# EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,<br><br>Plaintiffs,<br><br>v.<br><br>MODERNA, INC. and MODERNATX, INC.,<br><br>Defendants. | C.A. No. 22-252 (MSG)<br><br>**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY** |
| MODERNA, INC. and MODERNATX, INC.,<br><br>Counterclaim-Plaintiffs,<br><br>v.<br><br>ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,<br><br>Counterclaim-Defendants. | |

**DEFENDANTS' FIFTH SUPPLEMENTAL OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES (NOS. 1–10)**

Pursuant to Fed. R. Civ. P. 33, Defendants Moderna, Inc. and ModernaTX Inc. (collectively, "Moderna" or "Defendants") provide their Third Supplemental Objections and Responses to Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH's ("Genevant," collectively "Plaintiffs") First Set of Interrogatories (Nos. 1–10).

## SPECIFIC OBJECTIONS AND RESPONSES

**INTERROGATORY NO. 1:**

Do you admit that the manufacture, use, sale, offer for sale, and/or importation of the Accused Product would infringe, either literally or under the doctrine of equivalents, any of the asserted claims of the Patents-in-Suit, assuming the asserted claims to be valid and enforceable? If your answer is anything other than an unqualified "Yes," then for each claim for which your answer is anything other than an unqualified "Yes," state all bases on which you contend the asserted claim would not be infringed either literally or under the doctrine of equivalents, including any basis upon which you assert that Plaintiffs are estopped from asserting infringement by the doctrine of equivalents.

**RESPONSE TO INTERROGATORY NO. 1:**

Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not yet served Infringement Contentions or identified Asserted Claims of the Patents-in-Suit. Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not identified any theories under the doctrine of equivalents. Moderna objects to this Interrogatory on the ground that it seeks premature discovery in advance of the dates to be set out by the Court or agreed to by the parties because it seeks to elicit a claim construction position. Moderna objects to this Interrogatory to the extent it seeks to improperly shift the burden of proving infringement. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion.

Subject to the General and Specific Objections, Moderna responds as follows:

Because Plaintiffs have not yet identified the Asserted Claims of the Patents-in-Suit nor any theories of alleged infringement, including under the doctrine of equivalents, Moderna is unable to answer this Interrogatory completely. Regardless, Moderna does not admit that the

manufacture, use, sale, offer for sale, and/or importation of Moderna's COVID-19 Vaccine would infringe, either literally or under the doctrine of equivalents, any claim of the Patents-in-Suit. *See, e.g.*, D.I. 35.

Plaintiffs bear the burden of proving that the Accused Products infringe the Asserted Claims. Plaintiffs have not met that burden. Indeed, Plaintiffs have not yet served infringement contentions. Moderna does not concede that Plaintiffs have proven direct or indirect literal infringement or infringement under the doctrine of equivalents of any element of the Asserted Claims, and Moderna reserves the right to challenge the sufficiency of proof of infringement of any and all elements of the Asserted Claims.

**A. No Direct or Indirect Infringement: The Asserted Claims are Invalid**

The Accused Products do not directly or indirectly infringe any of the Asserted Claims because an invalid claim cannot be infringed. *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1291 (Fed. Cir. 2005) ("there can be no ... induced infringement of invalid patent claims"). Moderna incorporates by reference its forthcoming Invalidity Contentions to be served according to the scheduling order and any amendments or supplementations thereto that each Asserted Claim is invalid under, *inter alia*, 35 U.S.C. §§ 102–103, 112. Because the Asserted Claims are invalid, the Accused Products cannot infringe.

**B. No Direct or Indirect Infringement: 35 U.S.C. § 271(e)(1)**

Moderna's development activities relating to the Accused Products do not directly or indirectly infringe any of the Asserted Claims because they are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1), which reads, in relevant part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses *reasonably related* to the

> development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs* . . . .

The Supreme Court has construed the safe harbor provision broadly, holding that the exemption "extends to all uses of patented invention that are reasonably related to the development and submission of *any* information under the FDCA" (original emphasis), and that the "reasonably related" requirement will be met "[a]t least where a drugmaker has a reasonable basis for believing that a patented compound *may* work … and uses the compound in research that, *if successful*, would be appropriate to include in a submission to the FDA" (emphasis added). *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 202 (2005). Consistent with the broad construction, the safe harbor provision protects uses of patented compounds in both clinical studies and preclinical studies and research, whether or not the experiments are ultimately submitted to the FDA. *Id*.

The Federal Circuit similarly held that the safe harbor applies "as long as there is a reasonable basis for believing that the use of the patented invention will produce the type of information that are relevant to an FDA submission." *Amgen v. Hospira*, 944 F.3d 1327, 1338 (Fed. Cir. 2019); *see also, e.g.*, *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1360 (Fed. Cir. 2012) ("As long as the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor."); *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, 786 F.3d 892, 897-99, 115 U.S.P.Q.2d (Fed. Cir. 2015) (instructing that in some limited circumstances post-approval testing can be subject to the safe harbor of Section 271(e), and finding that accused infringer's post-approval clinical trials and additional FDA submissions were subject to the safe harbor provision since they were necessary to obtain continued approval of the generic drug).

Moderna's development, preclinical, and clinical activities relating to FDA Emergency Use Authorization and approval of the Accused Products are exempted from infringement under

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