16 No. 188

In The
Supreme Court of the United States

GENETIC TECHNOLOGIES LIMITED,

Petitioner,

v.

MERIAL L.L.C.,
BRISTOL-MYERS SQUIBB COMPANY,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

Robert R. Brunelli
Counsel of Record
Benjamin B. Lieb
Hiwot M. Covell
SHERIDAN ROSS P.C.
1560 Broadway, Suite 1200
Denver, Colorado 80202
(303) 863-9700
rbrunelli@sheridanross.com
blieb@sheridanross.com
hcovell@sheridanross.com

Counsel for Petitioner

Dated: August 8, 2016

THE LEX GROUP DC ♦ 1825 K Street, N.W. ♦ Suite 103 ♦ Washington, D.C. 20006
(202) 955-0001 ♦ (800) 856-4419 ♦ Fax: (202) 955-0022 ♦ www.thelexgroup.com

BLANK PAGE

QUESTION PRESENTED

As of the priority date for U.S. Patent No. 5,612,179 in 1989, scientists identified DNA haplotypes through the direct identification of allelic variants within coding DNA regions. Scientists ignored non-coding DNA because they believed those regions were merely accumulated debris or "junk DNA." Dr. Malcolm Simons discovered that, in the DNA of unrelated individuals, a polymorphism in a non-coding DNA region and a coding region allele could be inherited together. This natural phenomenon is known as "linkage disequilibrium." The discovery prompted Dr. Simons to invent a new and useful process for detecting a coding region allele of a multi-allelic genetic locus by interrogating a non-coding DNA sequence that is in linkage disequilibrium with that multi-allelic genetic locus. Dr. Simons' invention, as reflected in claim 1 of the '179 patent, was advantageous for a number of reasons, including that it was more reliable and quicker than prior art identification processes that used direct identification of allelic variants.

On *de novo* review, a Federal Circuit panel evaluated the patent-eligibility of claim 1 in response to a Rule 12(b)(6) motion and under the framework established by *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). The panel found that claim 1 is directed to a "natural law" comprising both: (1) "the relationship between non-coding and coding sequences in linkage disequilibrium"—undisputedly a naturally occurring phenomenon; and (2) "the tendency of such non-coding sequences to be

representative of the linked coding sequences"—which the parties disputed as a matter of fact, and GTG argued was Dr. Simons' application of the natural occurring phenomenon to achieve his intended purpose.

The panel also found the claimed laboratory techniques to be used in a routine and conventional manner, although it recognized "that at the time the '179 patent was filed, no one was 'using the non-coding sequence as a surrogate marker for the coding region allele. . .' [and claim 1] was found by the patent examiner to be novel over the prior art and survived multiple rounds of reexamination."

The panel then affirmed the Delaware District Court's judgment that claim 1 is patent-ineligible under 35 U.S.C. § 101.

The questions presented are:

1. Whether the Federal Circuit properly concluded—in conflict with other decisions of the Federal Circuit and this Court—that the definition of a patent-ineligible concept under the *Mayo/Alice* framework may include both a natural phenomenon and an inventor's ingenuity in applying that natural phenomenon to a new and useful purpose?

2. Whether a Rule 12(b)(6) motion may be properly granted based on patent-ineligibility—as the Federal Circuit determined below in conflict with other Federal Circuit decisions—when the record plausibly demonstrates that the claimed process inventively applies a natural phenomenon for a new and useful purpose, the claimed process does not improperly preempt the natural phenomenon, and the claimed process is not routine and conventional?

PARTIES TO THE PROCEEDING

The Petitioner here, and Plaintiff-Appellant in the Federal Circuit, is Genetic Technologies Limited ("GTG"). The Respondents here, and Defendants-Appellees in the Federal Circuit, are Merial L.L.C. ("Merial") and Bristol-Myers Squibb Company ("BMS").

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, GTG affirms that there is no parent corporation or publicly held company that owns 10% or more of GTG's stock.

BLANK PAGE

TABLE OF CONTENTS

* Exhibits are patent documents and have been produced in a separate appendix (see volume II), in compliance with Rule 33.1(c).

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

OTHER AUTHORITIES

PETITION FOR A WRIT OF CERTIORARI

GTG respectfully petitions for a writ of certiorari to review the judgment issued by the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The Federal Circuit panel Opinion (App. 1a) is published at 818 F.3d 1369. The Opinion and Order of the Delaware District Court (App. 23a; App. 25a) is reported at 72 F. Supp. 3d 521.[1]

JURISDICTION

The Federal Circuit entered judgment on April 8, 2016. (App. 1a.) This Court has jurisdiction under 28 U.S.C. § 1254(1). On June 20, 2016, GTG requested an extension of time to file its petition for a writ of certiorari to August 8, 2016. The Court granted the extension on June 24, 2016.

STATUTORY PROVISIONS INVOLVED

35 U.S.C. §§ 100, 101, and 282. *See* App. 95a-98a.

STATEMENT OF THE CASE

Dr. Simons discovered that, in unrelated individuals, a non-coding polymorphism and a coding region allele could be inherited together, a phenomenon known as "linkage disequilibrium." (App. 265a, 4:28-31; App. 104a-105a; App. 139a-

[1] Only documents from *Genetic Techs. Ltd. v. Merial L.L.C.*, No. 1:12-cv-00394-LPS ("*Merial*") will be cited when identical to documents from *Genetic Techs. Ltd. v. Bristol-Meyers Squibb Co.*, No. 1:12-cv-00396-LPS ("*BMS*").

140a.) Applying this discovery, Dr. Simons invented and claimed in the '179 patent a new and useful process for detecting a coding region allele of a multi-allelic genetic locus, using a non-coding DNA sequence in linkage disequilibrium with the multi-allelic genetic locus. Dr. Simons' invention was groundbreaking because it allowed scientists to reliably and quickly detect a coding region allele without having to identify that allele within the coding DNA region. Representative claim 1[2] of the '179 patent reads:

> 1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
>
> a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of noncoding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
>
> b) analyzing the amplified DNA sequence to detect the allele.

(App. 293a, 59:57-67.)

