

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NORTHWESTERN UNIVERSITY,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 24-1151 (RGA)
)	
MODERNA, INC., MODERNATX, INC.,)	
and MODERNA US, INC.,)	
)	
Defendants.)	

**DEFENDANT’S OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS
PLAINTIFF’S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(6)**

OF COUNSEL:

Amy K. Wigmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

Emily R. Whelan
Kevin S. Prussia
Andrew J. Danford
Annaleigh E. Curtis
Wenli Gu
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

December 23, 2024

TABLE OF CONTENTS

	<u>Page</u>
I. NATURE AND STAGE OF THE PROCEEDINGS	1
II. SUMMARY OF THE ARGUMENT	1
III. STATEMENT OF THE FACTS	3
A. The Asserted Patents.....	3
1. The '155 and '026 patents.....	3
2. The '686 patent	5
B. The Accused Products.....	7
C. Northwestern’s Pre-Suit Letter To Moderna	8
IV. LEGAL STANDARD.....	9
V. ARGUMENT	10
A. Northwestern’s Direct Infringement Claim For All Counts Should Be Dismissed.....	10
B. Northwestern’s Indirect Infringement Claims For All Counts Should Be Dismissed At Least In Part.	12
1. Northwestern has not pleaded a plausible claim for inducement under § 271(b) for at least the pre-suit period.....	12
2. Northwestern has not pleaded a plausible claim for contributory infringement under § 271(c).	14
3. Northwestern has not pleaded a plausible claim for infringement under § 271(f).....	15
C. Northwestern’s Willfulness Allegations Should Be Dismissed.....	17
D. Counts I and II Should Be Dismissed Because Northwestern Has Not Pleaded A Plausible Basis For Infringement Of The “Physisorbed” Limitations Of All Claims Of The '155 And '026 Patents.....	17
E. Count III Should be Dismissed Because Northwestern’s Infringement Theory For The '686 Patent Renders Claim 1 Invalid Under 35 U.S.C. § 101.....	18

1.	Claim 1 Is Directed To Patent-Ineligible Natural Phenomena Under Northwestern’s Infringement Theory.	19
2.	Claim 1 Lacks Any Inventive Concept Beyond Patent-Ineligible Natural Phenomena Under Northwestern’s Infringement Theory.....	20
VI.	CONCLUSION.....	20

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>Alice Corp. v. CLS Bank Int’l</i> , 573 U.S. 208 (2014).....	19, 20
<i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i> , 788 F.3d 1371 (Fed. Cir. 2015).....	19
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	9
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	9, 15, 17
<i>Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.</i> , 576 F.3d 1348 (Fed. Cir. 2009).....	16
<i>Commil USA, LLC v. Cisco Sys., Inc.</i> , 575 U.S. 632 (2015).....	12, 13
<i>Confluent Surgical, Inc. v. Hyperbranch Med. Tech., Inc.</i> , C.A. No. 17-688-LPS-CJB, 2017 WL 4804264 (D. Del. Oct. 25, 2017).....	16
<i>Dialect, LLC v. Amazon.com, Inc.</i> , Civ. No. 1:23CV581(DJN), 2024 WL 4010111 (E.D. Va. Aug. 30, 2024)	16
<i>Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.</i> , 96 F.4th 1347 (Fed. Cir. 2024)	11
<i>Elm 3DS Innovations, LLC v. Samsung Elecs. Co.</i> , C.A. No. 14-1430-LPS-CJB, 2015 WL 5725768 (D. Del. Sept. 29, 2015).....	12, 13
<i>Fujitsu Ltd. v. Netgear Inc.</i> , 620 F.3d 1321 (Fed. Cir. 2010).....	14
<i>Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.</i> , 72 F. Supp. 3d 521 (D. Del. 2014), <i>aff’d sub nom. Genetic Techs. Ltd. v. Merial L.L.C.</i> , 818 F.3d 1369 (Fed. Cir. 2016).....	19
<i>Genetic Techs. Ltd. v. Merial L.L.C.</i> , 818 F.3d 1369 (Fed. Cir. 2016).....	20
<i>Global-Tech Appliances, Inc. v. SEB S.A.</i> , 563 U.S. 754 (2011).....	13, 15, 16

In re Bill of Lading Transmission & Processing Sys. Pat. Litig.,
 681 F.3d 1323 (Fed. Cir. 2012).....12, 14

Lifetime Indus., Inc. v. Trim-Lok, Inc.,
 869 F.3d 1372 (Fed. Cir. 2017).....12

Mod. Telecom Sys., LLC v. TCL Corp.,
 C.A. No. 17-583-LPS-CJB, 2017 WL 6524526 (D. Del. Dec. 21, 2017)9

Sanofi v. Watson Lab’ys Inc.,
 875 F.3d 636 (Fed. Cir. 2017).....14

Schmidt v. Skolas,
 770 F.3d 241 (3d Cir. 2014).....9

Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.,
 785 F.3d 625 (Fed. Cir. 2015).....14

Warner-Lambert Co. v. Apotex Corp.,
 316 F.3d 1348 (Fed. Cir. 2003).....10

Waymark Corp. v. Porta Sys. Corp.,
 245 F.3d 1364 (Fed. Cir. 2001).....16

Wrinkl, Inc. v. Facebook, Inc.,
 C.A. No. 20-cv-13445-RGA, 2021 WL 4477022 (D. Del. Sept. 30, 2021)17

Rules and Statutes

35 U.S.C. §.....11

35 U.S.C. § 101.....3, 18, 19

35 U.S.C. § 271(a)1, 2, 10

35 U.S.C. § 271(b), (c), and (f).....2

35 U.S.C. §§ 271(c) and 271(f).....15

35 U.S.C. § 271(f).....2, 15, 16

Fed. R. Civ. P. 12(b)(6).....1

I. NATURE AND STAGE OF THE PROCEEDINGS

Northwestern University (“Northwestern”) filed this lawsuit on October 16, 2024, alleging that Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, “Moderna”) infringe U.S. Patent Nos. 9,216,155 (the “’155 patent”), 10,328,026 (the “’026 patent”), and 8,323,686 (the “’686 patent”) (together, “Asserted Patents”) through their manufacture, marketing, and sale of mRNA vaccines against COVID-19 and respiratory syncytial virus (RSV). Moderna now moves to dismiss this case in its entirety under Federal Rule of Civil Procedure 12(b)(6).

