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Attorneys for Plaintiffs Johnson & Johnson and Janssen Biotech, Inc.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

JOHNSON & JOHNSON, a New Jersey corporation; JANSSEN BIOTECH,	•	Civil Action No.
INC., a Pennsylvania corporation,	:	VERIFIED COMPLAINT FOR
Plaintiffs, v. SAMSUNG BIOEPIS CO. LTD., a	:	BREACH OF CONTRACT AND BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND DEALING
Korean corporation,	:	DEMAND FOR JURY TRIAL
Defendant.	:	PUBLIC VERSION

:

Plaintiffs Johnson & Johnson, having an address at One Johnson & Johnson Plaza, New Brunswick, NJ 08933, and Janssen Biotech, Inc., having an address at 800 Ridgeway Drive, Horsham, PA 19004 (collectively, "Janssen"), by and through their undersigned counsel, complain against Defendant Samsung Bioepis Co., Ltd., having an address at 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon 21987, Republic of Korea ("Samsung") and allege as follows:

NATURE OF THIS ACTION

1. Janssen has developed and sells STELARA[®], which is used to treat plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. STELARA[®] has helped hundreds of thousands of patients manage these diseases.

2. Janssen holds numerous patents relating to STELARA[®]. Competitors must either face suit or negotiate a settlement in order to sell their own biosimilar versions (which are analogous to generic drugs, but for more complex biologics like antibody-based therapeutics). One of these companies is Defendant Samsung.

3. Samsung and Janssen entered into a greement that authorized Samsung to sell specific **sector** of Samsung's branded product PYZCHIVA[®], a biosimilar of Janssen's STELARA[®], in the United States as of February 22, 2025 (the "Samsung Agreement" or the "Agreement").

4. After entering into the Agreement,

- 1 -

5. On or about December 10, 2024, Samsung informed Janssen that, in clear breach of the Agreement, it had purported to authorize **and and belief** the right to market its own private label biosimilar. On information and belief, **and and belief** is a **and and and belief**, **a** healthcare conglomerate. Samsung informed Janssen that it intends to authorize **and and and belief**, to launch a private label biosimilar to STELARA[®] under Janssen's patents and to **and and belief** has

announced it intends to launch the private label product "early" in 2025.

6. Janssen has entered into a number of pro-competitive settlement agreements allowing companies to market biosimilars to STELARA®. For example, on February 21, 2025, Teva Pharmaceuticals and Alvotech launched their licensed STELARA® biosimilar. But neither

signed an agreement with Janssen to that effect. And the Agreement does not permit Samsung to authorize **constant of** to introduce an additional, private label drug at the expense of Janssen's market share and fair competition. Samsung's attempt to authorize that additional biosimilar and to **constant of** for that purpose is a clear breach of the Agreement.

Samsung was so intent on concealing its plans with respect to 7. that Samsung failed to obtain the . Then, once the with was executed, Samsung still did not disclose it . Even today, Samsung continues to withhold substantial portions of the , in an effort to obscure the full scope of its breach. terms of the Samsung's surreptitious and deliberate breach with respect to 8. threatens irreparable harm to Janssen. is a member, is a vertically integrated health conglomerate that includes (i) the largest health insurer in the United States, (ii) one of the largest health care providers in the United States, (iii) one of the largest pharmacy chains in the United States, and (iv) a pharmacy benefits manager ("PBM")—a company that decides what prescriptions will be reimbursed—that public information indicates controls approximately of prescriptions in the United States. has the means, motive, and opportunity to steer its patients, the customers of its pharmacies, and the insurance companies it selects drugs for toward private label drug and thereby disadvantage or exclude STELARA[®] (and other biosimilars) from its formularies. This is no abstract hypothetical risk, but exactly what has previously effectuated through analogous private label arrangements.

9. Unless enjoined, Samsung's breach threatens irreparable harm, including significant diminution of STELARA[®]'s market share and ability to fairly compete. Between December 2024 and the filing of this action, Janssen has repeatedly made clear to Samsung its conduct is unlawful. Samsung has not even attempted to explain why its behavior is lawful, nor can it. Janssen advised Samsung that it would seek court intervention absent Samsung's assurance that it would not proceed with the private label. Samsung refused, necessitating this action.

