

No. 18-1763

United States Court of Appeals
for the
Federal Circuit

AMERICAN AXLE & MANUFACTURING, INC.,

Plaintiff-Appellant,

v.

NEAPCO HOLDINGS LLC AND NEAPCO DRIVELINES LLC,

Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE IN CASE NO: 1:15-CV-01168-LPS
LEONARD P. STARK, UNITED STATES DISTRICT JUDGE

**BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION
ORGANIZATION IN SUPPORT OF APPELLANT'S COMBINED
PETITION FOR REHEARING OR REHEARING EN BANC**

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December 12, 2019

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for *Amicus Curiae*

Biotechnology Innovation Organization certifies the following:

1. The full name of every party or *amicus* represented by me is:

Biotechnology Innovation Organization.

2. The name of the real party in interest represented by me is:

Same as above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus* represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

None.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal:

None.

Dated: December 12, 2019

/s/ Aaron F. Barkoff

Aaron F. Barkoff

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INTEREST OF *AMICUS CURIAE*

Biotechnology Innovation Organization (“BIO”) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range in size from start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO’s corporate members are small or midsize businesses that have annual revenues of under \$25 million.

BIO’s members are concerned that, more than seven years after the Supreme Court decided *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), there continues to be unabated uncertainty about the patent eligibility of inventions across an expanding range of technologies, including biotechnology.

The unstable state of patent-eligibility jurisprudence affects modern biotechnologies ranging from biomarker-assisted methods of drug treatment to companion diagnostic tests, fermentation products, industrial enzyme technology, and marker-assisted methods of plant breeding. As developers of, and investors in, such advanced technologies, BIO members have a strong interest in clear and predictable rules of patent-eligibility and their delineation to other requirements of patentability such as 35 U.S.C. § 112.

BIO members work in a field with well-developed law under Section 112, and they expend great effort during patent prosecution to meet the rigorous written description and enablement requirements of the statute. Accordingly, BIO members are concerned about the apparent ease with which a written description or enablement analysis can be circumvented under the guise of a Section 101 analysis, as happened in this case. Indeed, it seems that contrary to the concern expressed by the Supreme Court in *Mayo* that Section 101 would be subsumed by the other statutory requirements for patentability, it is now Section 101 that has engulfed the other statutory sections.

BIO submits this brief in the hope that it will assist the court in the orderly development of the law in this important area. BIO has no direct stake in the result of this appeal and takes no position on the ultimate validity of the patent at issue. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO certifies that no counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the *amicus curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

ARGUMENT

I. The district court and panel decisions incorrectly characterize the claimed subject matter as “directed to” a law of nature

The analytical framework used to assess the subject-matter eligibility of a claimed invention, or in more recent years to rationalize the lack of subject-matter eligibility, developed from the Supreme Court’s decisions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) and *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014). The two-part test first requires a determination of whether the claimed subject matter is “directed to” a judicially-created exclusion such as a law of nature, a natural phenomenon, or an abstract idea. Only after determining that the claim is directed to an underlying judicial exception is the second part of the two-part test used, to determine if the claims integrate the exception in a way that provides for a practical application. *Alice Corp.*, 134 S. Ct. at 2357.

Prior to describing the framework of the two-part eligibility analysis in its *Alice* opinion, the Supreme Court emphasized a previously articulated cautionary statement regarding the consequences that could result from the over-application of the exclusionary nature of judicial exceptions in determining patent-eligible subject matter:

[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law At some level, “all inventions . . .

embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”

Alice Corp., 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293).

This case embodies these very concerns. It serves to illustrate that the first step of the two-part test has become extremely diffuse and malleable in that it searches for a “focus of the claimed advance.” This makes available an almost limitless choice of articulations of what the claim is directed to, at any desired level of abstraction, around which an eligibility analysis under Section 101 can be tailored to render ineligible almost any invention.

Contrary to the district court’s holding, a proper application of the current patent eligibility analysis under 35 U.S.C. § 101 leads to a conclusion that the claims are not “directed to” Hooke’s law; rather they merely “embody, use, reflect, rest upon, or apply” the underlying natural phenomena that relate to the physical characteristics, properties, and arrangement of the elements and materials recited in the claimed method. As noted by Judge Moore in her dissenting opinion, “[e]ven the majority does not agree with the district court that the claims are directed to Hooke’s law . . . [and] . . . concludes that the claims are ineligible because they are ‘directed to the utilization of a natural law (here, Hooke’s law and possibly other natural laws) in a particular context.’” Dissent Op. at 2. Thus, the entire panel was unanimous in its analysis that the claimed methods involve the operation of several laws of nature that encompass the way the physical features, arrangement, and

properties of the liner(s) achieve the purported technological advance of developing a liner that can reduce two modes of vibration.

The panel majority, however, characterized the claims as being “directed to” an ineligible natural law. This leaves patentees awash in a sea of uncertainty; how can one determine if a claim is “directed to” a natural law without the natural law being apparent either on the face of the claim, or under a proper claim construction? The only workable conclusion that can be gleaned from this Court’s panel decision is that the claimed subject matter is *not* “directed to” a judicially-created exclusion as required by the first step of the Supreme Court’s two-step analytical framework.