II. SUMMARY OF THE ARGUMENT

This lawsuit should never have been filed. The Asserted Patents disclose the use of gold particles to manage high cholesterol or regulate gene expression—which is an entirely different technology used for an entirely different purpose from Moderna’s mRNA vaccines against infectious diseases. Northwestern’s attempt to stretch its patents to cover Moderna’s mRNA vaccines fails to state a plausible claim of infringement.

The complaint’s allegations of direct infringement by Moderna are facially defective. The claims of the ’026 and ’686 patents require particles that include “an apolipoprotein,” which Moderna’s vaccines undisputedly do not contain when they are manufactured and sold. Northwestern alleges only that apolipoproteins bind to the lipid nanoparticles in Moderna’s vaccines inside patients’ bodies after the vaccine is administered. The complaint cites no evidence that this occurs. But even if it were true, that would not state a claim for direct infringement by Moderna under 35 U.S.C. § 271(a), since there is no allegation that the claimed apolipoprotein-containing particles are formed by Moderna. The complaint alleges that apolipoprotein-containing particles form only *after* the vaccine is administered to patients by healthcare providers. Similarly, all claims of the ’155 patent are method claims that require administration to patients (e.g.,

“*delivering* a[n] oligonucleotide structure to a subject”), yet there is no allegation that Moderna directly infringes by administering vaccines to patients. Northwestern’s claims of infringement under 35 U.S.C. § 271(a) therefore should be dismissed for all Asserted Patents.

Northwestern’s claims for indirect infringement under 35 U.S.C. § 271(b), (c), and (f) fare no better. Indirect infringement at a minimum requires knowledge of the Asserted Patents and knowledge of the alleged infringement. Here, Northwestern alleges that it first sent Moderna a letter on October 13, 2023, identifying the Asserted Patents and seeking to initiate licensing discussions, but does not plausibly allege that Moderna was aware of any purported infringement at any time prior to the filing of this lawsuit. When Northwestern notified Moderna of its patents, Northwestern did not identify which, if any, Moderna allegedly infringed, let alone explain how those patents were supposedly infringed. Because Northwestern has not pleaded—and cannot plead—Moderna’s pre-suit knowledge of any alleged infringement, Northwestern’s indirect infringement claims should be dismissed for at least the period before the filing of this lawsuit on October 16, 2024. Also, Northwestern’s allegations of contributory infringement and related allegations under 35 U.S.C. § 271(f) simply parrot the legal standard without alleging any facts to state a plausible claim. Those deficient allegations should be dismissed in their entirety. Northwestern’s allegations under § 271(f) for Count I separately fail to state a claim because the only claims in the ’155 patent are method claims that cannot support infringement under § 271(f).

Northwestern’s willfulness allegations should be dismissed for the same reasons as Northwestern’s pre-suit indirect infringement claims. Further, the complaint contains no factual allegations that would support post-suit willfulness.

Northwestern’s infringement allegations under Counts I and II also fail to state a claim because Northwestern has failed to allege a plausible basis for Moderna’s infringement of the ’155

and '026 patents. The claims of the '155 and '026 patents require oligonucleotides that are “physisorbed,” which the complaint refers to as “physical absorption” (D.I. 1, ¶ 60), to the surface of a “synthetic carrier” or “shell.” But the complaint does not allege any plausible basis to establish that any components of Moderna’s vaccines are physisorbed to any surface; at most, the complaint alleges that “negatively charged mRNA (e.g., Spikevax’s oligonucleotide) may connect to, associate with, and/or physisorb to the lipid shell, due to (for instance) the charge difference between the mRNA and the cationic lipid.” D.I. 1, ¶ 106; *see also id.*, ¶¶ 127, 141. Because Northwestern has not pleaded a plausible basis for infringement of the '155 and '026 patents, Counts I and II should be dismissed.

Finally, under the infringement theory described in the complaint that apolipoproteins naturally bind to lipid nanoparticles inside the body, the claims of the '686 patent are invalid, *inter alia*, under 35 U.S.C. § 101 because they recite nothing more than patent-ineligible natural phenomena. Indeed, Northwestern specifically added the apolipoprotein limitation to overcome a § 101 rejection during prosecution because, as the examiner found, without that limitation, the '686 patent’s claims would encompass naturally occurring structures. Northwestern’s strained infringement theory reduces the apolipoprotein limitation to a natural phenomenon that would render the '686 patent ineligible, and Count III therefore should be dismissed.

III. STATEMENT OF THE FACTS

A. The Asserted Patents

1. The '155 and '026 patents

Counts I and II allege infringement of the '155 and '026 patents, which are two patents in the same family that share a common specification. Both patents are titled “Synthetic Nanostructures Including Nucleic Acids And/Or Other Entities.”

