EXHIBIT B

2022 WL 16635341
Only the Westlaw citation is currently available.
United States District Court, D. Delaware.

ARBUTUS BIOPHARMA CORPORATION and Genevant Sciences GmbH, Plaintiffs,

v.

MODERNA, INC. and ModernaTX, Inc.,

CIVIL ACTION NO. 22-252

|

Signed November 2, 2022

Synopsis

Background: Owner of patents directed to lipid nanoparticle delivery platform brought infringement action against COVID-19 vaccine manufacturer. Manufacturer asserted affirmative defense pursuant to statute governing patent infringement actions against the United States.

Holdings: The District Court, Goldberg, J., sitting by designation, held that:

[1] issue of whether affirmative defense applied could not be resolved because of factual dispute as to whether development of vaccine was for the government, and

[2] issue of whether affirmative defense applied could not be resolved because of factual dispute as to whether government authorized or consented to any infringing use.

Motion denied.

West Headnotes (23)

[1] **Federal Civil Procedure** Insufficiency in general

On a motion to dismiss for failure to state a claim, a complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Fed. R. Civ. P. 12(b)(6).

[2] **Federal Civil Procedure** Insufficiency in general

Federal Civil Procedure Matters deemed admitted; acceptance as true of allegations in complaint

To determine whether a complaint meets the pleadings standard on a motion to dismiss for failure to state a claim, the court first outlines the elements a plaintiff must plead to state a claim for relief, next, the court must peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth, and finally, the court looks for well-pled factual allegations, assumes their veracity, and then determines whether they plausibly give rise to an entitlement to relief. Fed. R. Civ. P. 12(b)(6).

[3] **Federal Civil Procedure** Insufficiency in general

Determining whether well-pled factual allegations plausibly give rise to an entitlement to relief, as required to survive a motion to dismiss for failure to state a claim, is a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. Fed. R. Civ. P. 12(b)(6).

[4] **Federal Courts** Intellectual property

Since the statute giving the Court of Federal Claims exclusive jurisdiction over patent infringement suits against the federal government is an affirmative defense rather than a jurisdictional bar, a court may not dismiss such an action for lack of subject matter jurisdiction. 28 U.S.C.A. § 1498(a); Fed. R. Civ. P. 12(b)(1).

[5] **United States** In general; remedy of patent owner

The intention and purpose of Congress in enacting the statute providing a cause of action against the United States for its unauthorized use or manufacture of a patented invention

is to stimulate contractors to furnish what is needed by the government, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents. 28 U.S.C.A. § 1498(a).

[6] **United States** Liability of government

United States Liability of government contractor

The statute providing a cause of action against the United States for its unauthorized use or manufacture of a patented invention creates an independent cause of action for direct infringement by the government or its contractors that is not dependent on the statute governing patent infringement. 28 U.S.C.A. § 1498(a); 35 U.S.C.A. § 271(a).

[7] **United States** In general; remedy of patent owner

For claims that fall within the ambit of the statute providing a cause of action against the United States for its unauthorized use or manufacture of a patented invention, the remedy against the United States is exclusive. 28 U.S.C.A. § 1498(a).

[8] **Courts** Particular questions or subject matter

Federal Circuit law applies to issues of substantive patent law.

[9] **Patents** Affirmative defenses

United States Evidence

A patent infringement defendant asserting an affirmative defense pursuant to the statute providing that when a patented invention is used or manufactured by or for the United States without a license, the remedy shall be by an action against the United States in the Court of Federal Claims bears the burden of establishing that (1) the infringing use is for the government, and (2) the infringing use is with the authorization and consent of the government. 28 U.S.C.A. § 1498(a).

[10] **United States** Liability of government contractor

An infringing use by a contractor is "for the Government," within the meaning of the statute governing patent infringement actions against the United States, if it is in furtherance and fulfillment of a stated government policy which serves the government's interests and which is for the government's benefit. 28 U.S.C.A. § 1498(a).

[11] **United States** Liability of government contractor

To satisfy the requirement under the statute governing patent infringement actions against the United States that an infringing use by a contractor be for the government, the government's benefit from an infringing use need not be the primary purpose of a government contract. 28 U.S.C.A. § 1498(a).

[12] **United States** Liability of government contractor

To satisfy the requirement under the statute governing patent infringement actions against the United States that an infringing use by a contractor be for the government, the government need not be the sole beneficiary of the infringing use. 28 U.S.C.A. § 1498(a).

[13] **United States** Liability of government contractor

The requirement under the statute governing patent infringement actions against the United States that an infringing use by a contractor be for the government must be applied on a case-by-case basis. 28 U.S.C.A. § 1498(a).

[14] **United States** Liability of government contractor

Incidental benefit to the government is insufficient to satisfy the requirement under the statute governing patent infringement actions against the United States that an infringing use by a contractor be for the government. 28 U.S.C.A. § 1498(a).

[15] **United States** Liability of government contractor

A governmental grant of authorization or consent, standing alone, does not satisfy the requirement under the statute governing patent infringement actions against the United States that an infringing use by a contractor be for the government. 28 U.S.C.A. § 1498(a).

[16] **Patents** Fact questions

Issue of whether affirmative defense pursuant to statute governing patent infringement actions against the United States applied in infringement action by owner of patents directed to lipid nanoparticle delivery platform against COVID-19 vaccine manufacturer could not be resolved at motion to dismiss phase because of factual dispute as to whether development of vaccine was for the government. 28 U.S.C.A. § 1498(a).