Claim 1 first requires amplification of "genomic DNA with a primer pair that spans a non-coding region sequence." The claimed primer pair

---

[2] The parties stipulated that claim 1 is representative of claims 1-25 and 33-36 of the '179 patent for purposes of appeal. Claims 26-32 of the '179 patent are not at issue in this appeal.

has two novel features: (1) it defines a DNA sequence in genetic linkage with a multi-allelic genetic locus; and (2) it defines a DNA sequence that contains "a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of [the coding region] allele." Claim 1 then requires analysis of the resulting amplified non-coding DNA sequence, and requires the result of that analysis to lead to the detection of a coding region allele of the multi-allelic genetic locus. (App. 293a, 59:57-67.)

In 1989, primer pair amplification was a newly emerging technology. The first patent for primer amplification to Dr. Kary Mullis did not issue until 1987, and that patent was not licensed for commercial use until 1989. (App. 269a, 12:55-56; Smithsonian Video History Collection, The History of PCR, http://siarchives.si.edu/research/video history_catalog9577.html (last visited Aug. 5, 2016) ("By 1988, Cetus was receiving numerous inquiries about licensing to perform PCR for commercial diagnostic purposes. On January 15, 1989, Cetus announced an agreement to collaborate with Hoffman-LaRoche on the development and commercialization of *in vitro* human diagnostic products and services based on PCR technology.")). As alleged in GTG's amended complaints against Respondents, before the priority date of the '179 patent in 1989, no one had used primer pair amplification to define a non-coding DNA sequence in linkage disequilibrium with a multi-allelic genetic locus. Critically, no one had analyzed an amplified non-coding DNA sequence in order to detect an allele in a coding DNA region. (App. 103a-104a; App. 107a-108a; App. 138a-139a; App. 142a-143a.)

As also detailed in GTG's amended complaints, there were numerous other technologies available in 1989 and after that could be used to exploit Dr. Simons' discovery. Those technologies include protein sequencing, immunological methods, northern blotting, restriction fragment length polymorphism, and sequencing of cloned DNA. (App. 110a-112a; App. 145a-147a.) Any of these technologies could be utilized with a non-coding DNA sequence in linkage disequilibrium with a multi-allelic genetic locus to detect a coding region allele without infringing claim 1. (App. 110a-112a; App. 145a-147a.)

During prosecution of the application for the '179 patent, the examiner rejected the pending claims for lack of enablement, asserting that "the specification does not enable one of skill in the art at the time the invention was made to perform such amplification reactions where the size of the nucleic acid to be amplified can be of virtually any length." Office Action, Serial No. 07/949,652, pp. 7-8 (May 17, 1995). This enablement rejection, construed in GTG's favor, evidences that the examiner believed those skilled in the art would be unable to use amplification in the manner claimed. GTG overcame that rejection by convincing the examiner, through declaration testimony, that the claimed amplification step could be "readily practiced" by those of skill in the art, i.e., that skilled artisans could perform the claimed amplification step on non-coding DNA sequences, just as they were able to on coding DNA sequences, now that there was a reason to perform amplification of that "junk DNA." The examiner then allowed the application for the '179 patent to issue, stating the following reasons:

> The claimed invention is allowable over the combined teachings of Kan et al., and Mullis et al., the closest prior art. . . . Kan et al., also does not teach a correlation between polymorphisms in a non-coding region and an allele of interest such that the identification of the polymorphism would allow for the determination of the coding region alleles. *Further, while Mullis et al., clearly does teach amplification of a target nucleic acid sequence, they do not teach nor reasonably suggest that primers be used to amplify a non-coding region that is in linkage to an allelic sequence.*

Notice of Allowance, Serial No. 07/949,652, p. 2 (Feb. 26, 1996) ("Notice of Allowance") (emphasis added). Construed in GTG's favor, this prosecution history evidences that primer amplification of a non-coding DNA sequence in linkage with a multi-allelic genetic locus is alone an inventive concept.

The inventive contributions of the '179 patent were also tested in four reexamination proceedings before the United States Patent and Trademark Office. In 2008, the validity of claims 26-32 was confirmed in an *ex parte* reexamination initiated by an anonymous petitioner. In March 2013, claims 1-18 and 26-32 were confirmed in an *ex parte* reexamination initiated by Respondent Merial. (*See* App. 316a-317a.) Later that month, Merial initiated a third *ex parte* reexamination of the same claims. (App. 318a-319a.) The examiner in that

reexamination relevantly stated that the 16 cited prior art references:

> [I]ndividually or in combination neither teach nor suggest the method of detecting a coding region allele of a multi-allelic genetic locus by amplifying the non-coding region sequence, wherein the amplified DNA sequence of the non-coding region is characteristic of the coding region allele as recited in the present claims.

Notice of Intent to Issue *Ex Parte* Reexamination Certificate, Serial No. 90/012,801, p. 10 (Aug. 27, 2013) ("Intent to Issue Reexamination Certificate 3"). Construed in GTG's favor, this statement confirms that amplification of a non-coding DNA sequence to detect a coding region allele is an inventive concept.

Merial then initiated a fourth *ex parte* reexamination of claims 1-15, 17, 18, 26-29 and 32. Request for *Ex Parte* Reexamination, Serial No. 90/012,971 (Sept. 5, 2013); (*see also* App. 320a-321a). In the Notice of Intent to Issue Reexamination Certificate for these claims, the examiner relevantly stated:

> To summarize briefly, prior to inventor Simons' discovery, it was believed that most non-coding genomic DNA sequences served no purpose; hence the term "junk DNA." Therefore those skilled in the art did not expect that specific sequence polymorphisms in coding region genomic DNA would be

> correlated with (or linked to) specific sequence polymorphisms in adjacent (or even relatively distant) non-coding region DNA. *The evidence indicates that the claimed methods were not obvious, and therefore the rejection is withdrawn.*

Serial No. 90/012,971, p. 4 (Jan. 23, 2014) ("Intent to Issue Reexamination Certificate 4") (emphasis added). This statement is consistent with prior findings of novelty and non-obviousness of the '179 patent made by numerous other examiners over a significant time frame. When construed in GTG's favor, the statement further confirms that the process of claim 1 contains an inventive concept.