The '155 and '026 patents describe nanoparticle formulations for “the targeted cellular

delivery of short therapeutic nucleic acid (NA) oligonucleotides (e.g., antisense-DNA (AS-DNA), siRNA, and microRNA)” for use in “gene regulation.” ’155 patent, 1:46-57; ’026 patent, 1:50-54. The nanoparticles exemplified in the patents comprise a gold core to which other components may be attached. *See* ’155 patent, 7:59-9:8; ’026 patent, 8:4-9:23. Figure 1 illustrates a structure for these particles, which contain a core (16) made of a solid material (e.g., gold) surrounded by a shell (20) and additional components (36), such as “proteins, nucleic acids, and bioactive agents”:

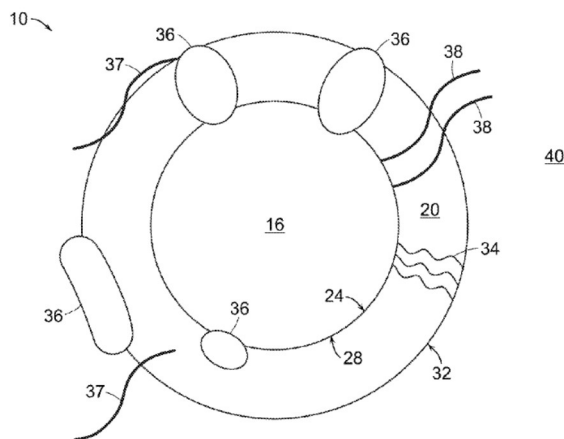


FIG. 1

’155 patent, 7:59-9:8, Fig. 1; ’026 patent, 8:4-9:23, Fig. 1. The shell “may be in the form of an apolipoprotein assembly” that facilitates the binding of lipids to the particles. ’155 patent, 8:64-9:3; ’026 patent, 9:11-18.

Figure 1 also shows that “nucleic acid 37 may be adsorbed (e.g., physisorbed) to a portion of the shell and the nucleic acid 38 may be covalently or near-covalently bonded to surface 24 of the shell.” ’155 patent, 8:6-9; ’026 patent, 8:18-22. “One or more components 36 may be associated with the core, the shell, or both” including the inner surface and outer surface of the shell, core, and/or embedded in the shell. ’155 patent, 8:55-59; ’026 patent, 9:1-5.

The patents describe the potential uses of the nanoparticles for treating lipid disorders, regulating gene expression to treat cancers, or acting as diagnostic agents. ’155 patent, 24:46-

29:23; '026 patent, 25:15-29:65. The patents do not describe compositions for vaccines or any use of the patented technology to prevent infectious diseases. The patents also do not describe delivering mRNA to express any protein, let alone immunogens, as with an mRNA vaccine.

The complaint discusses only claim 2 of the '155 patent (D.I. 1, ¶ 66), which recites:

A method for promoting cellular uptake of an oligonucleotide comprising:

delivering a oligonucleotide structure to a subject or a biological sample in an effective amount for promoting cellular uptake of the oligonucleotide in the subject or biological sample, the structure comprising a nanostructure core;

a shell comprising a lipid surrounding and attached to the nanostructure core or a hydrophobic shell surrounding the nanostructure core; and

an oligonucleotide adapted to regulate gene expression associated with at least a portion of the shell, wherein the structure is adapted to sequester cholesterol wherein the structure promotes the cellular uptake of the oligonucleotide, wherein the oligonucleotide is electrostatically physisorbed to a surface of the shell.

'155 patent, 55:56-56:39.

The complaint discusses only claim 1 of the '026 patent (D.I. 1, ¶ 69), which recites:

A nanostructure comprising an oligonucleotides adapted to regulate gene expression physisorbed to the surface of a synthetic carrier comprising a core surrounded by a lipid bilayer, and an apolipoprotein.

'026 patent, 57:2-5.

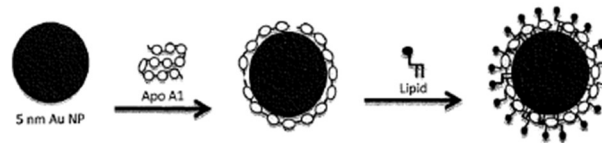
2. The '686 patent

Count III asserts infringement of the '686 patent, which is titled “Nanostructures Suitable For Sequestering Cholesterol And Other Molecules.” The '686 patent shares some disclosures in common with the '155 and '026 patent, but issued from an earlier-filed patent application.

The '686 patent includes the same Figure 1 and corresponding description of the disclosed nanoparticles as the '155 and '026 patents. *See* '686 patent, 6:9-7:15, Fig. 1. All claims of the

'686 patent require the nanoparticle to include an apolipoprotein, which facilitates its ability to sequester cholesterol. *See id.*, 7:8-11 (“[T]he shell may be in the form of an apolipoprotein assembly that ... regulates the uptake of lipids.”); *id.*, 8:16-19 (“Optionally, structure 10 may include one or more apolipoproteins (e.g., apolipoprotein-AI), proteins, or peptides, which can facilitate the sequestering of cholesterol.”); *id.*, 13:10-18 (listing apolipoproteins that “promote transfer of cholesterol and cholesteryl esters to the liver for metabolism”). Figure 9D depicts apolipoprotein (Apo-A1) binding to gold particles to form a “shell” to which lipids then attach.

FIG. 9D



The patent requires that the claimed structure includes inorganic material, which it explains can be in the form of solid material such as gold nanoparticles or the like. *Id.*, 10:12-18 (listing inorganic material as including a metal, a semiconductor, or an insulator). In all but one example in the '686 patent, the “nanostructure core” is a gold particle core. *Id.*, 29:61-38:40. In the remaining example, Example 4, the starting point was a gold nanoparticle but the gold was removed, which caused the structures to expand. *Id.*, 35:22-26, 35:42-54.

