").

Nevertheless, the contractual text "should not be construed [so] literally...as to defeat the probable intention of the parties; rather, particular words or clauses may be qualified by the context and given the meaning that comports with the probable intention." Kolbe v. BAC home Loans Servicing, LP, 738 F. 3d 432, 439-40 (1st Cir. 2013) (quoting Simonson v. Z Cranbury Assocs. P'ship, 149 N.J. 536, 540 (1997)). "Semantics cannot be allowed to twist and distort [the words'] obvious meaning in the minds of the parties." Conway, 187 N.J. at 269-70. Similarly, "words and phrases are not to be isolated but related to the context and the contractual scheme as a whole, and given the meaning that comports with the probable intent and purpose; and thus the literal sense

of terms may be qualified by the context." Newark Publishers' Ass'n v. Newark Typographical Union, No. 103, 22 N.J. 419, 426 (1956).

#### IV. THE CONTRACTS AT ISSUE

Four of the inventors of the '083 Patent, Epstein, Marsh, Monsell, and Ozturk executed the Agreements at issue during their employment with Centocor and before the '083 Patent issued.<sup>3</sup> The Agreements are Exhibit A to the declaration of Kenneth Dow (Docket No. 27-1).<sup>4</sup>

All the Agreements contain an assignment provision identifying "the COMPANY" as the assignee of inventions conceived in the course of the inventor's employment. The assignment provisions are identical and state, in relevant part:

I agree to disclose promptly to the COMPANY all INVENTIONS<sup>5</sup> conceived or made by me...during my employment with the COMPANY, and related to the actual or anticipated business or activities of the COMPANY, or related to its actual or anticipated research and

---

<sup>3</sup> The parties do not dispute that plaintiffs have demonstrated a chain of title between Centocor and Janssen, and consequently that anything previously assigned to Centocor is owned by Janssen. The parties also do not dispute, and the court finds, that Joseph Horowitz and Susan Lenk assigned their rights to the '083 Patent to Janssen. See C.A. No. 15-10698 Docket Nos. 452-3, 452-6, and 495 at 31.

<sup>4</sup> The parties agreed at the October 13, 2017 hearing that Epstein's agreement is sufficiently representative of the others to be used for the purposes of deciding the motion to dismiss. Unless otherwise noted, all citations to the "Agreement" refer to Epstein's Agreement in Exhibit A to Dow's declaration.

<sup>5</sup> "INVENTIONS" are identically defined in each contract as "discoveries, improvements and/or ideas, whether patentable or not." Dow Decl. Ex. A at 2 of 15.

development or suggested by or resulting from any task assigned to me or work performed by me for, or on behalf of, the COMPANY. I assign and agree to assign my entire right, title and interest therein to the COMPANY.

Dow Decl. Ex. A at 2, 4, 8, and 12 of 15 (emphasis added).

Each of the Agreements includes the following provision regarding the meaning of the term "the COMPANY":

As used in this Agreement:

The COMPANY means CENTOCOR<sup>6</sup> and JOHNSON & JOHNSON and any of their successors or assigns, purchasers, acquirers, and any of their existing and future subsidiaries, divisions or affiliates, including any such subsidiary, division or affiliate of Johnson & Johnson to which I may be transferred or by which I may be employed in the future. Affiliates of the COMPANY are any corporation, entity or organization at least 50% owned by the COMPANY, by Johnson & Johnson or by any subsidiary of Johnson & Johnson.

Id.

The term "the COMPANY" is used throughout the Agreements, including in several confidentiality and non-compete provisions. For example, the confidentiality provision in each Agreement states that the inventors:

recognize that CONFIDENTIAL INFORMATION is of great value to the COMPANY...and that the disclosure to anyone not authorized to receive such information...will cause immediate irreparable injury to the COMPANY. Unless I first secure the COMPANY's written consent, I will not disclose, use, disseminate, lecture upon or publish CONFIDENTIAL INFORMATION. I understand and agree that my obligations not to disclose, use, disseminate, lecture

---

<sup>6</sup> The Marsh and Ozturk agreements contain a comma here. However, the court does not consider this difference material to its conclusions.

upon or publish CONFIDENTIAL INFORMATION shall continue after termination of my employment for any reason.