THE PARTIES

10. Plaintiff Johnson & Johnson is a New Jersey Corporation headquartered at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

11. Plaintiff Janssen Biotech, Inc. is a Pennsylvanian corporation headquartered at 800 Ridgeway Drive, Horsham, PA 19004, and is a subsidiary of Johnson & Johnson.

12. Defendant Samsung Bioepis Co., Ltd. is a Korean corporation headquartered as 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon 21987, Republic of Korea.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332, including because there is complete diversity between the parties and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

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14. This Court has personal jurisdiction over Samsung, including because the parties have contracted that they

Personal jurisdiction also exists because Samsung has been approved to market and distribute PYZCHIVA[®] throughout the United States, including in New Jersey, and on information and belief, Samsung intends to manufacture PYZCHIVA[®]

to be sold in New Jersey. Samsung has also contracted with companies incorporated in and/or headquartered in New Jersey, including Plaintiff Johnson & Johnson, and negotiated the Agreement with Johnson & Johnson employees located in New Jersey. Samsung's breaches would injure Plaintiffs Johnson & Johnson and Janssen Biotech, Inc. in New Jersey. Furthermore, Samsung would not be burdened by litigating this suit in New Jersey, and New Jersey has an interest in protecting New Jersey companies from breaches of contract and infringement of their patent rights, and an interest in resolving breaches of contract relating to products to be sold in New Jersey.

15. Venue in this Court is proper pursuant to 28 U.S.C. § 1391, including because the parties have contracted that this Court

 Substantial part of the events or omissions giving rise to Janssen's claims occurred

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in New Jersey, as Plaintiff Johnson & Johnson is incorporated in and headquartered in New Jersey, and the individuals who negotiated the Agreement with Samsung on behalf of Plaintiffs Johnson & Johnson and Janssen Biotech, Inc. did so while located in New Jersey.

BACKGROUND

A. <u>The Janssen-Samsung Settlement Agreement</u>

16. Ustekinumab is a monoclonal antibody developed by Janssen and sold under the brand name STELARA[®]. STELARA[®] targets IL-12 and IL-23, proteins that regulate the immune system. Over a period of two decades, Janssen has invested hundreds of millions of dollars in research and development of the drug, with more than 100 clinical trials having been conducted to identify the safest and most effective uses of ustekinumab. After its initial approval in 2009 for plaque psoriasis, STELARA[®] was subsequently approved by the FDA for treatment of psoriatic arthritis, Crohn's disease, and ulcerative colitis. Since then, STELARA[®] has helped hundreds of thousands of patients living with these diseases.

17. Samsung sought to piggyback off Janssen's extraordinary investment by creating a copy of STELARA[®] and seeking approval through a Food and Drug Administration ("FDA") regulatory pathway that permits use of the data from Janssen's clinical trials that established the safety and efficacy of STELARA[®]. In the United States, this application process is called an abbreviated Biologics License Application ("BLA"). On March 23, 2023, Samsung submitted a biologics license application, BLA No. 761373, seeking regulatory approval for Samsung's branded ustekinumab biosimilar product called PYZCHIVA[®], which Samsung

18. Because approval of a BLA does not grant the right to infringe the patents of another, Janssen and Samsung became involved in litigations relating to the ustekinumab patents. For example, Samsung challenged the validity of Janssen's U.S. Patent No. 10,961,307 by filing a petition for *inter partes* review before the Patent Trial and Appeal Board in *Samsung Bioepis Co., Ltd. v. Janssen Biotech, Inc.*, IPR No. 2023-01103. Janssen also filed an action against Samsung in the District Court of The Hague, Netherlands, in *Janssen Biotech, Inc. v. Samsung Bioepis NL B. V*, No. C/09/648912 KG ZA 23-477 ("the Netherlands Action").

19. On July 25, 2023, Janssen and Samsung entered into the Agreement, resolving these disputes, providing Samsung a second secon

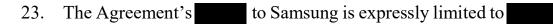
BLA No. 761373 is expressly limited to two subcutaneous presentations of Samsung's branded product PYZCHIVA®:

BLA 761373 seeks licensure of:
 Pyzchiva (ustekinumab-ttwe) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use as biosimilar to ustekinumab) injection 45 mg/0.5 mL single-dose prefilled syringe for subcutaneous use; and
 Pyzchiva (ustekinumab-ttwe) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use as biosimilar to use as biosimilar to ustekinumab) injection 90 mg/mL single-dose prefilled syringe for subcutaneous use as biosimilar to use as biosimilar

21. The Agreement permitted Samsung to begin selling this PYZCHIVA[®] product in the United States on February 22, 2025, and Janssen understands that Samsung has already begun to offer it for sale.