Claims 1 and 22 of U.S. Patent 7,774,911 (“the ‘911 Patent”), on their face, merely embody how the physical properties and characteristics of the claim elements operate in a method for manufacturing a shaft assembly that can dampen two or more vibration modes in a propshaft. The ‘911 patent explains that the structure of the liner materials, the number of liner(s), the positioning of the liner(s) within the shaft, and the characteristics of the liner(s) may be modified in order to tune the damping properties. *See, e.g.*, ‘911 patent at Col. 6, ln. 49 – Col. 8, ln. 2.

Nothing in the claims or specification of the ‘911 patent recites or implies that an application of Hooke’s law to a liner is necessary or sufficient to tune the

liner in accordance with the claim (thereby achieving the “advance”). Indeed, the specification invokes Hooke’s law no more than it does the law of gravity, and arguably even less so than an instruction to randomly vary the characteristics of the liner (*i.e.*, no law, *ad hoc* trial-and-error) in order to tune it in a way that achieves the claimed vibration attenuation. The district court simply focused on the “tuning” step of the methods, rather than undertake a complete analysis of the entirety of the claims. This allowed the district court to characterize the claims as being merely instructive to the reader that they apply Hooke’s law, without any instruction on how to do so, in order to achieve the claimed end result. Setting up the subject matter eligibility analysis in this way allowed the district court to dispose of the claims as being drawn to ineligible subject matter in summary fashion.

The panel majority did not correct the district court’s misapplication of the patent eligibility analysis despite acknowledging that a straightforward application of Hooke’s law alone was insufficient to provide the technical advance. Instead, the majority elected to sweep into its analysis one or more other unidentified natural laws in addition to Hooke’s law in order to assert that the claims were indeed “directed to” some number of natural laws. This abstract and non-specific rationale in analyzing subject-matter eligibility appears to be *exactly* what the Supreme Court has so strongly cautioned against: at some level any and all

inventions can be characterized as embodying, using, reflecting, resting upon, or applying laws of nature, natural phenomena, or abstract ideas.

Just because an invention operates according to the laws of nature (as all inventions must) cannot mean that it is “directed to” these laws. The panel decision should be reheard and reconsidered *en banc* at least to provide additional clarity to the analysis of the threshold determination of circumstances in which a claim is “directed to” a law of nature, a natural phenomenon, or an abstract idea.

II. The panel decision inappropriately applies a patent eligibility analysis under 35 U.S.C. § 101 as a substitute for a proper analysis of the disclosure requirements under 35 U.S.C. § 112

During prosecution, patent applicants in the field of biotechnology undertake great effort to show possession of the invention by including working examples and elucidating structure-activity relationships; and to demonstrate enablement across the full scope of the claims. Later, if a patent is enforced, there nonetheless often are arguments over compliance with Section 112. To resolve such disputes, patentees must be allowed to attempt to show that the working examples in the specification are sufficient in number and diversity to demonstrate possession of a claimed genus; that a skilled person would have known how to make and use the claimed invention in light of the specification and the knowledge in the art; and that any required experimentation would have been merely routine (or at least not undue). Determining whether a biotech patent specification complies with Section

112 almost always involves intensive fact-discovery and thorough expert testimony. The instant case, however, supplants this searching analysis with a Section 101 analysis that is less fact-bound, highly dependent on a judge's intuition, that looks to the claim elements and not the specification for the required teaching of how to make and use the invention; and that, in BIO's view, is more free-flowing and less reliable.

Even in the Background section of the majority opinion, when describing the '911 patent, the majority notes concerns about the '911 patent's specification that are relevant to an analysis under Section 112 but not Section 101. For example, the majority states: "Neither the claims nor the specification describes how to achieve such tuning. The specification also discloses a solitary example describing the structure of a tuned liner, but does not discuss the process by which that liner was tuned." Slip Op. at 7. The breadth and depth of these teachings in the specification may be relevant to the written description and enablement requirements of Section 112, but they have no relevance to patent eligibility under Section 101. Thus, to the extent the majority (and district court) had such concerns about the specification, they should have addressed those concerns through a proper analysis under Section 112, not through summary judgment under Section 101.

In short, BIO shares the dissent's concern that the majority has applied Section 101 in place of Section 112. The panel majority responds to the dissent's

concern in this regard by noting that “[t]he Supreme Court in *Mayo* made clear that Section 101 serves a different function than enablement.” Slip Op. at 20. This answer is neither satisfying nor accurate. Under the majority’s application of Section 101 here, the existing body of enablement law would no longer serve a separate purpose in policing claim scope, and the same may be true for written description as well. A more accurate statement of the majority’s view would have been: “Section 101 can do everything Section 112 does – and then some.” Either way, the long-term impact on the future development of Section 112 jurisprudence is uncertain, but it cannot be good. The majority’s application of Section 101 removes incentives to develop the law of enablement and written description in technology areas where Section 112 has arguably been underused. And at the same time it would tend to undercut settled expectations of patentees in technologies with well-developed Section 112 law, such as biotechnology.

For the foregoing reasons, the Court should grant rehearing en banc.

Dated: December 12, 2019

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CERTIFICATE OF SERVICE

On December 12, 2019, a copy of the **Brief of *Amicus Curiae***
Biotechnology Innovation Organization in Support of Appellant's Combined
Petition for Rehearing or Rehearing En Banc was filed and served using the
CM/ECF System.

Dated: December 12, 2017

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 32(a) because:

this brief contains 2061 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because:

this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman font.

Dated: December 12, 2019

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