The '179 patent is groundbreaking because it allowed scientists to reliably and quickly detect a coding region allele without actually finding that allele within the coding DNA region. (*See, e.g.,* App. 264a, 2:41-42.) At least 49 foreign patents have issued corresponding to the '179 patent and related inventions. *Merial*, Doc. No. 59, Ex. D, ¶ 9. The '179 patent has been cited as relevant prior art in 153 U.S. patents and published applications. Google Patents, U.S. Patent No. 5,612,179, https://www.google.com/patents/US5612179?dq=5612179&hl=en&sa=X&ved=0ahUKEwiIo-nS66XOAhVj4oMKHTV8BwoQ6AEIHDAA (last visited Aug. 3, 2016). The scientific importance of the '179 patent is further reinforced by the more than 45 license agreements taken to the '179 patent and related U.S. and foreign patents. (App. 119a-120a; App. 151a-152a.)

Many of the licenses to the '179 patent were entered through arms-length negotiations. However, occasionally GTG was required to use litigation to enforce the '179 patent, including cases against Respondents and others in 2011. (App. 99a; App. 119a-120a; App. 134a; App. 151a-152a.) Before discovery had begun in those cases, GTG anticipated that the patent-eligibility of the '179 patent might be challenged. GTG thus amended its complaints to add over eight pages of detailed factual allegations supporting patent-eligibility of the '179 patent. Those detailed allegations were based upon information that had been developed by GTG before discovery, including details regarding Dr. Simons' discovery (App. 104a-107a; App. 139a-142a), the state of the art as of 1989 (App. 103a-104a; App. 109a-112a; App. 138a-139a; App. 144a-147a), the use of machines and man-made DNA as part of the claimed processes (App. 110a-112a; App. 145a-147a), and the numerous technologies available in 1989 and after for applying Dr. Simons' discovery for the same purpose as claim 1, but without infringing claim 1. (App. 110a-112a; App. 145a-147a.)

As anticipated, Respondents jointly moved in the Delaware District Court to dismiss GTG's respective amended complaints under Rule 12(b)(6), asserting that the '179 patent is patent-ineligible. (App. 26a.) Simultaneously, defendants in cases pending in California and North Carolina District Courts also filed essentially identical motions to dismiss. The California and North Carolina District Courts denied those

motions.[3] (App. 61a; App. 66a-84a; App. 86a; App. 91a-93a.) Despite the fact that these two other motions had already been denied, the Delaware District Court issued a single Memorandum Opinion and Order finding claim 1 directed to patent-ineligible subject matter and dismissing GTG's amended complaints with respect to claim 1. (App. 23a; App. 25a-60a.) GTG then stipulated that claims 1-25 and 33-36 would be found patent-ineligible under the reasoning of the Memorandum Opinion, and final judgment for Respondents was entered by the Delaware District Court. (App. 258a-259a; App. 260a-261a.) GTG then timely appealed to the Federal Circuit, which had exclusive jurisdiction over the appeal pursuant to 28 U.S.C. § 1295(a)(1).

A Federal Circuit panel considered Respondents' motion to dismiss on *de novo* review. The panel concluded that claim 1 is patent-ineligible under the "now well-established two-step test for patent eligibility under § 101" set forth in *Mayo* and *Alice*. Though there is a factual dispute over the proper definition of the patent-ineligible concept underlying claim 1, the panel adopted Respondents' definition of the patent-ineligible concept to include

---

[3] Judge Seeborg of the Northern District of California held that "[t]he 'amplifying' limitation plausibly provides sufficient inventive concept to transform the unpatentable natural law into a patentable application of that law." *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 933 (N.D. Cal. 2014). Judge Eagles of the Middle District of North Carolina came to the same conclusion, noting further that *Alice* did not apply because that case involved only a computer implemented abstract idea and dismissal under Rule 56, not Rule 12(b)(6). *Genetic Techs. Ltd. v. Glaxosmithkline, LLC*, No. 1:12-CV-299, 2014 U.S. Dist. LEXIS 156473, at *2-3 (M.D.N.C. Aug 22, 2014).

both: (1) "the relationship between non-coding and coding sequences in linkage disequilibrium"—a naturally occurring phenomenon; and (2) "the tendency of such non-coding sequences to be representative of the linked coding sequences"—Dr. Simons' application for the natural occurring phenomenon to achieve his new and useful purpose. (App. 9a.) The panel did not explain how it arrived at this two-part definition, or identify the evidence in the Rule 12(b)(6) record supporting the definition. The panel next applied the overly-expansive definition of the patent-ineligible concept, thus inevitably finding claim 1 directed to a "law of nature."[4] (App. 9a.)

The panel justified its conclusion that claim 1 is directed to a patent-ineligible concept by comparing claim 1 to the claims held patent-ineligible in *Mayo* and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) ("*Ariosa*"), *en banc petition denied*, 809 F.3d 1282 (Fed. Cir. Dec. 2, 2015), *cert. denied*, No. 15-1182, 2016 U.S. LEXIS 4087 (June 27, 2016). The panel also appears to have justified its conclusion based on its belief that the claim 1 process is preemptive, citing the wide applicability of claim 1 to any eukaryotic organism and any coding region allele. (App. 10a.) However, the panel never explained why the wide applicability of the claimed process is preemptive of the patent-ineligible concept. Nor did

---

[4] To be precise, linkage disequilibrium between non-coding and coding DNA regions, where it exists, occurs naturally in DNA without any human intervention and is therefore properly characterized as a natural phenomenon—not a law of nature (such as represented by $E=mc^2$) as improperly classified by the panel.

the panel address the detailed allegations of GTG's amended complaints describing the numerous other technologies available in 1989 and after to exploit Dr. Simons' discovery in a non-infringing manner.

The panel then found under step two of the *Mayo/Alice* framework that "the additional elements of claim 1 are insufficient to provide the inventive concept necessary to render the claim patent-eligible." (App. 15a.) The panel reached this conclusion because: (1) the '179 patent recognizes that each of the claimed techniques were in the prior art (App. 15a-16a); (2) "GTG granted during prosecution of the '179 patent that it did not invent any new physical techniques" (App. 16a); and (3) GTG stated in response to the examiner's enablement rejection that "amplification . . . [was a] technique . . . readily practiced by those in skill at the time the application was filed." (App. 16a.) The panel did not explain how it reached this conclusion in view of the contradictory Rule 12(b)(6) record, including GTG's well-pled allegations (*see* App. 100a-114a; App. 136a-149a), and the examiner statements set forth in the original application and reexamination file histories. *Supra* Notice of Allowance, p. 5; Intent to Issue Reexamination Certificate 3, p. 6; Intent to Issue Reexamination Certificate 4, pp. 6-7. The panel's conclusion under the second step of the *Mayo/Alice* framework is also inconsistent with its recognition "that at the time the '179 patent was filed, no one was 'using the non-coding sequence as a surrogate marker for the coding region allele.' Claim 1 was found by the patent examiner to be novel over the prior art and survived multiple rounds of reexamination." (App. 21a.)

