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[Your Name]

[Your Title]

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[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 11566277 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 11566277 (the "11566277 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Analysis of U.S. Patent 11,566,277

Report Date: May 12, 2026

This report provides a concise summary of United States Patent 11,566,277, including details of its prosecution history, an overview of its independent claims, and its current legal status.

I. Patent Overview

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| Title | Compositions and methods for analyte detection |

| Assignee | Harvard University |

| Inventors | George M. Church, Jehyuk Lee, Daniel Levner, Michael Super |

| Filing Date | February 15, 2022 |

| Issue Date | January 31, 2023 |

| Application No. | 17/671,803 |

Abstract:

The patent describes methods and compositions for detecting multiple analytes in a sample. The core of the invention lies in...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 11566277 Patent:

V. Prior Art Analysis

This section analyzes the most relevant prior art references cited during the prosecution of U.S. Patent 11,566,277. The analysis focuses on how each reference relates to the independent claims of the '277 patent and its potential to anticipate those claims under 35 U.S.C. § 102. The key inventive concept in the '277 patent is the use of a "temporally-sequential" detection of subsequences on a nucleic acid label to generate a "temporal order of the signal signatures," which acts as a unique identifier for a probe.

1. U.S. Patent Application Publication No. 2007/0231824 ("the '824 application")

- Full Citation: US 2007/0231824 A1; Gunderson, et al.; "Methods for Decoding a Sensor Array"; Published Oct. 4, 2007; Filed Jan. 12, 2007.

- Brief Description: The '824 application describes methods for decoding sensor arrays, such as bead arrays, where each bead has a unique identifier. The decoding process involves sequentially applying different decoding probes to the array. In one embodiment, a first set of probes is hybridized, an image is taken, the probes...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Obviousness Analysis of U.S. Patent 11,566,277

This analysis assesses the validity of the claims of U.S. Patent 11,566,277 ("the '277 patent") under 35 U.S.C. § 103, focusing on whether the invention would have been obvious to a Person Having Ordinary Skill in the Art (PHOSITA) at the time of the invention.

A PHOSITA in this field circa 2011-2012 would typically have a Ph.D. in molecular biology, biochemistry, or a related field, with several years of postdoctoral or industry experience in areas such as nucleic acid chemistry, immunology, microscopy, and next-generation sequencing (NGS) technologies.

The central argument is that the claims of the '277 patent are rendered obvious by the combination of prior art teaching multiplexed analyte detection using nucleic acid barcodes with well-established methods for cyclic, sequential nucleic acid detection, such as sequencing-by-hybridization or sequencing-by-synthesis.

Primary Obviousness Combination

A compelling case for obviousness can be made by combining the teachings of:

1. U.S. Pat. No. 7,473,767 to Geiss et al. ("Geiss"...

4. Litigation History of the Patent

Public records reflect that the 11566277 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

• 10x Genomics, Inc. et al. v. Element Biosciences, Inc. — U.S. District Court for the District of Delaware · filed 2026-05-08 · pending

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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