The '686 patent does not describe particles, like those in Moderna's vaccines, that contain mRNA; in fact, the word “mRNA” appears nowhere in the '686 patent. And like the '155 and '026 patents, the '686 patent does not discuss protein expression, vaccines, or infectious diseases.

The complaint discusses only claim 1 of the '686 patent (D.I. 1, ¶ 72), which recites:

- A structure comprising:
- a nanostructure core comprising an inorganic material;
 - a shell comprising a lipid bilayer surrounding and attached to the nanostructure core, the shell having an inner surface and an outer surface; and
 - an apolipoprotein bound to at least the outer surface of the shell.

'686 patent, 39:23-29.

B. The Accused Products

Northwestern has accused Moderna's mRNA vaccines for COVID-19 (Spikevax) and RSV (mRESVIA) of infringement, but the particles in those vaccines differ in numerous ways from the particles described and claimed in the Asserted Patents. For example, as the package insert and FDA regulatory documents that Northwestern attached to its complaint make clear, Moderna's vaccines do not include (1) a core containing gold or any other solid inorganic material; (2) an apolipoprotein; or (3) oligonucleotides.¹ *See, e.g.*, Ex. U² at 28 (listing components of Moderna's COVID-19 vaccine); Ex. T at 4 (listing components of Moderna's RSV vaccine). And given the difference in components from the particles of the Asserted Patents, the particles used in Moderna's mRNA vaccines are also assembled in an entirely different way from those described in the Asserted Patents. For example, Moderna's vaccines encapsulate the mRNA—meaning the payload is protected—whereas the claims of the '155 and '026 patents require that an oligonucleotide is “physisorbed” to the *surface* of other components of the particle. *See* '155 patent, 55:56-56:39 (claim 2); '026 patent, 57:2-5 (claim 1). Northwestern has not alleged any facts suggesting that any components of Moderna's vaccines are “physisorbed” to the surface of a synthetic carrier or surface of the shell as claimed; in fact, the complaint admits that Moderna's lipid nanoparticles “encapsulate the mRNA,” as opposed to physically absorbing to the surface. D.I. ¶ 104. Northwestern has alleged that Moderna's vaccines contain “negatively charged mRNA” and a positively charged “cationic lipid” that “may connect to, associate with, and/or

¹ Moderna is not moving to dismiss based on the “core” and “oligonucleotide” limitations. But to the extent that the complaint survives a motion to dismiss, those issues and others could be resolved promptly through early claim construction.

² Every exhibit with a letter is an exhibit that Northwestern attached to its complaint.

physisorb to the lipid shell” (D.I. 1, ¶ 106), but that list of possibilities connected by an “and/or” does not actually allege physical absorption, let alone to the surface as claimed.

Moderna’s mRNA vaccines also serve an entirely different purpose from the particles described in the Asserted Patents. Unlike the cholesterol-sequestering particles described in the Asserted Patents, Moderna’s mRNA vaccines are administered intramuscularly and are not designed to bind cholesterol or treat high cholesterol in patients. Moderna’s vaccines instead are indicated only for the prevention of COVID-19 or lower respiratory tract disease (LRTD) caused by RSV. Ex. U at 1 (“indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older”); Ex. T at 4 (“indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older”). Similarly, Moderna’s vaccines do not regulate gene expression, as described in the ’155 and ’026 patents, which involves regulating the expression of a patient’s own genes. *See* ’155 patent, 37:10-48:54; ’026 patent, 37:61-49:40. The mRNA in Moderna’s vaccines has no effect on a patient’s endogenous gene expression; instead, the mRNA encodes for foreign, viral proteins that are not part of the human genome. Ex. M at 2 (F glycoprotein is expressed on the surface of the virus), Ex. U at 5 (spike S glycoprotein is “viral”).

C. Northwestern’s Pre-Suit Letter To Moderna

Because Northwestern’s patents relate to technologies that have no relationship to Moderna’s work, Northwestern has not alleged (nor can it) that Moderna was aware of the Asserted Patents before Northwestern first contacted Moderna by letter dated October 13, 2023. In that letter, Northwestern identified the ’155, ’026, and ’686 patents and offered to initiate licensing

discussions. *See* Ex. 1 at 2.³ Northwestern’s letter stated that “it appears that Moderna may use some or all of the inventions claimed in these patents” (*id.*), but failed to identify which of those patents Moderna supposedly infringed or how. Instead, the letter simply listed components that Moderna’s vaccines do not include, such as an “oligonucleotide” and “an apolipoprotein,” and referred to unspecified “scientific literature” supposedly describing “the importance and necessity of apolipoproteins to mediate the uptake of LNPs into a target cell.” *Id.* The complaint does not allege that Northwestern ever identified which, if any, of the Asserted Patents were allegedly infringed or ever explained the basis for its infringement allegations before filing this lawsuit. Moderna first learned of Northwestern’s infringement allegations with the filing of the complaint.

IV. LEGAL STANDARD

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Facial plausibility occurs when the plaintiff pleads facts that allow the court to draw a “reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* While a court must accept all factual allegations as true, legal conclusions are not entitled to the assumption of truth. *Id.* Similarly, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements,” are not entitled to the assumption of truth. *Id.*; *see also Twombly*, 550 U.S. at 555 (“[F]ormulaic recitation of the elements of a cause of action will not do.”).

Infringement can be resolved on a motion to dismiss where the complaint fails, as here, to allege a plausible basis for infringement. *See Mod. Telecom Sys., LLC v. TCL Corp.*, C.A. No. 17-

³ The complaint relies upon this letter to allege Moderna’s notice of the Asserted Patents. D.I. 1, ¶¶ 129, 143, 157. While the complaint did not attach it, the letter is integral to the complaint and should be considered on a motion to dismiss. *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014).

