IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OLINK PROTEOMICS AB AND OLINK PROTEOMICS INC.,	)	
	)	**C.A. No.**
Plaintiffs,	)	
	)	**JURY TRIAL DEMANDED**
v.	)	
	)	
ALAMAR BIOSCIENCES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Olink Proteomics AB and Olink Proteomics Inc. (collectively, "Olink" or "Plaintiffs"), by its undersigned attorneys, bring this action for patent infringement against Alamar Biosciences, Inc. ("Alamar" or "Defendant") and allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.* arising out of Alamar's manufacture, use, offer for sale, sale, marketing and/or distribution of its Nucleic acid Linked Immuno-Sandwich Assay ("NULISA") platform used with or without its ARGO system, prior to the expiration of United States Patent No. 7,883,848 ("the '848 patent" or "patent-in-suit"). A copy of the '848 patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Olink Proteomics AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at Salagatan 16F, SE-753 30 Uppsala, Sweden. Olink Proteomics AB is the owner of the '848 patent.

3. Plaintiff Olink Proteomics Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 130 Turner St. Building 2, Suite 230, Waltham, Massachusetts. Olink Proteomics Inc. holds an exclusive license to the '848 patent.

4. Upon information and belief, Defendant Alamar is a corporation organized and existing under the laws of Delaware with its principal place of business at 47071 Bayside Parkway, Fremont, California 94538.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Alamar because, *inter alia*, it is a corporation organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware; it has purposefully availed itself of the privilege of doing business in Delaware directly or indirectly.

7. Upon information and belief, Alamar has offered for sale, sold, marketed, and/or distributed, and will offer for sale, sell, market and/or distribute its NULISA platform used with or without its ARGO system throughout the United States, including the State of Delaware, and will derive substantial revenue therefrom.

8. Upon information and belief, Alamar intends its NULISA platform, with or without its ARGO system, to be used throughout the United States, including the State of Delaware, which use constitutes patent infringement, which has led and will lead to foreseeable harm and injury to Olink.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because Alamar resides in this judicial district.

FACTUAL BACKGROUND

A. The '848 Patent

10. Plaintiff Olink Proteomics AB is the lawful owner by assignment of all rights, title, and interest in and to the '848 patent. Plaintiff Olink Proteomics Inc. is the exclusive licensee of the '848 patent and holds the sole and exclusive right to sue for infringement of the '848 patent. The '848 patent, entitled, "Regulation Analysis by Cis Reactivity, RACR," was duly and legally issued on February 8, 2011, naming Olof Ericsson as inventor. U.S. Application No. 11/483,825, which issued as the '848 patent, claims the benefit of Provisional Application No. 60/697,415, filed on July 8, 2005.

11. The '848 patent is generally directed to methods of detecting functional interactions between at least two molecules of interest. In the field of immunoassays, functional interactions play a crucial role in detecting and quantifying specific molecules, typically proteins or other biomolecules.

12. Independent claim 1 recites the following:

> A method of detecting functional interactions between at least two molecules of interest, the method comprising:
>
> a. forming a plurality of interactors by coupling each molecule of interest with at least one nucleic acid moiety, the nucleic acid moiety comprising an identification sequence element and an association element;
>
> b. forming a plurality of cis-reactive cells wherein a cis-reactive cell comprises at least two interactors bound in proximity to one another by an associated oligonucleotide formed from the association between at least two nucleic acid moieties, wherein the associated oligonucleotide comprises at least two identification elements derived from the at least two nucleic acid moieties;
>
> c. subjecting the plurality of cis-reactive cells to conditions which stimulate a desired functional interaction having a detectable trace;

d. selecting all cis-reactive cells exhibiting the detectable trace; and

e. subjecting the associated oligonucleotides from the cis-reactive cells selected in step (d) to an analysis that permits detection of the at least two identification sequence elements.

13. The claims of the '848 patent are valid and enforceable.

B. Development of Olink's Patented Technology

14. Olink is a global leader in the field of proteomic analysis and traces its origins to 2004 when Olink AB was founded to develop and commercialize the groundbreaking Proximity Ligation Assay ("PLA"), invented by its founders. In PLA, pairs of antibodies are used, each linked to a DNA oligonucleotide. When the antibodies bind to their respective target proteins, the DNA oligonucleotides come into proximity. This proximity allows the DNA oligonucleotides to hybridize to a splint oligonucleotide, creating a unique DNA sequence that can be detected and quantified using various methods, such as microscopy, quantitative Polymerase Chain Reaction ("qPCR") or Next Generation Sequencing ("NGS"). The generated signals are proportional to the amount of the target proteins present in the sample, making PLA a valuable tool for quantitative protein analysis.