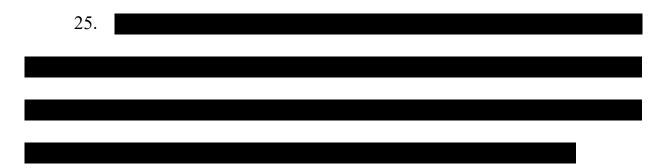
22. The Agreement was one of several agreements in which Janssen authorized different biosimilar manufacturers to introduce STELARA[®] biosimilars at specific dates and under specific conditions.

B. <u>The Agreement Does Not Permit Samsung To Authorize</u> <u>To Sell A Private Label Biosimilar</u>





1	



C. <u>Samsung Contracts With Sandoz To Sell PYZCHIVA®</u>

26. On September 11, 2023, Samsung and the Swiss corporation Sandoz AG announced that they had entered into a development and commercialization agreement to sell PYZCHIVA[®]. Sandoz announced that the agreement with Samsung "provides Sandoz with the exclusive rights to commercialize the biosimilar SB17 ustekinumab in the US" Consistent with Samsung and Sandoz's announcement, the FDA-approved package insert for PYZCHIVA[®] states:

Manufactured by: Samsung Bioepis Co., Ltd., 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea U.S. License No. 2046

Manufactured for: Sandoz Inc. Princeton, NJ 08540

27. Janssen contacted Samsung to obtain a copy of the agreement,

Samsung refused to

disclose the terms,

D. <u>Samsung Unsuccessfully Attempts To Broaden Its Rights</u>

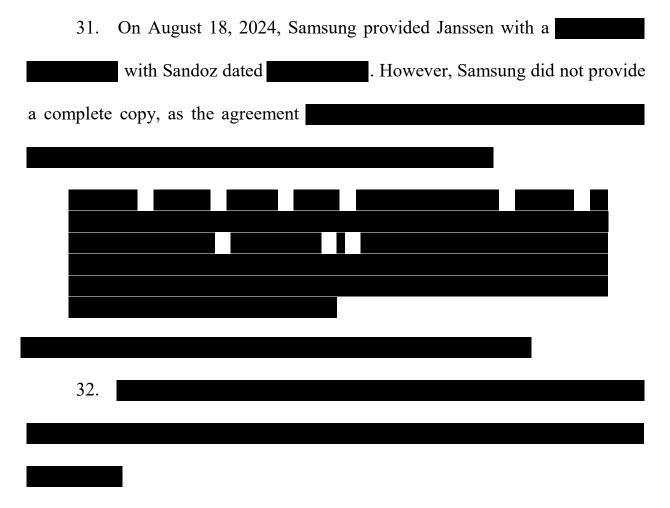
28. In March 2024, after receiving Janssen's demand to comply with its

obligation to produce any agreement with Sandoz,

29. Janssen ultimately rejected this attempted

E. The Samsung-Sandoz

30. On July 1, 2024, Samsung and Sandoz announced that they had received FDA approval for PYZCHIVA[®] and were planning for a February 2025 launch.



33. On September 16, 2024, Janssen again asked Samsung to comply with

Janssen further noted that at least one provision of
the Sandoz Agreement was unlawful,
34. On November 11, 2024, Samsung again refused to provide a copy of
the and provided no defense of its purported
F. <u>The Samsung-</u>
35. On December 10, 2024, Samsung for the first time provided notice of
another purported
but Samsung failed to provide notice within
36. Samsung deliberately kept the secret from
Janssen. When Samsung was
In contrast, Samsung did not breathe a word of its

	ne	egotiat	ions to Ja	nssen, and	d did no	ot se	ek appr	oval t	o sh	are the	Agre	ement
with												
	G.	<u>The</u> <u>Agre</u>	ement			Bi	reaches	Th	<u>e</u> J	Jansse	<u>n-Sar</u>	nsung
	37.	The			is	a	breach	of 1	the	Jansse	n-Sai	nsung
Agreer	nent.	The A	greemen	t does not	permit	Sam	nsung to	autho	orize	a	ŗ	orivate
label p	roduc	et.										
	38.	The S	Samsung	Agreemen	nt's							
Samsu	ng's	own]	PYZCHI	VA [®] .								
	39.	The j	purportec				also	is inv	alid	for an	add	itional
reason	ı, wh	ich is	that									

40.	
41.	
	autoridianias
	subsidiaries who will, on

information and belief, capture a windfall from selling the private label product.

