No. 2022-1116

United States Court of Appeals for the Federal Circuit

CHROMADEX, INC., TRUSTEES OF DARTMOUTH COLLEGE,

Plaintiffs-Appellants,

v.

ELYSIUM HEALTH, INC.,

Defendant-Appellee.

On Appeal from the United States District Court for the District of Delaware, No. 1:18-cv-01434-CFC-JLH, Chief Judge Colm F. Connolly

RESPONSE OF DEFENDANT-APPELLEE ELYSIUM HEALTH, INC. TO PLAINTIFFS-APPELLANTS' PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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April 24, 2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2022-1116

Short Case Caption ChromaDex, Inc. v. Elysium Health, Inc.

Filing Party/Entity Elysium Health, Inc.

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Elysium Health, Inc.		

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INTRODUCTION

Elyisum Health, Inc. respectfully opposes the petition for panel rehearing and rehearing *en banc* filed by ChromaDex, Inc. and Trustees of Dartmouth College (collectively, "ChromaDex").

The panel unanimously affirmed the Distict of Delaware's determination that the claims of the asserted patent, construed in accordance with a stipulated claim construction, are unpatentable under Supreme Court precedent. The panel decision is correct and raises no important question, let alone one of exceptional importance warranting *en banc* review. There is no reason for the panel or the full Court to reconsider it.

ARGUMENT

I. The Panel's Straightforward Application Of The Supreme Court's *Myriad* Decision Does Not Warrant Further Review

Based on a stipulated claim construction and the material undisputed facts, the panel correctly held that claims 1-3 (the "Asserted Claims") of U.S. Patent No. 8,197,807 (the "'807 patent") are patent ineligible under § 101.

The Asserted Claims are directed to compositions containing nicotinamide riboside (or "NR"), a naturally-occurring form of vitamin B3. Appx10095; *see also* Appx2526 at 27:42-45. Animal cells naturally convert NR into a coenzyme called NAD+. Appx2810-2812. Claim 1 of the '807 patent claims:

> A composition comprising isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic acid, or

> nicotinamide, wherein said combination is in admixture with a carrier comprising [list of carriers, including 'a sugar'], wherein said composition is formulated for oral administration and increases NAD+ biosynthesis upon oral administration.

Appx2539. Claims 2 and 3 depend from claim 1. Claim 2 requires the NR be "isolated from a natural or synthetic source." Claim 3 encompasses compositions formulated as, among other options, a "food." *Id*.

At the *Markman* hearing, ChromaDex initially sought a construction of "isolated NR" requiring that the NR be "at least 25% pure."[1] During the hearing, however, ChromaDex abandoned that position and stipulated to the Court's proposed construction of "isolated NR" (tracking definitional language in the specification) as requiring only that the NR be "separated or substantially free from ***at least some of the other components*** associated with the source of the nicotinamide riboside." Appx22 (emphasis added); Appx2880. This construction does not require any particular amount, purity, or concentration of NR; it does not require that the NR be separated from any one component in particular, achieve any functional result, or be stable or bioavailable. Inexplicably, nowhere in

[1] ChromaDex advanced this position in its claim construction briefing (District Court Dkt. No. 102 at, *e.g.*, 25, 33) and at the outset of its *Markman* hearing argument (District Court Dkt. No. 325 at 69-75). These parts of the record do not appear in the Appendix, which was prepared long before the Rehearing Petition.

ChromaDex's Rehearing Petition does ChromaDex even acknowledge the stipulated construction.

After reviewing the material undisputed evidence, including ChromaDex's admissions at summary judgment, the panel found that every element of the Asserted Claims is present in a naturally-occurring product, excepting only the requirement that the NR in the composition be "isolated." Panel Op. at 5-6. The panel then applied *Myriad* and *Chakrabarty* to the undisputed facts and stipulated claim construction. Specifically, the panel held: "As in *Myriad*, under the circumstances presented here, the act of isolating the NR compared to how NR naturally exists in milk is not sufficient, on its own, to confer patent eligibility." Panel Op. at 6 (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 569 U.S. 576, 590-93 (2013)).

The panel's decision was indisputably correct. In *Myriad*, the Supreme Court directly addressed the question whether a natural product, like DNA, was patentable where the claim adds a requirement that the natural product has been "isolated." There, the composition claims were directed to "isolated" DNA sequences, such as "[a]n ***isolated*** DNA coding for a BRCA1 polypeptide." *Myriad*, 569 U.S. at 584 (emphasis added). The Court explained that "isolating" a natural substance by separating, purifying, or otherwise isolating it from other components of its source does not transform an unpatentable product of nature into

patent-eligible subject matter. Myriad's claims to isolated DNA were directed to unpatentable products of nature, notwithstanding the "isolated" limitation. *Id.* at 591-94.