[17] **Evidence** Public or government websites

District court would take judicial notice of contract between federal government and COVID-19 vaccine manufacturer in determining, on manufacturer's motion to dismiss patent infringement claims by owner of patents directed to lipid nanoparticle delivery platform, whether affirmative defense pursuant to statute governing patent infringement actions against the United States applied; contract was public document published on the internet. 28 U.S.C.A. § 1498(a).

[18] **United States** Liability of government contractor

Under the statute governing patent infringement actions against the United States, the authorization and consent of the government to an infringing use by a contractor may be express or implied. 28 U.S.C.A. § 1498(a).

[19] **United States** Liability of government contractor

When the government provides express consent to infringement by a contractor, within the meaning of the statute governing patent infringement actions against the United States, that consent may be very broad, extending to any patented invention and any infringing use, or may be limited to only certain patented inventions or to only those uses that are necessary or are specifically consented to by the government. 28 U.S.C.A. § 1498(a).

[20] **United States** Liability of government contractor

Under the statute governing patent infringement actions against the United States, an implied authorization to infringe may be found where (1) the government expressly contracted for work to meet certain specifications, (2) the specifications cannot be met without infringing on a patent, and (3) the government had some knowledge of the infringement. 28 U.S.C.A. § 1498(a).

[21] **United States** Liability of government contractor

Even when the government expressly consents to infringement in order to perform a government contract, a government contractor's use of a patented device does not constitute authorization or consent, within the meaning of the statute governing patent infringement actions against the United States, where the choice of the device was the contractor's and where there was nothing in the contract that could not be performed without using the device. 28 U.S.C.A. § 1498(a).

[22] **Patents** Fact questions

Issue of whether affirmative defense pursuant to statute governing patent infringement actions against the United States applied in infringement action by owner of patents directed to lipid nanoparticle delivery platform against COVID-19 vaccine manufacturer could not be resolved at motion to dismiss phase because of factual dispute as to whether government authorized or consented to any infringing use. 28 U.S.C.A. § 1498(a).

[23] **United States** Liability of government contractor

Under the statute governing patent infringement actions against the United States, even express authorization and consent by the government to a contractor's use of patented invention may be limited by other clauses in a contract. 28 U.S.C.A. § 1498(a).

Attorneys and Law Firms

John W. Shaw, Nathan Roger Hoeschen, Karen Elizabeth Keller, Shaw Keller LLP, Wilmington, DE, Kira A. Davis, Pro Hac Vice, San Francisco, CA, for Plaintiff Arbutus Biopharma Corporation.

John W. Shaw, Karen Elizabeth Keller, Shaw Keller LLP, Wilmington, DE, Adam D. Harber, Pro Hac Vice, David I. Berl, Pro Hac Vice, Jessica Palmer Ryen, Pro Hac Vice, Shaun P. Mahaffy, Pro Hac Vice, Thomas S. Fletcher, Pro Hac Vice, Washington, DC, Daralyn J. Durie, Pro Hac Vice, San Francisco, CA, Denis R. Hurley, Pro Hac Vice, Latham, NY, Eric C. Wiener, Pro Hac Vice, Durham, NC, Lydia B. Cash, Pro Hac Vice, for Plaintiff Genevant Sciences GmbH.

Brian P. Egan, Jack B. Blumenfeld, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE, James F. Hurst, Pro Hac Vice, Chicago, IL, Jeanna M. Wacker, Pro Hac Vice, Mark C. McLennan, Pro Hac Vice, Patricia A. Carson, Pro Hac Vice, New York, NY, for Moderna, Inc., Modernatx, Inc.

MEMORANDUM

Goldberg, District Judge

***1** During the course of the COVID-19 pandemic, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") brought to market an mRNA-based vaccine in an effort to combat the effect of the COVID-19 virus. Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively "Plaintiffs") claim that, in order for the vaccine to succeed, Moderna used a revolutionary lipid nanoparticule ("LNP") delivery platform —created and patented by Plaintiffs—without paying for it or requesting a license.

On February 28, 2022, Plaintiffs filed suit seeking compensation for the use of the patented technology they claim to have developed. On May 6, 2022, Moderna filed a partial Motion to Dismiss, arguing that to the extent Plaintiffs seek royalties on the sale and provision of COVID-19 Vaccine doses to the United States Government, such claims can only proceed in the Court of Federal Claims and must be dismissed from this Court. For the following reasons, I will deny Moderna's Motion.[1]

I. FACTUAL BACKGROUND

The following facts are taken from Plaintiff's Complaint.[2]

A. General Background Regarding Virus Vaccines

As explained in the Complaint, viruses are typically described as small packets of deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"). If a virus enters a living host cell, the virus's DNA or RNA can hijack the cell's machinery and instruct the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus, and, left unchecked, the host organism itself can die. Vaccines traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection, but nonetheless retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus it if it invades in the future. (Id. ¶¶ 19–20.)

Moderna's COVID-19 vaccine belongs to a new class of medicines that deliver nucleic acids into the cells of the body to treat diseases or trigger an immune response to protect a person from future infection. Nucleic acids are molecules that encode the genetic information essential to sustain life.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.