583-LPS-CJB, 2017 WL 6524526, at *2-4 (D. Del. Dec. 21, 2017), *report and recommendation adopted*, 2017 WL 2569604 (D. Del. Jan. 9, 2018) (recommending granting a motion to dismiss because plaintiff simply parroted back the words of the claim and made bald allegations, thereby failing to provide plausible allegations of direct infringement).

V. ARGUMENT

A. Northwestern's Direct Infringement Claim For All Counts Should Be Dismissed.

Northwestern's infringement allegations for all Asserted Patents require administration of Moderna's vaccines to patients. But the complaint does not allege that Moderna administers its vaccines to patients. The complaint therefore fails to state a claim under 35 U.S.C. § 271(a) because it fails to allege any act of direct infringement by Moderna.

For Count I, all asserted claims of the '155 patent recite methods that require "delivering a[n] oligonucleotide structure to a subject or a biological sample." '155 patent, 55:56-56:39 (claim 2). Northwestern's infringement allegations are based solely on the administration of Moderna's vaccines to patients. *See* D.I. 1, ¶ 127 ("Defendants infringe the '155 patent ... because, when administered, the Accused Products deliver an oligonucleotide structure to a patient"). Northwestern has not alleged that Moderna administers vaccines to patients, and it is blackletter law that these type of method claims are not directly infringed by a vaccine manufacturer like Moderna. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003).

For Counts II and III, Northwestern does not allege that Moderna's mRNA vaccines as manufactured and sold by Moderna contain "an apolipoprotein" as required by all claims of the '026 and '686 patents. Instead, Northwestern's infringement allegations rest solely on the theory that apolipoprotein-containing particles form inside a patient's body after Moderna's vaccines are administered. *See* D.I. 1, ¶ 104 ("That LNP then interacts with an apolipoprotein in the body once

Spikevax is administered to the patient.”), ¶ 137 (“[T]he Accused Products’ LNP mimics a lipoprotein after administration.”), ¶ 150 (same). The complaint cites no evidence that these apolipoprotein-containing particles form inside persons receiving Moderna’s vaccines.⁴ But even if true, those allegations do not state a claim for direct infringement by Moderna, since they do not allege apolipoprotein-containing complexes form when the vaccine is in Moderna’s hands. Northwestern’s direct infringement claims for Counts II and III therefore should also be dismissed.

Separately, the complaint contains a boilerplate allegation that Moderna directly infringes through “*in vitro*⁵ testing in the laboratory and/or *in vivo* testing during clinical trials.” D.I. 1, ¶¶ 124, 138, 152. But those bare references to unidentified tests are insufficient to state a claim for direct infringement. Indeed, as the complaint acknowledges, such testing is what “established efficacy and safety of the Accused Products and led to FDA approval,” *id.*, ¶¶ 138, 152, which is not an act of infringement under 35 U.S.C. § 271(e)(1)’s safe harbor. *See, e.g., Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, 96 F.4th 1347, 1351-52 (Fed. Cir. 2024) (explaining that the safe harbor “provides a wide berth” for the use of patented inventions “reasonably related” to the federal regulatory process, irrespective of the stage of research and even if the information is never ultimately submitted to the FDA (citation omitted)).

⁴ Northwestern cites Federica Sebastiani et al., *Apolipoprotein E Binding Drives Structural and Compositional Rearrangement of mRNA-Containing Lipid Nanoparticles*, 15(4) ACS Nano 6709, 6710 (2021) (“Sebastiani”) to support its allegation that Spikevax binds with apolipoprotein post administration. D.I. 1, ¶ 110 & n.38. Sebastiani, however, does not address Moderna’s lipid nanoparticles. Moreover, Northwestern’s patent claims reciting the apolipoprotein limitation were rejected in a related pending application (18/456,371) as inherently anticipated by the prior art in view of Sebastiani’s disclosure of apolipoprotein binding by certain lipid nanoparticles. Ex. 2 at 18-21. In response, Northwestern argued that apolipoprotein binding does not necessarily result following the administration of all lipid nanoparticles. *Id.* at 45-46. Northwestern’s reliance on Sebastiani to suggest that apolipoprotein binding occurs inside the body for Moderna’s lipid nanoparticles contradicts the position that Northwestern has taken with respect to Sebastiani before the Patent Office.

⁵ Northwestern alleges direct infringement of the ’026 patent and ’686 patents based on *in vitro* laboratory testing, yet its infringement theory requires the “*in vivo* association of the Accused Products’ LNP with apolipoproteins.” D.I. 1, ¶¶ 136 (’026 patent), 150 (’686 patent).

B. Northwestern’s Indirect Infringement Claims For All Counts Should Be Dismissed At Least In Part.

1. Northwestern has not pleaded a plausible claim for inducement under § 271(b) for at least the pre-suit period.

“For an allegation of induced infringement to survive a motion to dismiss, a complaint must plead facts plausibly showing that the accused infringer specifically intended another party to infringe the patent and knew that the other party’s acts constituted infringement.” *Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1379 (Fed. Cir. 2017) (cleaned up) (quoting *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012)). In other words, liability under § 271(b) requires at least (1) knowledge of the patent in suit and (2) knowledge of the patent infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015). Knowledge of the infringement requires more than knowing “acts might infringe”; it “requires proof the defendant knew the acts were infringing.” *Id.* at 642.