The panel ignored GTG's argument that claim 1 is patent-eligible by statutory definition because it recites two new uses for the processes of DNA amplification and DNA analysis, and three new uses for compositions of matter or materials, i.e., primers, genomic non-coding DNA, and man-made amplified non-coding DNA. (App. 179a.) The panel also ignored GTG's argument that claim 1 is patent-eligible because it satisfies both the machine and transformation tests. (App. 186a-187a.)

GTG did not seek *en banc* review of the panel's decision at that time because the Federal Circuit indicated by its order denying *en banc* review that any clarification of the *Mayo/Alice* framework would have to come from this Court. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015). However, the Federal Circuit has very recently signaled a willingness to further clarify that framework. *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, No. 2015-1570, 2016 U.S. App. LEXIS 12352 (Fed. Cir. July 5, 2016); *BASCOM Global Internet Servs. v. AT&T Mobility LLC,* No. 2015-1763, 2016 U.S. App. LEXIS 11687 (Fed. Cir. June 27, 2016); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016).

REASONS FOR GRANTING THE WRIT

I. The Decision Creates An Intra-Circuit Split Over How To Properly Define A Patent-Ineligible Concept

The panel adopted a clearly erroneous definition of the patent-ineligible concept that underlies claim 1. In doing so, the panel disregarded both Rule 12(b)(6) axioms and fundamental science.

Had a proper definition of the patent-ineligible concept been used, the panel would have reversed the Delaware District Court's judgment—exactly as recently occurred in *CellzDirect*, 2016 U.S. App. LEXIS 12352.

It is undisputed that any linkage disequilibrium existing between non-coding and coding DNA regions is a naturally occurring phenomenon and is patent-ineligible by itself. However, the parties dispute whether "correlating" a non-coding DNA sequence in linkage disequilibrium with a multi-allelic genetic locus for detection of a coding region allele is also a patent-ineligible concept. (*Compare* App. 215a-219a *with* App. 244a-245a.) The Rule 12(b)(6) record plausibly supports GTG's position that this application for the naturally occurring phenomenon is not part of the proper definition, requiring dismissal of Respondents' motion to dismiss. Yet, ignoring Rule 12(b)(6) axioms, the panel adopted Respondents' definition of the natural phenomenon to include "the tendency of such non-coding DNA sequences to be representative of the linked coding sequences." (App. 9a.)

This so-called "tendency" is not properly part of the patent-ineligible concept that underlies claim 1 because it is not naturally occurring and it is not a building block of human ingenuity. Rather, it is Dr. Simons' application for the naturally occurring phenomenon to achieve a new and useful purpose—an act of human ingenuity.[5] The application for the

---

[5] By analogy, if one knows that Chief Justice Roberts and Justice Sotomayor always go to together for dinner on Thursdays, and one were to observe Chief Justice Roberts alone in a restaurant having dinner on a Thursday, the observer

naturally occurring phenomenon in claim 1 is analogous to the application of the Arrhenius equation in *Diamond v. Diehr*, 450 U.S. 175 (1981), where the claimed process relied upon the existence of a natural law (reflected by the Arrhenius equation) for the proper calculation of rubber cure time. So too with claim 1, where the process for detecting a coding region allele of interest relies upon the existence of a naturally occurring relationship between non-coding and coding DNA sequences to achieve the benefit of the claimed process.

The panel's overly-expansive definition of the patent-ineligible concept infected its application of the *Mayo/Alice* framework, leading the panel to conclude that claim 1 is patent-ineligible. By including Dr. Simons' specific application for the natural phenomenon recited by claim 1 within the definition of the underlying patent-ineligible concept, the panel's only option was to conclude that claim 1 is directed to that definition of the patent-ineligible concept. Judge Prost tacitly acknowledged in her *CellzDirect* decision that it was this overly-expansive definition of the patent-ineligible concept that led the panel to conclude that claim 1 is patent-ineligible. *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *11 ("Because the relationship between coding and non-coding sequences was a law of nature, [claim 1] amounted to nothing other than identifying

---

could deduce that Justice Sotomayor may also be found in the restaurant. That the Justices always go out together for dinner on Thursdays occurs without intervention by the observer. But the observer's use of Chief Justice Roberts to find Justice Sotomayor is an act of human ingenuity in applying that occurrence.

'information about a patient's natural genetic makeup.'").

Had the patent-ineligible concept been correctly defined as a matter of science, and properly construed in GTG's favor as required under Rule 12(b)(6), the panel would have concluded under the first step of the *Mayo/Alice* framework that claim 1 is not directed to linkage disequilibrium between non-coding and coding DNA regions. Rather, the panel would have concluded that claim 1 recites a process to detect a coding region allele of a multi-allelic genetic locus by merely taking advantage of the fact that a non-coding DNA sequence can be in linkage disequilibrium with that genetic locus. *See id.* at *12. It would have also recognized that claim 1 plausibly sets forth an inventive concept in its use of known techniques in new, useful, and non-obvious ways that were informed by Dr. Simons' discovery. Similarly, the panel would have found that performing a process using material that the prior art taught was "junk" and should not be used at all "can hardly be considered routine or conventional." *Id.* at *20.

The panel's decision aptly demonstrates that proper application of the *Mayo/Alice* framework is compromised if a patent-ineligible concept is defined to also include any human ingenuity in applying a natural phenomenon. The Federal Circuit panel in *CellzDirect* recognized this and reversed the lower court decision for failure to recognize the difference between a natural phenomenon and how it was applied. *Id.* at *12-13, 16. These decisions together evidence an intra-circuit split over how to properly define a patent-ineligible concept under the

Mayo/Alice framework that requires resolution by the Court.