Id. at ¶5. Epstein and Monsell's Agreements define "CONFIDENTIAL INFORMATION" to include "information disclosed to me or known by me as a result of my employment by the COMPANY, not generally known to the trade or industry in which the COMPANY is engaged, about the products, processes, technologies, machines, customers, clients, employees, services and strategies of the COMPANY." Dow Decl. at 2 & 4 of 15. The Agreements of Ozturk and Marsh contain definitions that are identical in all material respects.<sup>7</sup> Id. at 8 & 12 of 15.

#### V. ANALYSIS

As indicated earlier, the Agreements assign patent rights, which include the rights to the '083 Patent, to "the COMPANY," which is defined, in pertinent part, as (1) Centocor "and" (2) J&J, "and" (3) "any" of the J&J Family Companies, "including any" company in the J&J Family which may employ the inventor in the future. Defendants argue that this language assigns the rights to the '083 Patent not just to Centocor, but to J&J and the entire J&J Family, which includes more than 200 companies. Janssen

---

<sup>7</sup> Ozturk's and Marsh's Agreements protect information "of affiliates of the COMPANY," see Dow Ex. A at 8, 12 of 15, which Janssen has argued implies that "the COMPANY" at least sometimes excludes J&J affiliates. However, because the reference to "affiliates" does not appear in Epstein or Monsell's Agreements, the court is not relying on it.

contends that, in the context of the assignment provision, "the COMPANY" means the entity that employed the inventor when he or she "conceived or made" the invention--in this case Centocor.

The court finds that "the express terms of the contract" are ambiguous, and Janssen's interpretation is most consistent with "the intent of the parties" as discerned from the "surrounding circumstances." Manahawkin, 217 N.J. at 118. In particular, the "the interpretation placed on the [assignment] provision by the...conduct" of the inventors, Janssen, and the rest of the J&J Family manifest their intent to assign the '083 Patent to Centocor, and therefore Janssen, alone. Conway, 187 N.J. at 268-69.

The Agreements are poorly drafted and do not clearly identify the intended assignee of the rights at issue. The assignee, "the COMPANY," is defined to include not only Centocor, but also J&J and "any" of the J&J Family Companies. "Any" may have at least two meanings. The parties agree that "any" sometimes means "all" or "every." For example, "Any attempt to flout the law will be punished," or "You are required to produce any documents relating to the issue." See Bryan A. Garner, Garner's Modern Usage (3d Ed. 2009) at 52 (2015 Action Docket No. 521-2) ("Garner"). However, "in a sentence implying that a selection or discretionary act will follow, it may mean 'one or more (unspecified things or people); whichever; whatever,'" to be specified later. Garner at 52; see also First Bank & Trust v. Firststar Info. Servs. Corp., 276 F.3d



317, 325 (7th Cir. 2001); Black's Law Dictionary 94 (6th ed. 1990)). In the definition of "the COMPANY," "any" J&J Family Company could reasonably be construed to mean "one or more" such companies, to be specified further in another provision. Moreover, the assignment provision, which refers to "inventions conceived or made by me during my employment with the COMPANY," implies that "the COMPANY" means the inventor's employer.

Even if "any" means "one or more," "the COMPANY" is still defined as "Janssen and J&J and any [J&J Family Company]." Agreement at 1 (emphasis added). Interpreted literally, therefore, the term "the COMPANY" includes at least two entities--Janssen and J&J. As defendants argue, "if the drafter wanted "COMPANY" to mean only the employer or subsequent employers," and not to include J&J, he "could have easily done so in just those words..." Defs' Memo. at 10 (citing Assisted Living Assocs. of Moorestown, L.L.P. v. Moorestown Twp., 31 F. Supp. 2d 389, 400 (D.N.J. 1998)).