The Supreme Court reasoned that Myriad's claimed DNA sequences "existed in nature before Myriad found them," just as NR existed in nature before the inventor conceived the alleged inventions here. *Id.* at 590. The Court rejected Myriad's arguments that the human intervention involved in "isolating" the claimed DNA could confer patent eligibility: "Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Id.* at 593. Even though Myriad had "found an important and useful gene," the Court held, "separating that gene from its surrounding genetic material is not an act of invention." *Id.* at 591. In short, "a naturally occurring [molecule] is a product of nature and not patent eligible merely because it has been isolated." *Id.* at 580; *see also Funk Brothers Seed Company v. Kalo Inoculant Co.,* 333 U.S. 127, 130-32 (1948) (discovery that six strains of bacteria could be "isolated and used in mixed cultures" as inoculants not patent eligible).[2] The Supreme Court precedent could not be clearer: requiring

[2] ChromaDex's argument (Rehearing Pet. at 11) that "the combination of isolated NR with tryptophan" renders the claims patentable under *Funk Brothers* was waived: ChromaDex never so argued in its briefing to the district court or to the panel. *See Sage Prods. v. Devon Indus*., 126 F.3d 1420, 1426 (Fed. Cir. 1997)

that a product found in nature be "isolated" from its natural source cannot render the composition patent eligible.

This Court has applied *Myriad* to invalidate claims that rely on isolation or separation of a natural molecule. For example, in *In re BRCA1—and BRCA2—Based Hereditary Cancer Test Patent Litigation*, the Court analyzed a claim to a "pair of single-stranded DNA primers" that were "structurally identical to the ends of DNA strands found in nature." 774 F.3d 755, 758-60 (Fed. Cir. 2014). The Court rejected arguments that the claimed DNA fragments were patentable because they could not be found in the human body, explaining that separating a fragment of DNA from its natural environment did not make the separated DNA patentable. *Id.* at 760.

Similarly, in *In re Bhagat*, a panel of this Court affirmed the USPTO's rejection under § 101 of claims directed to fatty acid mixtures that occurred naturally in walnut and olive oils. 726 Fed. Appx. 772, 778-79 (Fed. Cir. Mar. 16,

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(argument not presented to district court was waived); *Rumsfeld v. Freedom NY, Inc.*, 346 F.3d 1359, 1361 (Fed. Cir. 2003) (rehearing argument not presented to panel was waived). The argument also is wrong. Nothing in *Funk Brothers*, a case holding claims unpatentable, suggests that a combination found in nature (it is undisputed that the combination of NR with nicotinamide and/or tryptophan is found in milk) may be made patentable by requiring that one component of the composition is "isolated." Moreover, such an argument is flatly inconsistent with the Supreme Court's more recent decision in *Myriad*.

2018) (nonprecedential). The panel rejected arguments that extracts from naturally-occurring plants "are not natural products because the extraction processes… transform the claimed lipids from natural products." *Id.* So too here: separating NR from one or more components of milk or another natural source does not transform the claims into non-natural products.

Because the claimed compositions "lack markedly different characteristics from milk" and, as the panel also determined, fail the *Alice/Mayo* two-step framework, the panel correctly found that the Asserted Claims are not patent eligible. Panel Op. at 9-10. Nothing about its decision warrants further review.

II. The Panel Did Not Resolve Disputed Factual Issues Against ChromaDex

A. The Panel Properly Refused To Read Unrecited Limitations Into The Claims

ChromaDex's first argument is that the panel improperly resolved factual issues against ChromaDex when it rejected the argument that the claimed NR composition is markedly different from the naturally-occurring compositions containing NR because NR in milk allegedly is bound to lactalbumin whey protein and not bioavailable. Rehearing Pet. at 6-7. The panel explained that the problem with this argument "is two-fold":

> First, as discussed above, milk increases NAD+ biosynthesis… and that is the only therapeutic effect that the claims require. Second, the claims simply do not reflect the distinctions Appellants rely on: they do not require any specific quantity of isolated NR, and the district court's construction for "isolated [NR]," which Appellants do not

> challenge on appeal, does not require that the NR be separated from the lactalbumin whey protein but only from "*some* of the other components associated with the source of [NR]." J.A. 22 (emphasis added).