II. The Decision Creates An Intra-Circuit Split Over Proper Application Of The *Mayo/Alice* Framework

When this decision is compared to the *CellzDirect* decision, it demonstrates that the panel here clearly misapprehended how to properly apply the *Mayo/Alice* framework. Indeed, the conclusion that claim 1 is patent-ineligible here is irreconcilable with the conclusion of patent-eligibility in *CellzDirect*. Thus, at a minimum, these decisions together evidence an intra-circuit split over how to properly apply the *Mayo/Alice* framework that requires resolution by the Court.

A. The Panel's Misapplication of the First Step of *Mayo/Alice* Framework

Claim 1 of the '179 patent is indistinguishably analogous to the representative claim found patent-eligible by the Federal Circuit in *CellzDirect*.[6] There, the discovery was that "some fraction of hepatocytes are capable of surviving multiple freeze-thaw cycles."

---

[6] The *CellzDirect* process is essentially three steps: (1) thawing the cells; (2) separating the surviving cells (fractionate); and then (3) freezing the cells a second time. *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *4. By analogy, the claim 1 process: (1) amplifies a non-coding DNA sequence; (2) analyzes that amplified non-coding DNA sequence; and (3) detection of a coding region allele of a multi-allelic genetic locus as a result of that analysis. Both claimed inventions are predicated upon a new discovery, and implement the use of the discovery to effect an improvement over prior art methods. And both cases use known steps to engage in unconventional activity. *Cf. Mayo*, 132 S. Ct. at 1298.

Id. at *4. In evaluating whether the representative claim was directed to this discovery, the panel distinguished between the discovery, and the human ingenuity in applying the "natural ability of the subject matter to *undergo* the process" to achieve the "desired outcome" of the claimed process. *CellzDirect,* 2016 U.S. App. LEXIS 12352, at *12-13 (emphasis in original). The panel thus found that re-freezing the fraction of hepatocytes that had survived a first freezing cycle, using well-known techniques, was an inventive concept even though this inventive concept was informed by the discovery. *Id.* at *22. In applying step one of the *Mayo/Alice* framework, the *CellzDirect* panel focused on the character of the representative claim as a whole, and recognized that the claim "requires an artisan to carry out a number of *concrete steps* to achieve the desired preparation." *Id.* at *9 (emphasis added).

In contrast, the panel here failed to even acknowledge the concrete steps required by claim 1 to achieve the desired result of detecting a coding region allele. For example, the panel simply ignored GTG's argument that claim 1 is patent-eligible because it satisfies both the machine and transformation tests due to the required use of primers (machines), required creation of man-made amplified non-coding DNA (a chemically distinct molecule that lacks the methylation of genomic DNA), and required performance of the analysis step upon that man-made non-coding DNA. (App. 166a.) The panel instead focused on the definition of the

patent-ineligible concept[7] and, as discussed *supra*, misdefined that concept to include both the naturally occurring phenomenon and Dr. Simons' ingenuity in applying that natural phenomenon to achieve his new and useful purpose. Stated another way, the panel here found that claim 1 is directed to a patent-ineligible concept because it mischaracterized claim 1 as the ability to use non-coding DNA sequences as surrogates for linked coding region sequences. However, "[t]hat one way of describing the process is to describe the natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability." *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *12 (emphasis in original).

The *CellzDirect* panel also confirmed its analysis under step one of the *Mayo/Alice* framework by acknowledging that the accused infringers had "managed to engineer around the patent." *Id.* at *21-22. The *CellzDirect* panel found this evidenced that the "patent is not 'directed to' a patent-ineligible building block of human ingenuity." *Id.* at *22. The panel here, in contrast, ignored the detailed allegations of GTG's amended complaints describing numerous technologies that were available in 1989 and after to use Dr. Simons' discovery for the same purpose as claim 1 but without infringing claim 1. It is impossible to reconcile these plausible and specific allegations, taken as true and construed in GTG's favor, with the

---

[7] This approach also conflicts with the caution in *CellzDirect* that "it is not enough to merely identify a patent-ineligible concept" under step one of the *Mayo/Alice* framework. *CellzDirect*, 2016 U.S. App. 12352 LEXIS, at *16.

panel's conclusion that claim 1 is directed to a patent-ineligible concept.

B. The Panel's Misapplication of the Second Step of *Mayo/Alice* Framework

The panel clearly misapprehended how to apply step two of the *Mayo/Alice* framework when compared to the proper approach utilized in *CellzDirect*. There, the panel recognized that the prevailing wisdom at the relevant time was that hepatocytes could only be frozen once, then either had to be used or discarded. *Id.* at *3. The inventors discovered that "some fraction of hepatocytes are capable of surviving multiple freeze-thaw cycles." *Id.* at *4. That discovery enabled the inventors to develop an advantageous process for preserving hepatocytes. *Id.* The panel thus concluded that, as a result of these advantages, the representative claim was patent-eligible "because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process." *Id.* at *17-18.

In contrast to *CellzDirect*, and in violation of Rule 12(b)(6) axioms, the panel here failed to acknowledge the advantages of Dr. Simons' invention over prior art processes as alleged in GTG's amended complaints and the '179 patent. (App. 100a-114a; App. 149a-153a.) Before Dr. Simons' discovery, the prevailing wisdom was that non-coding DNA was useless "junk." (App. 104a; App. 139a.) Dr. Simons discovered that, in the DNA of unrelated individuals, a non-coding polymorphism and a coding region allele could be inherited together. That discovery enabled Dr. Simons to develop an improved process for detecting a coding

region allele of a multi-allelic genetic locus. Dr. Simons' invention was advantageous because it was more reliable and quicker than prior art processes. *Supra* Notice of Allowance, p. 5; Intent to Issue Reexamination Certificate 3, p. 6; Intent to Issue Reexamination Certificate 4, pp. 6-7.

The *CellzDirect* panel then examined the individual steps of the representative claim and, while acknowledging that each step was well-known, it concluded that the steps were not routine and conventional when viewed "*as a whole*, considering their elements both individually and as an ordered combination." *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *19 (emphasis added, internal quotations omitted); *BASCOM*, 2016 U.S. App. LEXIS 11687, at *20-21. In support of this conclusion, the panel relied on examiner statements from the application and reexamination of the subject patent acknowledging the novelty of the claimed invention. *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *19-20.