With respect to knowledge of the Asserted Patents, the complaint does not allege that Moderna knew of the Asserted Patents before Northwestern first contacted Moderna to initiate licensing discussions on October 13, 2023. D.I. 1, ¶¶ 129, 143, 153. At most, Northwestern alleges that “Moderna recognized the importance of the Asserted Patents” because it cited to the “Asserted Patents’ family, both in the patents that cover Spikevax and in its other patents,” and that patents purportedly covering Spikevax “cite to a family member with the same disclosures as those of the Asserted Patents.” D.I. 1, ¶¶ 82-84. Northwestern’s threadbare allegations are insufficient to allow a plausible inference that Moderna had actual knowledge of the Asserted Patents before October 13, 2023 based on the surrounding circumstances, i.e., through related patents in the same family. For example, in *Elm 3DS Innovations, LLC v. Samsung Elecs. Co.*, C.A. No. 14-1430-LPS-CJB, 2015 WL 5725768, at *3 (D. Del. Sept. 29, 2015), *report and recommendation adopted*, 2016 WL 1274812 (D. Del. Mar. 31, 2016), the plaintiff alleged sufficient facts demonstrating that

the defendants had pre-suit knowledge of a patent-in-suit based, indirectly, from surrounding circumstances because the complaint alleged: (1) the inventor of the patent-in-suit made a presentation to defendants and sent them a copy of the patent parent; (2) “the presentation included several slides depicting figures from the [parent] patent”; (3) the defendants then cited the parent patent and three children which share “the same specification as the [patent-in-suit]” in prosecuting their own patents; and (4) the patent-in-suit was “well known in the [relevant] industry.” By contrast, there is no allegation of “fairly detailed, specific discussions about the [patent-in-suit’s] parent” or knowledge of the patents-in-suit in the industry. *Id.* Northwestern does not even identify the patent family members nor allege actual knowledge of the Asserted Patents through the family members. Northwestern’s inducement claim should therefore be dismissed at least for the period before October 13, 2023. *See Commil*, 575 U.S. at 639 (“[L]iability for inducing infringement attaches only if the defendant knew of the patent and that the ‘induced acts constitute patent infringement’” (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011))).

The complaint also fails to allege that Moderna had any knowledge of the alleged infringement before this lawsuit was filed on October 16, 2024. The complaint points to the letter that Northwestern sent to Moderna on October 13, 2024 (D.I. 1, ¶¶ 129, 143, 157), but that letter does not allege that Moderna infringed any particular patent, let alone explain the basis for any infringement allegations. *See* Ex. 1 at 2 (“From our preliminary review, it appears that Moderna may use some or all of the inventions claimed in these patents in the United States in connection with its COVID-19 vaccines, including the original and updated versions of Spikevax.”). The mere suggestion that “acts might infringe” is not enough to plead intent to induce infringement. *Commil*, 575 U.S. at 642. Moreover, Northwestern has not pleaded any other facts to suggest that

Moderna had any intent to encourage infringement of the Asserted Patents before the filing of this lawsuit. For example, Moderna’s package inserts and other materials for healthcare providers say nothing about (1) apolipoprotein binding (’026 and ’686 patents); (2) regulating gene expression (’155 and ’026 patents); or (3) sequestering cholesterol (’155 patent)—since that is not what Moderna’s vaccines are designed to do. *See Sanofi v. Watson Lab ’ys Inc.*, 875 F.3d 636, 644 (Fed. Cir. 2017) (“When proof of intent to encourage depends on the label accompanying the marketing of a drug, [t]he label must encourage, recommend, or promote infringement.” (quoting *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)); *see, e.g.*, Ex. U.⁶

Because Northwestern has failed to plead the knowledge required for induced infringement before this lawsuit was filed, Northwestern’s claims under § 271(b) should be dismissed at least for the period before October 16, 2024.

2. Northwestern has not pleaded a plausible claim for contributory infringement under § 271(c).

To state a claim for contributory infringement, a complaint must plead facts plausibly showing (1) direct infringement; (2) knowledge of the patent; (3) that the component has no substantial noninfringing uses; and (4) that the component is a material part of the invention. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). “Where the product is equally capable of, and interchangeably capable of both infringing and substantial non-infringing uses, a claim for contributory infringement does not lie.” *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d at 1338. Northwestern’s contributory infringement allegations should be dismissed for at least two reasons.

First, the same knowledge elements for induced infringement are also required for

⁶ Northwestern did not even cite or discuss the mRESVIA Package Insert in its complaint.

contributory infringement. *Global-Tech*, 563 U.S. at 765-66. Northwestern’s contributory infringement allegations for at least the pre-suit period should be dismissed for the same reasons discussed above with respect to inducement.

Second, the complaint alleges no facts supporting the bare allegation that Moderna has “contributorily infringed and continue[s] to contributorily infringe the [Asserted Patents] under 35 U.S.C. §§ 271(c) and 271(f) by selling, offering to sell, or causing to be supplied in or from the United States the Accused Products, knowing that the Accused Products are specially made or specially adapted for practicing the invention of the [Asserted Patents] and are not staple articles or commodities of commerce suitable for substantial non-infringing use.” D.I. 1, ¶¶ 126, 140, 154. To the contrary, the Accused Products are not “specially made or specially adapted” to bind apolipoproteins (’026 and ’686 patents), to regulate gene expression (’155 and ’026 patents), or to sequester cholesterol (’155 patent). The Accused Products are vaccines designed to prevent infection by SARS-CoV-2 or RSV; Northwestern has cited no evidence associated with the Accused Products even mentioning binding apolipoproteins or regulating gene expression. Parroting the legal standard without more is insufficient to survive a motion to dismiss. *See Twombly*, 550 U.S. at 555. Northwestern’s contributory infringement allegations for all counts therefore should be dismissed in their entirety.