Panel Op. at 8-9.[3]

The panel's analysis made no factual findings against ChromaDex; it simply (and correctly) evaluated the scope of the claims under the agreed-upon claim construction, consistent with this Court's well-established precedent. In case after case, this Court has held that the § 101 inquiry focuses on the invention that is claimed, not on the narrower invention the patentee in hindsight wishes it had claimed. This Court has emphasized repeatedly that "[t]he § 101 inquiry must focus on the language of the Asserted Claims themselves." *E.g., Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016); *Accenture Global Servs. v. Guidewire Software, Inc.*, 728 F.3d 1336, 1345 (Fed. Cir. 2013) ("the important inquiry for a § 101 analysis is to look to the claim"); *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 769 (Fed. Cir. 2019) ("the specification

[3] The Rehearing Petition does not require consideration of whether NR is bioavailable in milk. The panel decision ChromaDex challenges did not depend in any way on whether the NR in milk, as opposed to other components present in milk, enhances NAD+ biosynthesis. Panel Op. at 8-9. ChromaDex's attempt to seize on a harmless error in the district court's Memorandum Opinion cannot support rehearing, where the panel correctly explained that it had no effect on the outcome of the case.

cannot be used to import details from the specification if those details are not claimed").

As the panel correctly noted, the claim language does not include the limitations ChromaDex continues to rely upon as its basis for asserting patentability. The panel's reasoning followed the Supreme Court's decision in *Myriad*, which rejected the patentee's argument that isolated DNA claims were patentable because, unlike naturally-occurring DNA, isolated DNA contains severed chemical bonds. *Myriad,* 569 U.S. at 593. This argument was untenable because "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id*. Likewise, the Asserted Claims here are not expressed in terms of the bioavailability of NR. There was no material factual dispute bearing on § 101 in this case.[4]

[4] ChromaDex's reliance on *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018) is misplaced. That case merely held that, in some instances, a factual dispute concerning whether a claim element is well-understood, routine, and conventional (*Alice* step two) can preclude summary judgment. *Id*. at 1368-71. The Court emphasized that "[p]atent eligibility has in many cases been resolved on motions to dismiss or summary judgment. Nothing in this decision should be viewed as casting doubt on the propriety of those cases." *Id*. at 1368. Moreover, the *Berkheimer* decision stresses the primacy of claim scope to the § 101 analysis: the patentee's argument that a factual dispute concerning the application of *Alice* step two to an allegedly "inventive feature" discussed in the specification could not prevent summary judgment as to claims that did not recite the "inventive feature."

The Rehearing Petition provides no reason to upset the panel's analysis of claim scope. ChromaDex rehashes its argument that the claims should be construed to exclude compositions in which NR is bound to whey without addressing the argument's fatal flaw: ChromaDex ***stipulated*** to a claim construction that does not require that NR be separated from whey. Instead, the NR need be separated only from "some" components associated with its source, not from any one component in particular. Thus, as a matter of ***claim construction***, "isolated nicotinamide riboside" encompasses NR that is bound to whey in natural milk, so long as it is separated from some other components of the milk.

Similarly, ChromaDex's assertion that the claims should be interpreted to require that the NR in the composition be "bioavailable" and have "therapeutic value" contradicts the stipulated claim construction and ChromaDex's admissions as to claim scope. The claims do not require that ***the NR*** in the composition, as opposed to, for example, the tryptophan, be responsible for increasing NAD+ biosynthesis. Rather, as the panel noted, the claims require that "***the composition***" must "increase NAD+ biosynthesis." Panel Op. at 8 n.4.

Id. The same is true here. ChromaDex's alleged factual disputes about unclaimed features do not support rehearing.

ChromaDex's argument here directly contradicts the argument it made below. In its *Markman* briefing, ChromaDex asserted that "the claimed 'composition'—***not any one of its particular components***—'increases NAD+ biosynthesis upon oral administration.'" Appx1990-1991 (emphasis added); *see also* Appx2823-2824. Here, it was undisputed that milk, as a composition, achieves that effect. Appx10096. Whether the NR in milk is independently responsible for enhancing NAD+ biosynthesis does not affect the § 101 analysis, as the panel correctly held. Panel Op. at 8 n.4.