42.	As to	

43.	In clear breach of these contractual limitations, in the
	Samsung nonetheless purports to grant rights to Janssen's licensed
patents to	permit the sale of a biosimilar
44.	Additionally,
45.	
46.	

47. Samsung first provided parts of the _______ on February 7, 2025, long after the _______; that copy was heavily redacted and missing entire sections and exhibits, and Samsung still has not provided a copy of

H. <u>Samsung Continues To Breach, Including By Failing To Produce</u> <u>The Complete Agreements</u>

48. On December 26, 2024, Janssen wrote again to Samsung, seeking to resolve these issues without litigation. In response, Samsung made no attempt to argue that the agreements with Sandoz and **Constant** comply with the Agreement, and continued to refuse to provide complete documentation of the purported

49. On January 21, 2025, Janssen again requested copies of the complete documentation and again informed Samsung that the purported

with Sandoz and are not in compliance with the Agreement:



Samsung continues to offer no defense and continues to refuse to provide complete copies of the purported

50. On February 2, 2025, Johnson & Johnson's Worldwide Vice President and General Counsel, Innovative Medicine, held a telephonic meeting with senior legal personal at Samsung and made clear that Janssen was prepared to initiate this action to stop Samsung's actions because of the irreparable harm they will cause Janssen. On that call, Samsung agreed



The next day, Samsung provided heavily redacted copies of (1) and (2), although key sections and terms are redacted and crucial attachments and amendments are missing. Samsung also provided a third document, supposedly the missing (3)

however, it does not appear to be the correct document.

52. Both the limited parts of the documents disclosed and Samsung's continued withholding of the complete documentation relating to its purported

the planned private label launch. Indeed, Samsung

53.	Since then, Janssen has repeatedly sought to engage with Samsung,
54.	
54.	

55. In sum, Samsung has repeatedly demonstrated it is not acting in good faith and in accordance with the Agreement, failing to

documents in violation of the Agreement, concealing its negotiations and agreements with **manage**, failing to obtain permission to share the Agreement with **manage**, and even now continually concealing and holding back required information needed to assess and mitigate the full extent of Samsung's breaches.

I. <u>Irreparable Harm</u>

56. **Constraints** is not a pharmaceutical company as that term is generally understood. **Constraints** is owned by **Constraints**, a health care conglomerate. **Company** in the United States (**Constraints**), the **Constraints** largest insurance company in the United States (**Constraints**), and one of the largest networks of specialty pharmacies that fill prescription for drugs such as STELARA[®] and its biosimilars (**Constraints**). A PBM decides what drugs an insurer will cover and at what price it will be reimbursed when a prescription is filled at a pharmacy, and even what pharmacy the prescription can be filled at. On information and belief, **Constraints**

controls approximately of all prescriptions in the United States.

57. The playbook common among vertically-integrated healthcare conglomerates calls for a private label distributor to obtain the generic or biosimilar drugs from a manufacturer, brand the generics or biosimilars with its name, increase their prices far above wholesale acquisition cost, and then steer patients it treats, patients it insures, and other insurance groups that use its PBM services, to purchase

its private label from the specialty pharmacies it owns. The FTC reported that in a

single year,

oligopoly reaped

over \$7.3 billion in profit from this strategy. As the FTC has found:

The result is that the dominant PBMs can often exercise significant control over which drugs are available, at what price, and which pharmacies patients can use to access their prescribed medications.

Vertical integration in PBM business structures, particularly with respect to integrated health insurers and specialty and mail order pharmacies, likely creates the ability and incentive for PBMs to increase utilization of certain drug products at affiliated pharmacies to generate the greatest revenue and profits for their respective conglomerates.