15. Olink AB obtained several patents relating to PLA technology, including the '848 patent, and subsequently entered into a number of agreements with external parties for the development, commercialization, and distribution of products implementing Olink's patented PLA technology.

16. Employees of Olink AB subsequently invented the Proximity Extension Assay ("PEA"). Building on similar principles as PLA, PEA was developed to be a more robust method, in particular for analyzing blood-derived samples. PEA differs from PLA in that the DNA oligonucleotides linked to the antibodies hybridize to each other instead of a splint oligonucleotide,

but otherwise functions similarly in creating a unique DNA sequence for detection and quantification.

17. Olink provides several PEA-based solutions for protein biomarker discovery and analysis. For example, Olink offers "Olink Explore HT," a platform that enables researchers to simultaneously measure multiple proteins in a highly multiplexed manner using PEA. *See* Ex. B.

C. Alamar's NULISA Platform and ARGO System

18. Alamar's NULISA platform is a biomarker detection and quantification assay for proteins which may be run on Alamar's ARGO System, "a fully automated, high-throughput precision proteomics platform." *See* Ex. C at 1.

19. Like Olink's PLA and PEA platforms, Alamar's NULISA platform, used with or without its ARGO system, aims to achieve "superior sensitivity for detecting low-abundance proteins" and "ultra-high sensitivity enabled the detection of previously difficult-to-detect but biologically important, low-abundance biomarkers." *See* Ex. D at 2 (authored by Wei Feng, Director of R&D at Alamar). In fact, Alamar acknowledges that Olink's PLA technology is the basis of NULISA. *See* Ex. E at 1 ("The NULISA system is based on the proximity litigation assay (PLA) originally commercialized by Olink Bioscience, the forerunner of Olink."); *see also* Ex. D.

20. The use of the NULISA platform with or without the ARGO system practices at least one claim of the '848 patent. *See* The NULISA™ Platform by Alamar Biosciences, YouTube, at https://www.youtube.com/watch?v=24nVyCoJv4w (the "NULISA Commercial").

21. In general, the NULISA platform, used with or without its ARGO system, uses probes consisting of an antibody and a nucleic acid. These form "a plurality of interactors."

22. The NULISA platform, used with or without its ARGO system, further includes matched antibody pairs conjugated with oligonucleotides. Specifically, one antibody conjugate

contains a poly-A tail, which is termed as the "capture antibody," and the other contains a biotinylated oligo, which is termed as the "detection antibody." *See* Ex. D at 6.

23. The oligonucleotides of each antibody pair in the NULISA platform, used with or without its ARGO system, contain the claimed "identification sequence element" as the oligonucleotides of both the "capture antibody" and "detection antibody" consist of partially double stranded DNA and a target-specific barcode for detection. For the NULISA multiplex assays, a DNA strand containing a further barcode, unique to a specific sample, is ligated between the two oligos.

24. The nucleic acid moieties in the NULISA platform, used with or without its ARGO system, also satisfy the claimed "association element" that facilitates association between the DNA probe arms as "a ligation mix containing T4 DNA ligase and a specific DNA ligator sequence is added to the streptavidin beads, allowing the ligation of the proximal ends of DNA attached to the paired antibodies." *See id.*

25. Further, a highly specific immunocomplex forms when a specific protein target is present in the sample while using the NULISA platform – that is, the two NULISA probes are bound to an analyte to form "a plurality of cis-reactive cells" comprising "at least two interactors." In fact, the NULISA platform functions so that "[w]hen both antibodies are incubated with a sample containing the target molecule, an immunocomplex is formed. The formed immunocomplexes are captured by added paramagnetic oligo-dT beads and subsequent dT-polyA hybridization." *Id.*

26. After the immunocomplex is formed, the "specific DNA ligator sequence" in the NULISA probe binds to the single stranded nucleic acid moieties, and this association forms a double-stranded DNA molecule connecting the interactors, *i.e.* an "associated oligonucleotide."

