No. 22A-_____

IN THE SUPREME COURT OF THE UNITED STATES

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Applicants

v.

NATERA, INC.

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Applicants

v.

EUROFINS VIRACOR, INC.

APPLICATION FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE FEDERAL CIRCUIT**:**

Pursuant to Supreme Court Rules 13.5 and 30.2, counsel for CareDx, Inc. and The Board of Trustees of the Leland Stanford Junior University respectfully requests a 60-day extension of time, to and including May 1, 2023, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in these consolidated cases. The court of appeals issued an opinion and entered judgment on July 18, 2022. App. A, App. B. The court of appeals denied a petition for rehearing on December 2, 2022. App. C. Unless

extended, the time to file a petition for a writ of certiorari will expire on March 2, 2023. The jurisdiction of this Court would be invoked under 28 U.S.C. 1254(1).

1. This case raises the fundamental question of whether improved human-made methods for measuring a natural phenomenon are patent eligible under Section 101 of the Patent Act. Section 101 broadly permits patents of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. 101. Yet, driven by a concern of "pre-emption"—*i.e.*, the "monopolization of" "basic tools of scientific and technological work," this Court has long held that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty.* v. *CLS Bank Intl*, 573 U.S. 208, 216 (2014).

2. The Federal Circuit in this case held that a claim to an improved human-made method of measuring a natural phenomenon was ineligible as a claim to the natural phenomenon itself, notwithstanding that the claimed method is plainly human-made, it improves upon prior human-made methods, and no preemption concern has ever been raised. App A at 15-17. That decision is clearly incorrect, and it underscores the confusion in the lower courts over how to apply this Court's Section 101 precedents faithfully and coherently. See, e.g., Order of October 17, 2022, *Tropp* v. *Travel Sentry, Inc.*, No. 22-22 (inviting the Solicitor General to file a brief expressing the views of the United States on a question relating to the interpretation of Section 101); Order of October 3, 2022, *Interactive Wearables, LLC* v. *Polar Electro Oy*, No. 21-1281 (same); Order of May 3, 2021, *Am. Axle & Mfg., Inc.* v. *Neapco Holdings LLC*, No. 20-891 (same); Order of March 18, 2019, *Hikma Pharm. USA Inc.* v. *Vanda Pharm. Inc.*, No. 18-817 (same); Order of January 7, 2019, *HP Inc.* v. *Berkheimer*. No. 18-415 (same). This case presents an ideal vehicle in which to clarify the inquiry with a meaningful guidepost derived directly from the statutory text.

3. The patents at issue are for a new and improved method for measuring a well-known natural phenomenon that occurs during organ rejection. When a person has received an organ transplant, small fragments of the donor's DNA (known as cell-free DNA) can be found in the recipient's bloodstream. And since the 1990s, scientists have known that, when the transplant recipient begins undergoing organ rejection, the proportion of the donor's cell-free DNA in the recipient's blood increases. Scientists immediately recognized that measuring an increase in the proportion of a donor's DNA thus could be used for early and non-invasive detection of organ rejection, a life-threatening medical condition. For over a decade, however, scientists struggled to design methods to effectively measure the proportion of a donor's cell-free DNA in a recipient's bloodstream. The conventional methods suffered from serious limitations. For example, the leading method relied on finding fragments of Y-chromosomes, but that only works if the donor is male and the recipient female.

4. Based on the work of pioneering researchers at Stanford University, the Applicants' patents solve those problems by claiming an improved human-made method for obtaining accurate measurements of the proportion of a donor's cell-free DNA. The patents specify a method using human-made tools (next-generating sequencing and digital PCR) in particular ways, to identify "single nucleotide polymorphisms" in fragments of cell-free DNA that uniquely correspond to the donor or the recipient, and thus can be used to measure the relative proportion of DNA from each. That improved method works for all patients and is far more accurate, and thus a dramatic and life-saving improvement upon prior methods.

5. This in turn should have been an easy case. Section 101 expressly protects "process[es]" and "improvement[s]" upon preexisting processes, 35 U.S.C. 101, and the patents clearly claim an improved human-made process and not the natural

phenomenon itself. Indeed, they affirmatively *disclaim* discovery of the natural phenomenon, *disclaim* the prior conventional methods for measuring it, and instead claim a new, specific process that improves upon those prior methods. Whether these claims are entitled to patent protection is a question of novelty, obviousness, and the other requirements of the Patent Act, not whether the very subject matter is eligible for patent protection.

6. Yet seriously misapplying the two-step inquiry set forth in *Alice Corp. Pty.* v. *CLS Bank International*, the court of appeals concluded that the patents "are ineligible under § 101." App A at 19. First, applying *Alice* step one, the court of appeals held that the Applicants' patents were "directed to natural phenomena," specifically "the level of donor [cell-free]DNA and the likelihood of organ transplant rejection." App A. at 15, 17. The court reached that conclusion despite the fact that the patents claimed only specific improvements to human-made methods for measuring donor cell-free DNA; the only claimed advance was that the new human-made measurement method was better than the previous ones. Such a claim is directed to improving prior art methods, not patenting the underlying natural phenomenon itself. Second, at *Alice* step two, the court held that Applicants' asserted claims merely used "conventional measurement techniques." App A. at 17. That is plainly wrong. The specification identifies *and expressly disclaims* the conventional methods for measuring this phenomenon, which included the Y-chromosome technique. The whole point of this patent is to claim a measurement method that is new, different, and better.

7. Counsel for CareDx, Inc. and the Board of Trustees of the Leland Stanford Junior University respectfully requests a 60-day extension of time, to and including May 1, 2023, within which to file a petition for a writ of certiorari. The Federal Circuit's decision presents an important issue of federal patent law, the resolution of

which will have significant impact on innovation. The decision below is the latest in a line of cases showing that the Federal Circuit has lost sight of both the statutory text and the pre-emption concerns that underlie this Court's Section 101 jurisprudence. Moreover, the attorneys with principal responsibility for drafting the petition have been heavily engaged with the press of other matters. Among others, undersigned counsel has been engaged in preparing a petition for a writ of certiorari that was filed on February 2, 2023, see *Pac. Gas & Elec. Co.* v. *Ad Hoc Comm. of Holders of Trade Claims*, No. 22-733, a merits-stage amicus brief that was filed on February 10, 2023, see Brief for Small and Medium Biotechnology Cos. as Amici Curiae in Support of Respondents, *Amgen Inc.* v. *Sanofi*, No. 21-757, and is counsel in several Federal Circuit cases being argued on March 8, 2023, e.g., *Ethicon LLC* v. *Intl Trade Comm'n*, No. 22-1111 (Fed. Cir.), as well as a Fourth Circuit case in which the opening brief is due March 24, 2023, see *Williamson* v. *Prime Sports Mktg., LLC*, No. 22-1793 (4th Cir.). Accordingly, additional time is needed to permit the preparation and printing of an effective petition in this matter.

Respectfully submitted,

/s/ Zachary D. Tripp

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