The panel here in contrast never examined the steps of claim 1 as a whole. Instead, the panel considered the physical steps of claim 1 individually and out of the context in which they are employed in claim 1 to inventively apply Dr. Simons' discovery.[8]

---

[8] The panel said that "[c]laims directed to laws of nature are ineligible for patent protection when, '(*apart from the natural laws themselves*) they involve well-understood, routine, conventional activity previously engaged in by researchers in the field.'" (App. 14a (quoting *Mayo*, 132 S. Ct. at 1294 (emphasis added))). The panel apparently misunderstood this quoted language from *Mayo* to require evaluation of the techniques of claim 1 apart from the context in which those techniques are used in the claim. The panel's approach squarely conflicts with the Court's instruction that the claims

Ignoring Rule 12(b)(6) axioms, the panel only considered evidence that these individual techniques *in the abstract* were known in the prior art. The panel did not explain how these disjointed findings could satisfy the clear and convincing evidentiary standard of 35 U.S.C. § 282, especially in view of the significant contradictory evidence in the Rule 12(b)(6) record.[9] (App. 100a-114a; App. 135a-149a.)

If process steps are considered individually and in the abstract, as here, those steps will inevitably appear to be routine and conventional. *See Diehr*, 450 U.S. at 188 ("A new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").[10] Cognizant of this problem, and perhaps the panel's error here, another Federal Circuit panel

---

are considered as a whole. *Alice*, 134 S. Ct. at 2355. ("Because the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims must be considered as a whole.").

[9] In the panel's view, it is apparently not enough that Dr. Simons had conceived of a specific process to carry out his new and useful purpose using one of many available technologies. Instead, the decision here stands for the proposition that, for life sciences inventions, the *Mayo/Alice* framework requires a separately patentable invention apart from applying known techniques in a new and useful way to achieve a desired purpose. (App. 14a.) This has never been the law.

[10] This approach also conflicts with the statutory definition of "process" in 35 U.S.C. § 100. Under the panel's approach, any known technique, in the abstract, would be considered routine and conventional even if the manner in which the technique is used is new and the compositions of matter or materials to which those techniques are applied is new or newly discovered.

recently recognized that the inventive concept analysis requires "more than recognizing that each claim element, by itself, was known in the art. . . . [A]n inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces." *BASCOM*, 2016 U.S. App. LEXIS 11687, at *6. That proper analysis was not applied here.

The panel here also rejected GTG's argument that the application of the natural phenomenon by claim 1—analyzing a man-made non-coding DNA sequence in order to detect a coding region allele—conferred an inventive concept to claim 1. In doing so, the panel again considered the process only in dissected parts. The panel then dismissed those individual parts as mental steps that are separately insufficient to confer patent-eligibility to claim 1.[11] Incredibly, the panel reasoned that "to apply a law of nature for a purpose" could not confer an inventive concept to a claim. (App. 19a.) By this reasoning, the panel completely overlooked how it took Dr. Simons' ingenuity to utilize the emerging technology of DNA amplification to take advantage of his discovery and, in the process, invented an entirely new and useful DNA analysis method that is reflected by the concrete steps of claim 1. *Mayo*, 132 S. Ct. at 1298-99 (The Court pointed out "that the basic mathematical

---

[11] As legal support for this conclusion, the panel cited decisions holding that processes that can be performed *entirely* in the human mind are patent-ineligible. (App. 18a.) But claim 1 cannot be performed in the human mind because it requires the use of machines (primers), transformation of genomic DNA into man-made amplified DNA, and analysis of that man-made amplified DNA, which cannot be performed without significant tools to examine the DNA.

equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. . . . These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula."); *CellzDirect*, 2016 U.S. App. LEXIS 12352, at *20 ("Repeating a step that the art taught should be performed only once can hardly be considered routine or conventional. This is true even though it was the inventor's discovery of something natural that led them to do so. Just as in *Diehr*, it is the particular 'combination of steps' that is patentable here.").

Finally, the panel erroneously justified its conclusions by characterizing claim 1 as similar to the patent-ineligible claims in *Mayo* and *Ariosa*. Claim 1 is nothing like those claims.

The claim in *Mayo* merely required administration of thiopurine to a patient and determination of the metabolite levels for the drug in a patient's blood. These two steps were inherently necessary to cause metabolization of the drug and measurement of those metabolite levels. As recognized by the Court, the claim did not require doctors to do anything beyond these two steps. *Mayo*, 132 S. Ct. at 1298. Therefore, the claim did not recite a useful purpose for the discovery of the range of metabolite levels correlated to the safe and effective dosage of thiopurine.

In *Ariosa*, the inventors discovered a new source for cffDNA (a previously known material) in maternal blood or serum. The representative claims did not apply this discovery for a new and useful purpose. The claims merely directed scientists to obtain cffDNA from that discovered source using amplification techniques in a way that had become well-known by 1997.[12] Had the inventors instead claimed a useful purpose for their discovery, such as a pregnancy test that utilized the cffDNA status of a patient's blood or serum, that application would have been a patent-eligible invention.[13]

Unlike *Mayo* and *Ariosa*, claim 1 recites a new and useful purpose for Dr. Simons' discovery. Claim 1 recites a process that applies the natural phenomenon—linkage disequilibrium—by directing a scientist to amplify a non-coding DNA sequence, analyze that amplified non-coding DNA sequence in a particular way, and to then detect a coding region allele of a multi-allelic locus as a result of that

---

[12] The use of amplification in claim 1 is also qualitatively different than the use of amplification in *Ariosa* because the 1989 priority date of the '179 patent is much earlier in time than the 1997 filing date in *Ariosa*. It was also undisputed in *Ariosa* that, by the time of the invention, the use of amplification in the claimed manner was well-known. *Ariosa*, 788 F.3d at 1377-78. That fact is disputed in this case.

[13] This case is also different from *Mayo* and *Ariosa* in another important aspect—the standard of review. In *Mayo* and *Ariosa*, patent-eligibility was considered under Rule 56. The courts had the benefit of a fully developed record and the patentees had a fair opportunity to develop and present any and all available evidence supporting eligibility of the claims. GTG has been unfairly denied that opportunity in this case, although (as explained herein) there is significant additional evidence available that supports patent-eligibility of claim 1.

analysis. Claim 1 does not claim linkage disequilibrium, does not instruct scientists to perform steps that are inherently necessary to realize linkage disequilibrium, and does not merely require the scientist to obtain patent-ineligible material. Claim 1 reflects a genuine act of invention that applies Dr. Simons' discovery to a new and useful purpose.