However, if "the COMPANY" means Centocor and J&J, at minimum, this definition conflicts with the meaning implied in various other provisions of the agreement. The last sentence of the definition of "the COMPANY" defines "affiliates of the COMPANY" to mean "any corporation, entity or organization at least 50% owned by the COMPANY, by Johnson & Johnson or by any subsidiary of Johnson & Johnson." Agreement at 1. This definition of "affiliates" suggests that "the COMPANY" does not include J&J and its subsidiaries, or

always include them. If "the COMPANY" included, or always included, J&J and its subsidiaries, the clause could have easily ended at "the COMPANY," to read "any corporation, entity or organization at least 50% owned by the COMPANY."

Interpreting the "the COMPANY" to include J&J and its subsidiaries would render the additional references to those entities redundant and violate the "cardinal principle that each term of a contract should be given meaning so that no term is superfluous." Dubrosky v. Colonial Life & Acc. Ins. Co., 129 F. App'x 691, 693 (3d Cir. 2005). Contracts, like statutes, are sometimes drafted with redundancy to remove doubt or potential ambiguity. See TMW Enter., Inc. v. Fed. Ins. Co., 619 F.3d 574, 578 (6th Cir. 2010); cf. Marx v. General Revenue Corp., 133 S. Ct. 1166, 1176 (2013). However, in this case, the definition of affiliates does not remove any ambiguity. Rather, by including the reference to J&J and its subsidiaries, the drafters did not use obvious alternative language that would have made the definition of "the COMPANY" more clear and consistent with defendants' interpretation of the contract. Cf. Advocate Healthcare Network v. Stapleton, 137 S. Ct. 1652, 1659 (June 5, 2017) ("When legislators do not adopt 'obvious alternative' language, 'the natural implication is that they did not intend' the alternative."). Therefore, the reference to J&J and its subsidiaries in the

definition of "affiliates" creates ambiguity rather than resolving it.

In addition, as indicated earlier, in the assignment provision, the employee agrees to assign to "THE COMPANY" any invention made by the employee "during [his] employment with the COMPANY." See Agreement at 1. The inventors were employed only by Centocor. See Dow Decl. Ex. B at 4 of 26. Defendants do not contend that they had an employment relationship with J&J, or that the Agreements created one. Therefore, while the first sentence of the definition of "the COMPANY" literally includes both Centocor and J&J, the language of the assignment provision suggests that the term "the COMPANY" means only the inventor's employer.

As the literal definition of "the COMPANY" conflicts with the sense in which the term is used in at least two provisions of the contract, including the assignment provision, the term is ambiguous. See Woodhaven Lumber, 2014 WL 1326994, at \*6; 5907 Blvd. L.L.C., 2013 WL 3762695, at \*4. In view of the conflicting provisions, this ambiguity is not created by a "tortured" reading of the language. 259 Holdings Co., LLC v. Union Dry Dock & Repair Co., 2007 WL 3274272, at \*3 (N.J. Super. Ct. App. Div. Nov. 7, 2007). Rather, conflicting language in the Agreement makes it ambiguous.

As explained earlier, when a contract's written terms are ambiguous, the contracting parties' common understanding of the

agreement has "controlling weight." Cnty. of Morris, 153 N.J. at 103. "Where there is no dispute between the contracting parties about which of two reasonable interpretations of their agreement is correct, the parties' shared understanding...govern[s]--barring some collateral reason to depart from ordinary principles." Kolbe, 738 F. 3d at 459. The parties' "shared understanding" can be determined from the parties' "custom[s]" and "the interpretation placed on the disputed provision by the parties' conduct" concerning the agreement. Conway, 187 N.J. at 268-69.