As one health economist explained, "instead of competing on the best price," vertically integrated PBM-insurer-drug private labeler entities will "manage the price" of drugs they choose to market and distribute.

58. A bipartisan letter from the then-Chair and Ranking Member of the

Senate Finance Committee warned of the extreme market harm caused by the

private labelling engages in:

Vertical integration of PBMs into yet another aspect of the health system intensifies our concerns about the ability of PBMs to markup the cost of biosimilars and steer patients to their higher cost "comanufactured" products while limiting access to products from nonaffiliated manufacturers. Steering patients in this manner would effectively ensure PBMs capture a larger share of the market for "comanufactured" products and reduce competition among manufacturers.

59. The irreparable harm to Janssen includes the loss of market share,

particularly due to the potential for to block access to its own

ecosystem.

The recent example of AbbVie's HUMIRA[®], which is used to treat 60. some of the same medical conditions as STELARA[®], is illustrative. After a vertically integrated health conglomerate—CVS Health Corporation—introduced its private label biosimilar to HUMIRA[®] through its subsidiary, Cordavis, it announced that it would cease reimbursing patients for HUMIRA[®] by excluding it from the formulary, attempting to drive HUMIRA® out of the CVS Healthcare ecosystem. Cordavis rapidly gained market share at the expense of AbbVie's HUMIRA[®], reportedly capturing 22% of the total share of the market within a month. In the face of this staggering erosion of molecule share, AbbVie was only able to maintain a foothold within the CVS ecosystem by securing an arrangement whereby HUMIRA[®] would be reimbursed (albeit to custom clients only and not on the standard, preferred formulary), but only if funneled through CVS's subsidiary to be sold as Cordavis-branded HUMIRA[®].

61. also causing HUMIRA[®] prescriptions to quickly decline. Samsung's

breach of the Agreement by purportedly

This will, in turn, likely cause the same harm to Janssen: erosion of the share of STELARA[®] and other STELARA[®] biosimilars within the solution of prescriptions that the solution controls.

FIRST CLAIM FOR RELIEF

Breach Of Contract

62. Janssen incorporates the allegations contained in the preceding paragraphs as if set forth fully herein.

63. Janssen and Samsung entered into a valid and enforceable "Settlement and License Agreement" on July 25, 2023.

64. Janssen performed its own contractual obligations under the Agreement, including by

65. Samsung violated the Agreement in multiple ways, each of which damaged Janssen and each of which constitutes an actionable breach.

66. Samsung breached at least Sections of the Agreement by its attempt to authorize , to launch a private label biosimilar to STELARA[®] under Janssen's patents and for that additional, private label product. The Agreement gives Samsung a

Agreement does not permit Samsung to authorize **constant automatication** to introduce an additional, private label drug at the expense of Janssen's market share and fair

of Samsung's PYZCHIVA®. The

competition. Samsung's attempt to authorize that additional biosimilar and to for that purpose is a clear breach of the Agreement. The further violates 67. Additionally, 68. unpermitted entry into the market will irreparably harm 69.

Janssen by decreasing STELARA[®]'s share of the market, including over time materially decreasing STELARA[®]'s share of the market in ways that are entirely different from the ways that a biosimilar marketed at arms-length by Sandoz will impact the market. This includes **Constant and SteleARA**[®].

70. Samsung also breached
Samsung failed to provide any
notice of the . Furthermore,
Samsung still has not provided a true and complete copy of the
Samsung continues to refuse to produce complete, accurate versions of the
Samsung has also breached its by providing only an
unsigned, heavily redacted version of the
71. Samsung's active concealment of these documents
has damaged Janssen by undermining its ability to police
the compliance of Samsung and its
72. Samsung also breached the Agreement by purporting to give Sandoz
The existence of the provision is a breach of the Janssen-Samsung
Agreement, and the potential for causes

present damage to Janssen by making it impossible to fully monitor and control who has access to Janssen's patent rights.

73. The conduct alleged above will cause Janssen irreparable injury if Samsung is not enjoined. Janssen lacks an adequate remedy at law as money damages and other remedies at law alone are inadequate to address a loss of market share, the adverse impact on the public, and other incalculable impacts of Samsung's wrongful conduct.