C. The Decision Warrants Review to Clarify Proper Application of the *Mayo/Alice* Framework

The decision here, when compared to the *CellzDirect* decision, highlights three important issues affecting application of the *Mayo/Alice* framework that require clarification. The Court should grant this petition to address these issues.[14]

First, the Court should clarify that the proper definition of a patent-ineligible concept cannot include any aspect of human ingenuity in applying a natural phenomenon. By including human ingenuity in the definition of the patent-ineligible concept here, the panel fatally compromised the proper application of the *Mayo/Alice* framework.

Second, the Court should clarify that a patent claim that does not "inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity" does not implicate the judicial exclusions to § 101—such a claim is not directed to a patent-ineligible concept. When the

---

[14] Alternatively, the Court should grant this petition and vacate and remand this case for further consideration in view of the *CellzDirect* decision.

well-pled allegations describing the numerous other technologies available to use Dr. Simons' discovery for the same purpose as claim 1 but without infringing claim 1 are considered, as it must, claim 1 cannot be considered directed to Dr. Simons' discovery.

Third, the Court should clarify that, when determining whether a process claim contains an inventive concept under the second step of the *Mayo/Alice* framework, courts must consider the steps of the process as a whole and in the context that those steps are used to apply a patent-ineligible concept to achieve a new and useful end. If claim steps are evaluated individually and in the abstract, as the panel did here, those steps will inevitably appear routine and conventional.

III. The Panel's Decision Authorizes A Patent-Specific Exception To The Inviolate Safeguards Of Rule 12(b)(6)

There are at least four fundamental factual disputes in this case that must be resolved to apply the *Mayo/Alice* framework: (1) the proper definition of the patent-ineligible concept; (2) the proper interpretation of claim 1; (3) whether claim 1 improperly preempts the patent-ineligible concept; and (4) whether the steps of claim 1 were routine and conventional. Yet, instead of denying Respondents' motion to dismiss in view of these factual disputes, the panel adopted Respondents' versions of the facts to the exclusion of the well-pled allegations of GTG's amended complaints and other evidence in the Rule 12(b)(6) record.

A. Examples of the Panel's Rule 12(b)(6) Errors

The panel construed the patent-ineligible concept against GTG. Rather than limit that definition to the undisputed fact that the existence of linkage disequilibrium between non-coding and coding DNA is a naturally occurring phenomenon, the panel also adopted Respondents' disputed definition to include "the tendency of such non-coding sequences to be representative of the linked coding sequences." (App. 9a.) As explained above, whether this "tendency" was properly part of the definition was a disputed issue that required the panel to deny Respondents' motion to dismiss.

The panel also inherently engaged in claim construction by its characterizations of the limitations of claim 1, such as the meaning of "analyzing" that was not construed in GTG's favor. (App. 16a.) The Court has previously held that claim construction is imbued with factual findings. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 843 (2015) (A determination about "how a skilled artisan would understand" an undefined term is a "factual finding."); *see also, KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) (treating level of ordinary skill in the art as factual issue); *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (skilled artisan's knowledge is "basic factual inquiry"). The necessity for claim construction required denial of Respondents' motion to dismiss. *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1348 (Fed. Cir. 2013) (The defendant bears the burden to "establish that the only plausible construction was one that, by clear and convincing evidence rendered the subject matter

ineligible (with no factual inquiries). . . ."), *vacated on other grounds by Wild Tangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014).

The panel also cited the wide applicability of the claimed process as support for its apparent conclusion that claim 1 is preemptive. However, wide applicability of a claimed process has never been held to be synonymous with preemption, and GTG's amended complaints plausibly and specifically describe numerous other technologies available in 1989 and after for practicing the application of claim 1 without infringing claim 1. (App. 110a-112a; App. 145a-147a.) At best, this evidence together presents a factual dispute that required the panel to deny Respondents' motion to dismiss.

The panel construed the only two facts it cited in support of its conclusion that the steps of claim 1 are routine and conventional against GTG. Contrary to the panel's conclusion, the fact that "the '179 patent repeatedly characterizes primer pair amplification as prior art" (App. 15a) evidences merely that the technique of primer pair amplification was known in 1989. When properly construed in GTG's favor, this fact does not evidence that amplification of a non-coding DNA sequence was routine and conventional in 1989. Similarly, construed in GTG's favor, the fact that GTG overcame an enablement rejection[15] by arguing that the claimed amplification step was "readily practiced by those in skill at the time the application was

[15] The fact that the examiner—a skilled artisan by definition—questioned whether amplification of a non-coding DNA sequence was enabled demonstrates that the step was *not* well-understood, routine, and conventional in 1989.

filed" evidences merely that it would not be difficult for one skilled in the art to practice the claimed use of amplification on a non-coding DNA sequence once there is a reason to perform such an act.[16] However, the panel construed "readily practiced" against GTG to be an admission that the claimed use of amplification was well-known, despite the fact that a technique can be easily performed but not well-known. *See CellzDirect*, 2016 U.S. App. LEXIS 12352, at *4. When these two facts are properly construed together in GTG's favor, they do not support the panel's conclusion that the steps of claim 1 were routine and conventional in 1989. And in view of other Rule 12(b)(6) evidence, these two facts do not constitute clear and convincing evidence that the steps of claim 1 were routine and conventional in 1989. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

There is also other evidence supporting patent-eligibility of claim 1 that GTG could have developed had Respondents' motion to dismiss been properly denied. For example, in response to the motion to dismiss at the Delaware District Court, GTG submitted a declaration from Dr. John Sutherland, a world-renowned scientist who discovered a method to synthesize RNA building blocks under potentially prebiotic conditions. *Merial*, Doc. No. 45, ¶ 6. In 1989, Dr. Sutherland was a junior research fellow at University of Oxford. *Id.* at ¶ 4. In his declaration, Dr. Sutherland explained why the claims of the '179 patent were not directed to the discovery, but instead recited a

---

[16] With deference to the ordinary meaning of "readily" as "in a ready manner without hesitation or without much difficulty."

combination of limitations that were neither routine nor conventional. *Id.* at ¶ 27. Dr. Sutherland also explained in his declaration how the claims of the '179 patent do not preempt or monopolize Dr. Simons' discovery. *Id.* at ¶¶ 28-29. However, the Delaware District Court did not consider this declaration due to the procedural posture of the case. In another example, during oral argument GTG highlighted for the panel that the first patent for PCR amplification was not granted until 1987, that another patent application for the PCR amplification was still pending in 1989, and that these patents were not licensed for commercial use until 1989. (App. 256a.) This evidence supports the conclusion that amplification was merely an emerging technology in 1989, and conflicts with the panel's conclusion that the claimed use of amplification was routine and conventional by 1989. Had GTG been afforded the protections of Rule 12(b)(6), GTG would have had the opportunity to further develop and rely upon the foregoing and other evidence before the Delaware District Court.