The extrinsic evidence establishes that the inventors, Janssen, and the other companies in the J&J Family understand the Agreements to have assigned the '083 Patent to Centocor, and therefore to Janssen, alone. Janssen customarily treats patent rights as being owned only by the inventor's employer, rather than by J&J or the entire J&J Family. Janssen's patent databases show that all of its patents are assigned either to Janssen alone or to Janssen and one other entity that was involved in the invention. See Dow Decl. Ex. I. In addition, J&J's lead employment counsel, Anne Martinson, revised J&J's standard employment agreement in 2008, before this litigation began, to provide clearly that inventions are assigned only to the inventor's employer. See Martinson Dep. at 154-155. She used three terms: (1) "COMPANIES," defined as "all" J&J Family companies; (2) "COMPANY," defined as "any of the COMPANIES;" and (3) "EMPLOYER," defined in Centocor

agreements as Centocor "or, if applicable, any other COMPANY by which you are (or were) employed at the time an issue arises under this agreement." Def. Ex. 10 (Sealed Docket No. 18-5) at 2 of 8. Patent rights are assigned to the inventor's "EMPLOYER" rather than to the "COMPANY" as they were in the pre-2008 version of the standard agreement. Id. at 3 of 8. The confidentiality provision covers "information about the business of any COMPANY." Id. at 3-4 of 8. Martinson testified that these changes reflected J&J's custom. See Martinson Dep. at 154-55, 182.

The practices of one contracting party in performing a contract are not always consistent with the parties' shared intent. For example, in Gabriel v. Jackson Life Ins. Co., this court found that an insurance company's consistent practice of "overstating the premium payments necessary to keep coverage in force" was a breach of contract and a violation of Massachusetts General Laws, Chapter 93A. See 2015 WL 1410406, at \*1, 11, 18 (D. Mass. Mar. 26, 2015).

In this case, however, the evidence demonstrates that both parties shared a common understanding. More specifically, the evidence regarding the inventors' intent shows that they, like Centocor and Janssen, understood the Agreements to have assigned patent rights, including the rights to the '083 Patent, to Centocor alone. First, the '083 Patent states that the assignee is "Centacor, Inc." and does not include J&J or other members of the

J&J Family. Compl. Ex. A. Second, as indicated earlier, the Agreements required the inventors "to disclose promptly" to "the COMPANY all INVENTIONS conceived or made by me...during my employment with the COMPANY." Agreement at ¶1. The inventors of the '083 patent complied with this disclosure obligation by submitting an invention disclosure to Centocor alone in May 2004. Dow Decl. Ex. B. The disclosure is on Centocor letterhead, is addressed to Kenneth Dow in his capacity as "V.P. Patent Law, Centocor," states that it is "Centocor confidential information," and identifies the inventors as Centocor employees. See id. Third, the Agreement also required that the employees "execute any applications, assignments or other instruments which the COMPANY shall consider necessary to apply for and obtain Letters Patent." Agreement at ¶3. The inventors executed several such assignments to Centacor or Janssen alone, and never to J&J or any other company in the J&J Family. This indicates that they understood their obligations to be only to Centocor or Janssen. Dow Decl. Exs. C-H.

Finally, there is no evidence that the other members of the J&J Family, which under defendants' interpretation would be intended beneficiaries of the Agreements as assignees, have ever asserted any rights to the '083 Patent or any invention conceived by the inventors. J&J and companies in its Family were on notice that the '083 Patent stated that Centocor was the only assignee.

According to Janssen's patent database this was consistent with the practice concerning inventions by employees of Centocor or Janssen. See Dow Decl. Ex. I. As explained earlier, J&J recently entered into an agreement with Janssen stating that it "has never asserted any ownership rights in the '083 patent..." and that none of the J&J Family of Companies "has or will assert any ownership rights to the '083 patent." C.A. No. 15-10698, Docket No. 521-7. Defendants have not presented any evidence rebutting these assertions.