SECOND CLAIM FOR RELIEF

Breach Of The Implied Covenant Of Good Faith And Fair Dealing

74. Janssen incorporates the allegations contained in the preceding paragraphs as if set forth fully herein.

75. Alternatively, or additionally, Samsung's actions have breached the implied covenant of good faith and fair dealing, which, under New Jersey law, is an inherent aspect of every contract. The implied covenant allows for the inclusion of additional terms and conditions not expressly set forth in the contract but consistent with the parties' contractual expectations, or rectifies a party's unfair exercise of discretion.

Samsung abandoned its efforts and then proceeded to negotiate in secret
an agreement with a private label competitor to STELARA [®] .
Samsung deliberately kept the
secret from Janssen for as long as possible.
On information and belief, Samsung failed to do so in order to avoid breathing a
word of its negotiations to Janssen while they were occurring.
77. Samsung's failure to timely and completely disclose counterpart
documents and agreements similarly frustrates the purposes of the
and the newtice' expectations are undermined
and the parties' expectations are undermined
by Samsung's decision to hide material terms and obligations in counterpart agreements that it refuses to fully disclose. Samsung does not have the discretion to
decline to produce documents that are
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, nor does

Samsung have the discretion to overly redact the documents or exclude exhibits, attachments, or amendments thereto in order to hide relevant and material terms.

78. For the same reasons stated above with respect to the First Cause of Action, Janssen has been injured by Samsung's breach of the implied covenant of good faith and fair dealing.

79. The conduct alleged above will cause Janssen irreparable injury if Samsung is not enjoined. Janssen lacks an adequate remedy at law as money damages and other remedies at law alone are inadequate to address a loss of market share, the adverse impact on the public, and other incalculable impacts of Samsung's wrongful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Johnson & Johnson and Janssen Biotech, Inc. seek the following relief:

A. A preliminary injunction and a permanent injunction requiring rescission of the second and prohibiting Samsung from purporting to authorize or for a second private label product;
B. Rescission of second se

in violation of the Agreement;

C. A preliminary injunction and a permanent injunction requiring Samsung to comply with

, including any

documents attached or incorporated by reference;

D. Compensatory damages in an amount to be determined at trial, but which alone can never make Janssen whole because of the irreparable harm Janssen has suffered and will suffer;

E. An award of costs, interest, and attorney's fees;

F. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Janssen hereby demands a trial by jury on all issues triable to a jury.

Respectfully submitted,

SILLS CUMMIS & GROSS P.C. One Riverfront Plaza Newark, New Jersey 07102 (973) 643-7000 By: <u>s/ Jeffrey J. Greenbaum</u> JEFFREY J. GREENBAUM KATHERINE M. LIEB PETER C. URMSTON

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application forthcoming) 1800 Avenue of the Stars, Suite 900 Los Angeles, California 90067 (310) 277-1010

Attorneys for Plaintiffs Johnson & Johnson and Janssen Biotech, Inc.

Dated: February 24, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify to the best of my knowledge, information and belief that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

I certify under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Respectfully submitted,

SILLS CUMMIS & GROSS P.C. One Riverfront Plaza Newark, New Jersey 07102 (973) 643-7000

By: <u>s/Jeffrey J. Greenbaum</u> JEFFREY J. GREENBAUM KATHERINE M. LIEB PETER C. URMSTON

IRELL & MANELLA LLP Jason G. Sheasby (*pro hac vice* application forthcoming) Lisa S. Glasser (*pro hac vice* application forthcoming) 1800 Avenue of the Stars, Suite 900 Los Angeles, California 90067 (310) 277-1010

Attorneys for Plaintiffs Johnson & Johnson and Janssen Biotech, Inc.

Dated: February 24, 2025

VERIFICATION

I, Nathan Monroe-Yavneh, of full age, declare as follows:

I am Senior Counsel at Johnson & Johnson, with responsibility for Janssen Biotech, Inc. (collectively, "Plaintiffs"). I am authorized to verify the attached Verified Complaint on their behalf.

I have read the foregoing Verified Complaint. The facts therein are based on my personal knowledge, my review of documents and other information of the Plaintiffs, and information supplied to me by others. As to facts based on my personal knowledge, they are true. As to facts based on my review of documents and other information, and information supplied by others, I believe them to be true.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on February 24, 2025

nm.y

Nathan Monroe-Yavneh