In the NULISA platform "a ligation mix containing T4 DNA ligase and a specific DNA ligator sequence is added to the streptavidin beads, allowing the ligation of the proximal ends of DNA attached to the paired antibodies and thus generating a new DNA reporter molecule containing unique target-specific barcodes." *See id.*

27. The NULISA platform, used with or without its ARGO system, also practices claim limitations related to the "detectable trace." Specifically, "the levels of the DNA reporter can be quantified by quantitative PCR or NGS" and the key aspect that Alamar touts regarding the NULISA platform – "the highly specific immunocomplex" that forms when the target protein is present in the sample – practice the claim limitation "selecting all cis-reactive cells exhibiting detectable trace" as a result of NULISA's "dual capture and release mechanism." *Id.* at 2; *see also* NULISA commercial.

D. Alamar's Infringing Conduct and Knowledge of the '848 Patent

28. Alamar has and continues to actively market, offer to sell, and/or sell its NULISA platform and ARGO system.

29. On or around April 13, 2023, Alamar announced the unveiling of its NULISA platform for "early-access release later this year and a broad commercial launch in 2024." *See* Ex. E at 1.

30. In additional to the early-release and commercial launch, Alamar also advertises that its NULISA program is available "today through [its] Technology Access Program." *See* Ex. F at 3.

31. Alamar also advertises that "Early Access" to its ARGO system will be "Available 2nd half of 2023." *See* Ex. C at 11.

32. Alamar is actively installing its ARGO system at its customers' facilities. For example, on November 9, 2023, Alamar "announced the successful installation of its ARGO HT System at Stanford University, its first early access site, ahead of its planned commercial launch in 2024." *See* Ex. G at 1.

33. Alamar has knowledge of the '848 patent. On August 11, 2023, Olink President Carl Raimond sent a letter to Alamar's CEO Yuling Luo, notifying Alamar of several patents, including the '848 patent.

COUNT I
INFRINGEMENT OF THE '848 PATENT

34. Olink realleges and incorporates by reference the allegations contained in ¶¶ 1–33.

35. Upon information and belief, Alamar's manufacture, use, offer for sale, sale, marketing and/or distribution of its NULISA platform used with or without its ARGO system, prior to the expiration of the '848 patent, constitutes direct infringement, either literally or under the doctrine of equivalents, of the '848 patent under at least 35 U.S.C. § 271(a).

36. Upon information and belief, Alamar has and is actively inducing others to infringe the '848 patent in this District and elsewhere in the United States by making, using, offering to sell, selling, and otherwise marketing and distributing the NULISA platform used with or without the ARGO system in the United States in violation of 35 U.S.C. § 271(b). Alamar's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing consumers to use the NULISA platform with or without the ARGO system.

37. Upon information and belief, Alamar has been and is contributing to the infringement of the '848 patent in this District and elsewhere in the United States by making, using, offering to sell, selling, importing, and otherwise marketing and distributing the NULISA platform with or without the ARGO system in violation of 35 U.S.C. § 271(c). Upon information

and belief, the NULISA platform used with or without the ARGO system is not a staple article or commodity of commerce suitable for substantial noninfringing use.

38. Upon information and belief, Alamar will continue to directly and indirectly infringe the ’848 patent unless enjoined by the Court.

39. Alamar’s infringement has caused and is continuing to cause Olink to suffer significant damages, and will continue to inflict additional severe and irreparable harm unless stopped.

40. Alamar is knowingly and willfully infringing the ’848 patent.

JURY DEMAND

Olink demands a jury trial for all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Olink requests entry of judgment against Defendant Alamar and respectfully requests the following relief:

A. A judgment that the ’848 patent is infringed by Alamar;

B. A judgement pursuant to 35 U.S.C. § 283 preliminarily and permanently enjoining Alamar, its officers, agents, servants, employees, parents, subsidiaries, affiliates, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns, from infringing, contributorily infringing, or inducing others to infringe the ’848 patent;

C. A judgement awarding Olink any available damages pursuant to 35 U.S.C. § 284, including, but not limited to, lost profits and/or reasonable royalty;

D. A judgment in favor of Olink and against Alamar determining that Alamar has willfully and deliberately committed the act of patent infringement, and awarding

Olink enhanced damages in light of Alamar's willful infringement pursuant to 35 U.S.C. § 284, including reasonable attorneys' fees and costs;

E. A judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and that Olink be awarded its attorneys' fees incurred in this action;

F. An award of costs and expenses in this action to Olink; and

G. Such other and further relief as the Court deems just and appropriate.

/s/ Kelly E. Farnan

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