As defendants argue, in at least eleven other cases, J&J and/or other companies in the J&J Family have interpreted "the COMPANY," as used in the confidentiality and non-compete provisions of similar or identical agreements, to include J&J and/or certain of its subsidiaries. See App'x A to Def. Memo (Docket No. 18-1); App'x C to Def. Supp. Br. (Docket No. 52-1). As indicated earlier, the confidentiality provision protects information "disclosed to [the employee] as a result of [his] employment with the COMPANY, not generally known to the trade or industry in which the COMPANY is engaged, about the products, processes, technologies, machines, customers, clients, employees, services and strategies of the COMPANY" disclosure of which it asserts "will cause immediate irreparable injury to the COMPANY." Agreement at 1 & ¶5. In these cases, J&J and/or J&J Family companies in addition to the employer alleged that their

confidential information was protected under these provisions and that they were entitled to enforce them. App'x A to Def. Memo (Docket No. 18-1); App'x C to Def. Supplemental Br. (Docket No. 52-1). The positions taken in these cases provide some support for defendants' assertion that "the COMPANY" as used in the Agreements means more than just Centocor.

Defendants argue that because Janssen's parent company has adopted this interpretation of "the COMPANY" in one section of the contract, Janssen cannot claim that it has a different meaning in the assignment provision. The "principle[] of statutory construction is that identical words used in different parts of the same act are intended to have the same meaning" is "equally applicable" to a contract, "particularly when the contract under consideration is [] clearly the product of careful lawyering on both sides." Celanese Ltd. v. Essex Cty. Improvement Auth., 962 A.2d 591, 601 (N.J. Super. Ct. App. Div. 2009). However, in this case there is no evidence that the inventors had counsel or that the Agreements were the result of careful lawyering. Rather, the court finds that they were poorly drafted. In any event, "the presumption of consistent usage 'readily yields' to context, and a statutory [or contractual] term--even one defined in the statute [or contract] --may take on distinct characters from association with distinct statutory [or contractual] objects calling for different implementation strategies." Util. Air Regulatory Group



v. EPA, 134 S. Ct. 2427, 2441 (2014); see also Robinson v. Shell Oil Co., 519 U.S. 337, 343-44 (1997). As explained earlier, the language of assignment provision and the extrinsic evidence persuades the court that, at least for the purposes of patent assignments, "the COMPANY" means only Centocor and its successor Janssen.

Assuming, without finding, that "the COMPANY" should be given a single consistent meaning throughout the Agreement, the positions taken by J&J and/or companies in its Family in the other cases do not compel the conclusion that the term refers to all of the companies in the J&J Family. Those suits were brought by J&J or J&J subsidiaries other than Janssen. The positions of companies in the J&J Family other than Janssen in other cases is not necessarily inconsistent with Janssen's position in this case. As indicated earlier, the other cases were brought to enforce provisions protecting "CONFIDENTIAL INFORMATION," or secret information "disclosed to [the employee] as a result of [his] employment with the COMPANY...about the products, processes, technologies, machines, customers, clients, employees, services and strategies of the COMPANY." Agreement at 1. This definition can be reasonably interpreted to cover information that also belongs to J&J Family companies in addition to the employer. Such information could include information about the employer's

products that also belongs to a company in the J&J Family company which jointly developed the product.

Indeed, this was alleged to be the case in DePuy Spine, Inc. and Johnson and Johnson Regenerative Therapies v. Stryker Biotech LLC and Joseph Ross, Suffolk Super. Ct. C.A. No. 07-1464 (Docket No. 15-3 at 9-10). In DePuy Spine, the plaintiffs were two companies in the J&J Family--DePuy Spine, which was the individual's employer, and another company, JJRT. It was alleged that "DePuy Spine's product development work is performed by [plaintiff non-employer] JJRT," which "works in partnership with the J&J operating companies, performing the research and development work necessary to bring products through FDA or other required regulatory approval." Id. The plaintiffs in DePuy Spine cited the "broad[]" definition of "CONFIDENTIAL INFORMATION" to support their assertion that the Agreements protected information about products that DePuy and JJRT were jointly developing and strategies concerning those products. Id. at 8, 10-16. Therefore, the position of the other companies that the Agreements protect their confidential information, as well as the employer's, is not necessarily inconsistent with Janssen's position that "the COMPANY" means only the employer. In any event, the conduct of other companies concerning other cases is not evidence of Janssen's customary practice or intent concerning the Agreement.