3. Northwestern has not pleaded a plausible claim for infringement under § 271(f).

Liability under § 271(f) requires supplying components of a patented invention, uncombined in whole or in part, while (1) actively inducing the combination of such components outside the United States in an infringing manner (§ 271(f)(1)); or (2) intending such combination for components that are “especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use” (§ 271(f)(2)).

35 U.S.C. § 271(f); see *Confluent Surgical, Inc. v. Hyperbranch Med. Tech., Inc.*, C.A. No. 17-688-LPS-CJB, 2017 WL 4804264, at *1 (D. Del. Oct. 25, 2017), *report and recommendation adopted*, 2017 WL 11556764 (D. Del. Nov. 13, 2017). Northwestern’s infringement allegations under § 271(f) fail for multiple independent reasons.

First, § 271(f) does not apply to method claims. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1364 (Fed. Cir. 2009) (en banc as to Part C.2). Northwestern cannot state a claim under § 271(f) for the ’155 patent (Count I), which includes only method claims.

Second, Northwestern’s § 271(f) infringement allegations are based on its allegations of inducement and contributory infringement and fail for at least the pre-suit period for the same reason discussed above. See *supra* § V.B.1. For example, § 271(f)(2) requires “*intending* that such component will be combined outside of the United States *in a manner that would infringe*,” i.e., requires knowledge of the patent and of the alleged infringement.⁷ And § 271(f)(1) mirrors the “actively induce” language of § 271(b),⁸ which requires “knowledge that the induced acts constitute patent infringement.” *Global-Tech*, 563 U.S. at 766, 771; see also *Dialect*, 2024 WL 4010111, at *4 (holding that § 271(f)(1) has a scienter requirement).

Third, Northwestern has not pleaded any facts supporting that “the Accused Products are specially made or specially adapted for practicing the invention of the [Asserted Patents] and are not staple articles or commodities of commerce suitable for substantial non-infringing use,” which

⁷ Although § 271(f)(2) does not incorporate the doctrine of contributory infringement, *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1367-68 (Fed. Cir. 2001), the plain language of the text requires “intending” that combining components “would infringe,” therefore requiring knowledge of both the patent and the infringement. See *Dialect, LLC v. Amazon.com, Inc.*, Civ. No. 1:23CV581(DJN), 2024 WL 4010111, at *6-8 (E.D. Va. Aug. 30, 2024) (discussing how the text and legislative history of § 271(f)(2) support a scienter requirement).

⁸ “The term ‘actively induce’ [in 271(f)(1)] is drawn from existing subsection 271(b) of the patent law[.]” Patent Law Amendments of 1984, Pub.L. No. 98-622, 1984 U.S. Code Cong. & Admin. News (98 Stat.) at 5828.

simply mirrors the language in § 271(f)(2). D.I. 1, ¶¶ 126 ('155 Patent), 140 ('026 Patent), 154 ('686 Patent). As discussed above for contributory infringement, such bare recitations of the legal standard are insufficient to survive a motion to dismiss. *See Twombly*, 550 U.S. at 555.

C. Northwestern's Willfulness Allegations Should Be Dismissed.

The complaint contains conclusory assertions of willful infringement, and fails to plead any facts concerning Moderna's state of mind beyond what is alleged for indirect infringement. *See* D.I. 1, ¶¶ 144, 150, 158. Because Northwestern has failed to plead pre-suit knowledge of any alleged infringement for purposes of indirect infringement (*see supra* § V.B.1), it has also failed to plead a plausible claim for willful infringement, which requires a higher showing of culpability. *See Wrinkl, Inc. v. Facebook, Inc.*, C.A. No. 20-cv-13445-RGA, 2021 WL 4477022, at *7 (D. Del. Sept. 30, 2021) ("The bad state of mind [for willful infringement] is worse than the bad state of mind required to prove indirect infringement."). And, to allege willfulness "when there is no pre-suit knowledge, it is not sufficient merely to allege the defendant has knowledge since the filing of the original complaint and has not ceased doing whatever the infringing behavior is alleged to be." *Id.* Thus, Moderna's post-suit knowledge of Northwestern's infringement allegations does not provide a plausible claim for willful infringement. *Id.* ("[U]nless the pieces necessary to allege post-suit willfulness are in place before the suit is filed, I will, in the usual case, grant motions to dismiss that are entirely based on post-suit conduct. Such allegations are not plausible.").

D. Counts I and II Should Be Dismissed Because Northwestern Has Not Pleaded A Plausible Basis For Infringement Of The "Physisorbed" Limitations Of All Claims Of The '155 And '026 Patents.

All asserted claims of the '155 and '026 patents require an "oligonucleotide" that is "physisorbed" to the surface of "a shell" or "a synthetic carrier." *See* '155 patent, 55:56-56:39; '026 patent, 57:2-5. The complaint states that "physisorbed" refers to "physical absorption." D.I. 1, ¶ 60.

Northwestern has failed to plead a plausible basis for infringement of the "physisorbed"

limitations of the '155 and '026 patents. The complaint alleges that Moderna's vaccines contain "negatively charged mRNA" that "may connect to, associate with, and/or physisorb to the lipid shell, due to (for instance) the charge difference between the mRNA and the cationic lipid." D.I. 1, ¶ 106. But that discussion with an "and/or" listing of multiple possibilities does not allege that physisorption actually occurs, let alone that it occurs at the surface as claimed. '155 patent, 55:56-56:39 (claim 2); '026 patent, 57:2-5 (claim 1). In fact, the complaint alleges that Moderna's lipid nanoparticles "encapsulate[] the mRNA," rather than physically absorb the mRNA to the surface. D.I. 1, ¶ 104. Counts I and II include conclusory allegations on information and belief that repeat the claim language but fail to plead additional facts to plausibly allege physisorption to the surface of a shell or synthetic carrier. *See* D.I. 1, ¶¶ 127, 141. The only facts alleged in paragraphs 127 and 141 are the same "charge difference[s]" that were insufficient for paragraph 106 of the complaint to even say whether physisorption occurs. *Id.*, ¶ 106. Because Northwestern has failed to adequately plead that Moderna's mRNA vaccines include an oligonucleotide that is "physisorbed" to a surface as claimed, Counts I and II should be dismissed.