B. The Implications of This Decision Warrant Review

The irregularities in the panel's decision evidence an exception to Rule 12(b)(6)—a failing that only tends to "move patent cases [further] from the mainstream of . . . procedural law." *Ohio Cellular Prods. Corp. v. Adams USA, Inc.*, 175 F.3d 1343, 1355 (Fed. Cir. 1999) (Newman, J. dissenting) (*rev'd sub nom Nelson v. Adams USA, Inc.*, 529 U.S. 460 (2000)). To be sure, a pattern has now emerged where, as here, the Federal Circuit: (1) declares that it has "repeatedly recognized that in many cases it

is . . . proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion" (App. 7a); (2) makes no further reference to or application of Rule 12(b)(6) or 35 U.S.C. § 282 standards; and (3) treats patent-eligibility as a pure question of law, even where there are numerous underlying factual disputes that must be resolved. The panel's approach here conflicts with other Federal Circuit decisions, *see, e.g., BASCOM*, 2016 U.S. App. LEXIS 11687, at *28 (remanding case because the Rule 12(b)(6) record supported the conclusion that the ordered combination provided an inventive concept to the claims); *Ultramercial*, 722 F.3d at 1399 ("Analysis under § 101, while ultimately a legal determination, is rife with underlying factual issues."); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1055-56 (Fed. Cir. 1992) (The determination of patent-eligibility requires "findings of underlying facts specific to the particular subject matter and its mode of claiming."), demonstrating an intra-circuit split that the Court must resolve.

The panel's decision, if allowed to stand, would sanction lower courts to continue deciding the patent-eligibility of life sciences inventions without a full understanding of underlying science, without all relevant facts (such as the scope of preemption), and without a full and proper understanding of claim meaning and scope.[17] No other statutory defense to patent infringement is permitted to be summarily decided in this manner. Indeed, GTG

[17] This case is the first involving a life sciences invention that has been declared patent-ineligible by the Federal Circuit at the Rule 12(b)(6) stage. This decision extends the Federal Circuit's Rule 12(b)(6) exception from cases involving historical facts to, as here, scientific facts and revolutionary inventions.

has been unable to locate a single decision from this Court or the Federal Circuit that affirms a Rule 12(b)(6) dismissal for a defense based upon 35 U.S.C. §§ 102, 103, or 112. This is not surprising given the factually intensive nature of these other defenses,[18] as it is with § 101. There is no legal or logical justification for an exception under § 101 that allows patents, particularly for life sciences inventions, to be eviscerated at the nascent point of litigation proceedings—with little to no factual development and while ignoring the Rule 12(b)(6) record and the presumption of patent validity afforded by 35 U.S.C. § 282. *Cf. Teva*, 135 S. Ct. at 837 (holding that "[o]ur opinion in *Markman* neither created, nor argued for, an exception to Rule 52(a)."). Supervision by this Court is required because without vacatur and remand, the panel's decision will continue to control all federal districts courts.

The Court's decision in *Tolan v. Cotton*, 134 S. Ct. 1861 (2014) reinforces the need for review in this case. There, the Court vacated and remanded a Fifth Circuit decision because the appellate court failed to adhere to the Rule 56 standard that "the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in . . . favor [of the non-moving party]." *Tolan*, 134 S. Ct. at 1863 (internal

---

[18] *See Microsoft Corp.*, 131 S. Ct. at 2242 ("In evaluating whether [§§ 101, 102 and 103] and other statutory conditions have been met, PTO examiners must make various factual determinations—for instance, the state of the prior art in the field and the nature of the advancement embodied in the invention."); *see also Dennison Mgmt. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1996) (obviousness); *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1299 (Fed. Cir. 2010) (indefiniteness); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (enablement).

quotation omitted). The Court found that the Fifth Circuit impermissibly weighed evidence and failed to credit competing evidence in the record supportive of the plaintiff's position. *See id.* at 1867-68. The evidence of record contradicted four facts that were dispositive to the Fifth Circuit's determination, and those contradictions led "to the inescapable conclusion that . . . the opinion below reflect[ed] a clear misapprehension of summary judgment standards." *Id.* As in *Tolan*, the panel's errors here are so egregious that they warrant remand. *See also Dennison*, 475 U.S. at 811 (vacating where Federal Circuit reversed an obviousness ruling without applying Rule 52(a)).

For the above reasons alone, the Court should grant this petition and vacate and remand this case to the Federal Circuit with instructions to faithfully apply the inviolate safeguards of Rule 12(b)(6). *Cf. id.* (Rule 52(a)) *and Tolan,* 134 S. Ct. 1861 (Rule 56(a)).

IV. This Petition Should Also Be Granted For All The Concerns Articulated By Amici In *Ariosa*

Additional reasons for granting this petition are articulated in the numerous amici briefs submitted in support of the petition of Sequenom, Inc. in *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, No. 15-1182 (Petition for Writ of Certiorari) (2016) (cert. denied). Those concerns remain valid and unaddressed. This case presents an ideal vehicle for the Court to address those concerns.

CONCLUSION

For the reasons set forth above, GTG respectfully submits that the Court should grant certiorari in this case.

Respectfully submitted,

Robert R. Brunelli
rbrunelli@sheridanross.com
Counsel of Record
Benjamin B. Lieb
blieb@sheridanross.com
Hiwot M. Covell
hcovell@sheridanross.com
SHERIDAN ROSS P.C.
1560 Broadway, Suite 1200
Denver, CO 80202-5141
(303) 863-9700

Counsel for Petitioner