Finally, while defendants identified eleven cases in which a company in addition to the individual's employer brought suit, Janssen has presented un rebutted testimony that the vast majority of the suits seeking to enforce similar or identical employment agreements have been brought only on behalf of the individual's employer. See Martinson Dep. at 354-55.<sup>8</sup>

In view of the forgoing, the court finds that the contracting parties' subsequent actions resolve the ambiguity in the assignment of patents provision and, for the purposes of that provision, "the COMPANY" means Centocor alone. While this conclusion is in tension with the literal definition of "the COMPANY," which refers to Centocor "and" J&J, a "[d]isproportionate emphasis upon a word or clause or a single provision does not serve the object of interpretation." Borough of W. Caldwell, 138 A.2d at 410. Particular "words or clauses" in the text "should not be construed literally...as to defeat the probable

---

<sup>8</sup>In addition, defendants have submitted two letters written by Janssen's Human Resources Manager, on behalf of Janssen, to two departing employees. In them, Janssen writes that the employee secrecy agreements created confidentiality obligations to "the Johnson and Johnson family of companies." See Defs. Exs. 10 & 11 (Docket Nos. 18-5 & 18-6). However, the positions in these letters are also not necessarily inconsistent with Janssen's position here because, as explained earlier, the confidentiality provisions can be reasonably interpreted to protect the information of other companies in the J&J family. In any event, the evidence in favor of Janssen's interpretation outweighs any inference that can be drawn from these two non-public letters to particular employees.

intention of the parties; rather, [they] may be qualified by the context and given the meaning that comports with the probable intention." Simonson, 149 N.J. at 540. In light of the extrinsic evidence that the inventors, Centocor, and J&J each understood the ambiguous Agreements to assign patent rights solely to Centocor, the court finds that Janssen is the only owner of the '083 Patent. Therefore, the court has jurisdiction concerning this case. See Ethicon, 135 F.3d at 1467.

This conclusion is not, as defendants argue, altered by the doctrine of judicial estoppel. "As a general matter, the doctrine of judicial estoppel prevents a litigant from pressing a claim that is inconsistent with a position taken by that litigant either in a prior legal proceeding or in an earlier phase of the same legal proceeding." InterGen N.V. v. Grina, 344 F.3d 134, 144 (1st Cir. 2003) (citing Pegram v. Herdrich, 530 U.S. 211, 227 n.8 (2000)) (emphasis added). "The doctrine is designed to ensure that parties proceed in a fair and aboveboard manner, without making improper use of the court system." Id. (citing New Hampshire v. Maine, 532 U.S. 742, 749-50 (2001)). "The contours of the doctrine are hazy, and there is no mechanical test for determining its applicability." Alternative System Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 33 (1st Cir. 2004). "Because the rule is intended to prevent improper use of judicial machinery judicial estoppel is an equitable doctrine invoked by a court at its

discretion." New Hampshire v. Maine, 532 U.S. 742, 749-51 (2001) (internal quotation marks and citation omitted).

The Supreme Court has identified three factors that courts should consider in determining whether to exercise this discretion:

First, a party's later position must be clearly inconsistent with its earlier position. Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create the perception that either the first or the second court was misled...A third consideration is whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.

Id. (citations omitted). The Court cautioned, however, that "[i]n enumerating these factors, we do not establish inflexible prerequisites or an exhaustive formula for determining the applicability of judicial estoppel. Additional considerations may inform the doctrine's application in specific factual contexts."

Id.

It is doubtful that the doctrine of judicial estoppel is relevant in this case. Neither Janssen nor Centocor was a party to any of the eleven prior suits on which defendants rely to invoke the doctrine. "[A] party against whom judicial estoppel is invoked, typically, must be the same party who made the prior inconsistent representation." Knowlton v. Shaw, 704 F.3d 1, 10 (1st Cir. 2013).

The First Circuit has recognized, however, that "courts sometimes have allowed judicial estoppel when the estopped party was responsible in fact for the earlier representation or when the estopped party was the assignee of a litigation claim or assumed the original party's role." Perry v. Blum, 629 F.3d 1, 9 (1st Cir. 2010) (internal citations omitted). In this case there is no evidence that Janssen, rather than J&J or other companies in its Family, was "responsible in fact" for the positions taken by other companies in other cases. Nor is Janssen the assignee of any of the litigation claims on which defendants rely.