E. Count III Should be Dismissed Because Northwestern's Infringement Theory For The '686 Patent Renders Claim 1 Invalid Under 35 U.S.C. § 101.

Moderna's accused mRNA vaccines do not include particles containing "an apolipoprotein" as required by claim 1 of the '686 patent. Instead, Northwestern's sole basis for alleging infringement rests on the theory that particles containing an apolipoprotein naturally form within patients' bodies after they receive Moderna's vaccines. *See* D.I. 1, ¶¶ 104, 150. But that is not a viable infringement theory for the '686 patent because the apolipoprotein limitation is the only allegedly non-naturally occurring element of the claim; indeed, Northwestern added the apolipoprotein limitation to overcome a § 101 rejection during prosecution because the other claim elements are met by naturally-occurring particles. Northwestern cannot pursue its infringement

theory for the '686 patent without reducing claim 1 to patent-ineligible natural phenomena, and Count III therefore should be dismissed for failure to state a claim.

1. Claim 1 Is Directed To Patent-Ineligible Natural Phenomena Under Northwestern's Infringement Theory.

The first step in the § 101 analysis is determining whether the asserted claim is directed to a patent-ineligible concept, such as a natural phenomenon. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (claims reciting methods using “naturally occurring” fetal DNA directed to a patent-ineligible natural phenomenon).

Under Northwestern's infringement theory, claim 1 of the '686 patent is directed to nothing more than patent-ineligible natural phenomena. Indeed, during prosecution, the examiner rejected claim 1 under § 101 because the claimed structure was otherwise disclosed by naturally-occurring magnetic bacteria particles (e.g., particles containing magnetite surrounded by a lipid membrane that are produced by certain bacteria). Ex. 3 at 4.⁹ To overcome that rejection, Northwestern amended claim 1 to add a limitation requiring “an apolipoprotein bound to at least the outer surface of the shell” of the lipid bilayer, as shown below:

A structure comprising:

a nanostructure core comprising an inorganic material; and
 a shell comprising a lipid bilayer surrounding and attached to the nanostructure core, the shell having an inner surface and an outer surface; and an apolipoprotein associated with bound to at least the outer surface of the shell, ~~wherein the structure is adapted to sequester cholesterol.~~

Ex. 3 at 13.

⁹ The Court may take judicial notice of the prosecution history of the Asserted Patents and consider the prosecution history in connection with a motion to dismiss. *See Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014), *aff'd sub nom. Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

Later in prosecution, the examiner recommended adding the word “isolated” to claim 1 because “otherwise the structure could be claimed *in a human*,” which “would produce a 101 rejection.” *Id.* at 30. The examiner, however, ultimately accepted Northwestern’s representation that the claimed compositions—with the apolipoprotein limitation—were not directed to materials “naturally occurring” within the body and allowed the claims to issue. *Id.* at 50.

Now, years later, Northwestern is advancing an infringement theory in this case that depends upon the apolipoprotein limitation also being a natural phenomenon that occurs inside a person’s body. *See* D.I. 1, ¶¶ 104, 150. That infringement theory places claim 1 squarely within the realm of patent-ineligible natural phenomena under *Alice* step one.

2. Claim 1 Lacks Any Inventive Concept Beyond Patent-Ineligible Natural Phenomena Under Northwestern’s Infringement Theory.

Alice step two requires examining “the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the [patent-ineligible concept] into a patent-eligible application.” 573 U.S. at 221. To survive under *Alice* step two, a patent claim as a whole must amount to “significantly more” than the patent-ineligible concept itself. *Id.* at 218. Here, besides the apolipoprotein binding limitation (which Northwestern alleges occurs naturally inside the body), claim 1 recites a particular “nanostructure core” and “shell comprising a lipid bilayer” that is also natural phenomena, as the prosecution history for the ’686 patent shows. Ex 3 at 4. Under Northwestern’s infringement theory, claim 1 thus fails under *Alice* step two because it recites nothing more than patent-ineligible natural phenomena that cannot supply any inventive concept. *See Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016).

VI. CONCLUSION

Moderna respectfully requests that Counts I, II, and III be dismissed with prejudice.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

OF COUNSEL:

Amy K. Wigmore
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

Emily R. Whelan
Kevin S. Prussia
Andrew J. Danford
Annaleigh E. Curtis
Wenli Gu
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

December 23, 2024

/s/ Travis J. Murray

Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 23, 2024, upon the following in the manner indicated:

Kelly E. Farnan, Esquire
Katharine Lester Mowery, Esquire
RICHARDS, LAYTON O& FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

Rebecca T. Horwitz, Esquire
Mac S. LeBuhn, Esquire
Katherine E. Rhoades, Esquire
Katerina A. Kokkas, Esquire
BARTLIT BECK LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

John M. Hughes, Esquire
BARTLIT BECK LLP
1801 Wewatta Street, 12th Floor
Denver, CO 80202
Attorneys for Plaintiff

VIA ELECTRONIC MAIL

/s/ Travis J. Murray

Travis J. Murray (#6882)