Nevertheless, defendants contend that the doctrine is applicable because there is evidence that Janssen's parent company, J&J, is controlling Janssen in this litigation and also controls all litigation concerning similar or identical employment agreements brought by companies in the J&J Family, including the eleven prior cases on which defendants rely. Most of the authority defendants cite in support of this proposition, however, is inapposite. For example, several of the cases that defendants cite involve situations in which the estopped party was the legal successor to the party that had taken an inconsistent position in a prior litigation. See, e.g., Milton H. Greene Archives, Inc. v. Marilyn Monroe LLC, 692 F.3d 983, 998 (9th Cir. 2012) (estopped party was beneficiary of estate whose executor had taken

inconsistent position in prior litigation).<sup>9</sup> Another case cited by defendants involve an estopped party that had controlled the prior litigation. See, e.g., Lia v. Saporito, 541 F. App'x 71, 73 (2d Cir. 2013) (estopped party was sole owner of entity that took inconsistent position in prior case).

There are some cases in which a party has been estopped because it was controlled by an entity that took the inconsistent position in the prior case. See Patriot Mfg. LLC v. Hartwig, Inc., 996 F. Supp. 2d 1120, 1127 (D. Kan. 2014) (estopped party was controlled by entity that took inconsistent position in earlier litigation); Raizberg v. JV CJSC Gulfstream Sec. Sys., 2013 WL 1245545, at \*6 (S.D.N.Y. Mar. 26, 2013) (estopped party was owned by individual who took inconsistent position).<sup>10</sup> Neither of these

---

<sup>9</sup> See also Mathison v. Berkebile, 988 F. Supp. 2d 1091, 1103 (D.S.D. 2013) (warden estopped because of inconsistent position taken by warden who had preceded him); Nat'l Union Fire Ins. Co. v. Allfirst Bank, 282 F. Supp. 2d 339, 348 (D. Md. 2003) (subrogee was estopped because subrogor took inconsistent position in prior litigation); Capsopoulos on Behalf of Capsopoulos v. Chater, No. 95 C 3274, 1996 WL 717456, at \*2 (N.D. Ill. Dec. 9, 1996) (party seeking social security survivor benefits estopped by inconsistent position taken by decedant); In re 815 Walnut Assocs., 183 B.R. 423, 431-32 (Bankr. E.D. Pa. 1995) (assignee of claim estopped because owners of assignor took inconsistent position in prior litigation).

<sup>10</sup> Defendants also cite Ladd v. ITT Corp., 148 F.3d 753 (7th Cir. 1998) in support of their "controlling" entity argument. That case, however, held that judicial estoppel did not apply to the defendants because they were not parties in the prior litigation, even if the doctrine's purpose would be served if it were applied. Id. at 756.

district court decisions in other circuits are consistent with the only two situations in which the First Circuit has held that judicial estoppel may apply to litigants that were not parties in the prior cases: "when the estopped party was responsible in fact for the earlier representation or when the estopped party was the assignee of a litigation claim or assumed the original party's role." Perry, 629 F.3d at 9 (internal citations omitted).

Defendants cite only a single First Circuit case, In re Colonial Mortg. Bankers Corp., 324 F.3d 12 (1st Cir. 2003), in support of their argument that Janssen may be estopped based on positions taken by J&J. That case, however, concerned res judicata, not judicial estoppel. Id. at 16. The court held that res judicata could apply to a litigant that was not a party to the prior litigation. Id. at 17. However, the court based its holding on the fact the estopped party and the party in the prior litigation "were treated as a single entity throughout the earlier litigation, and neither of them disputed that characterization." Id. No similar circumstances exist here or in any of the eleven prior lawsuits relied upon by defendants. In re Colonial Mortg. Bankers Corp. is, therefore, inapposite.

Even if Janssen could be estopped by the positions taken by J&J or other companies in its Family in other cases, the court would not find the requirements for estoppel to be satisfied. Janssen's position that, for the purpose of the assignment



provision, "the COMPANY" means the "Employer" is not "clearly inconsistent" with the positions taken by J&J affiliates concerning non-compete and confidentiality provisions in other cases. Perry, 629 F.3d at 9. Nor have defendants shown that any court adopted or relied upon a previous inconsistent position concerning the assignment provision asserted by a company in the J&J Family. Id. at 11-12. In view of these facts and the fact that Janssen was not a party in the other cases, Janssen will not derive an unfair advantage if not estopped. See RFF Family P'ship, LP v. Ross, 814 F.3d 520, 528 (1st Cir. 2016).

Moreover, judicial estoppel is an equitable, discretionary doctrine. See New Hampshire, 532 U.S. at 750 (internal citations omitted); Guay, 677 F.3d at 16 (1st Cir. 2012) (internal citations omitted). The court finds that even if it had discretion, the equities do not favor finding Janssen is estopped from asserting it is the sole owner of the '083 Patent. This case concerns the enforcement of patent rights that are evidently worth hundreds of millions of dollars. Patent rights encourage innovation and, therefore, serve an important public interest. It would not be equitable to estop Janssen from pursuing its patent claims because of any inconsistent positions taken by other companies in the J&J Family in employment cases brought against different defendants and concerning contract provisions that are not at issue in this case.

The final issue raised by the parties relates to the March 6, 2017 agreement between J&J and Janssen. As previously discussed, that agreement states that neither J&J nor any company in the J&J Family has ever had an ownership interest in the '083 Patent. See C.A. No. 15-10698 Docket No. 521-7. Janssen argues that this "disclaimer" provides an independent basis to find that it has standing as the sole owner of the '083 Patent.

This issue is moot in view of the court's decisions that the Agreements assigned the '083 Patent to Centocor alone, and that Janssen is not estopped from advocating this conclusion. In the interest of completeness, however, the court finds Janssen's argument unmeritorious. The Federal Circuit has never held that co-owners of a patent are not required to be joined as plaintiffs if they disclaim their interest in the patent. Janssen relies primarily on IpVenture, Inc. v. Prostar Computer, Inc., 503 F.3d 1324 (Fed. Cir. 2007). IP Venture involved the question of whether a contract was an assignment of a patent or an agreement to assign it. See id. at 1325-26. The Federal Circuit held that the contract was an agreement to assign. See id. at 1327. The court further found that this interpretation was "reinforced" by a statement made by the purported assignee that it never had any legal or equitable rights to the patent at issue. Id. Therefore, the court in IP Venture essentially considered the disclaimer as extrinsic evidence supporting its interpretation of the agreement at issue.

IP Venture does not provide an alternative basis for finding that Janssen has standing to bring this cases because the Agreements assigned the '083 Patent to its predecessor Centocor alone.

VI. CONCLUSION

In view of the foregoing, the court finds that the Agreements assigned the inventors' patent rights to Centocor only. Janssen, therefore, is the sole owner of the '083 Patent and has standing to bring this case. The doctrine of judicial estoppel does not alter this conclusion. While the court finds that the March 6, 2017 agreement between J&J and Janssen does not provide a basis for finding that Janssen has standing, that issue is moot.

In view of the forgoing, it is hereby ORDERED that defendants' Motion to Dismiss (Docket No. 13) is DENIED.

  
UNITED STATES DISTRICT JUDGE

**CERTIFICATE OF SERVICE**

On February 11, 2019, this brief was submitted to the Court through the CM/ECF system, and thereby served on all parties.

*/s/James F. Hurst*

**CERTIFICATE OF COMPLIANCE WITH  
TYPE-VOLUME LIMITATION**

This brief complies with the type-volume limitation of Fed. Cir. Rule 32 and Fed. R. App. P. 32. According to the word processing system used to prepare this document, the brief contains 16,289 words.

*/s/James F. Hurst*