The panel's rejection of ChromaDex's attempt to establish patentability by reading limitations into the claims faithfully applied this Court's precedents. For example, in *Synopsys*, this Court rebuffed the patentee's argument that the asserted claims were not abstract ideas because they would be expected to be performed on a computer. The Court explained, "while Synopsys may be correct that the inventions… were intended to be used in conjunction with computer-based design tools, the Asserted Claims are not confined to that conception." *Synopsys*, 839 F.3d at 1149. Synopsys's arguments failed because Synopsys "stop[ped] short of arguing that the Asserted Claims must be *construed* as requiring a computer to perform the recited steps." *Id.* (emphasis added). This case is no different. Applying the parties' stipulated construction of "isolated," the panel correctly

concluded that "the claims simply do not reflect the distinctions Appellants rely on." Panel Op. at 9.

The panel correctly observed that its decision is supported by this Court's opinion in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019). Panel Op. at 7. *Natural Alternatives* came to this Court in an unusual procedural posture. The district court had entered a Rule 12 judgment on the pleadings that the claims were invalid under § 101. *Id.* at 1341-42. Since there had been no *Markman* claim construction, the district court accepted the patentee's ***proposed*** constructions for purposes of the Rule 12 motion, as did this Court for purposes of appeal. *Id.* at 1343. Notably, the patentee's proposed constructions added critical functional limitations that were not recited in the claims. *Id.* at 1343-44.

On appeal this Court considered, among other claims, "Product Claims" directed to beta-alanine compositions. Applying the patentee's proposed constructions, the Court treated the Product Claims as requiring that the compositions "effectively increase athletic performance," a functional property that natural compositions containing beta-alanine did not possess. *Id.* at 1348. In addition, some of the claims expressly recited dosage forms requiring "between 0.4 grams to 16 grams" of beta-alanine, far higher than the amounts present in natural sources. *Id.* at 1348, 1357, n.3.

On this basis, the Court reversed. It accepted for purposes of appeal that the claims "have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot." *Id.* at 1348. The Court remanded the case for further proceedings, which, as the dissent noted, "could include a formal claim construction and a potential revisit of the § 101 issue." *Id.* at 1354.

By contrast, the Asserted Claims here were construed by the district court following a *Markman* hearing. Under the court's unchallenged construction, as the panel correctly explained, "the asserted claims do not have characteristics markedly different from milk." Panel Op. at 7. Indeed, unlike the claims in *Natural Alternatives*, ChromaDex's claims do not require any non-natural properties, dosage amounts, or results, and the panel correctly rejected ChromaDex's attempt to read § 101-inspired limitations into them.

B. ChromaDex Admitted That All Claim Elements Other Than "Isolated" Are Found In Products Of Nature

Contrary to ChromaDex's argument, the panel rightly found that, except for the requirement that the NR in the composition be "isolated," every element of the Asserted Claims is present in a natural product. Panel Op. at 6. It was undisputed, for example, that milk is a natural composition containing NR, tryptophan, and nicotinamide, and that it increases NAD+ biosynthesis upon oral administration. Appx10095-10097.

ChromaDex's argument that the "admixture" and "formulated" elements render the claims patent eligible is wrong (and, as to "admixture," was not presented to the panel and therefore is waived). ChromaDex does not even attempt to show how a composition created by mixing together two separate ingredients is markedly different from a product of nature that naturally contains both. Nor can it show that milk is markedly different from a product that is "formulated" for oral administration under whatever (unstated) construction ChromaDex would apply to that term.

C. The District Court Did Not Guarantee ChromaDex a Jury Trial on § 101

ChromaDex's assertion that the panel robbed ChromaDex of its right to try the § 101 question to a jury —a right the district court supposedly guaranteed to ChromaDex at the *Markman* hearing—was waived two times over. It also is groundless.

To preserve an argument for appeal, ChromaDex was required to raise the argument before the district court and to raise it again in its opening brief to this Court. *See Sage*, 126 F.3d at 1426; *Rumsfeld*, 346 F.3d at 1361. ChromaDex's summary judgment briefing to the district court and its briefing to the panel never argued that the district court's comments during the *Markman* hearing somehow promised ChromaDex that the court would deny summary judgment on Elysium's § 101 defense if ChromaDex stipulated to the construction of "isolated."

Appx9678-9693. Accordingly, the argument is waived and cannot provide the basis for rehearing.

Even if the argument had not been waived, nothing in the record remotely suggests that the district court made such a promise. On the contrary, the district court simply recognized that ChromaDex would be required to prove that the accused product meets the "isolated" element under the stipulated construction to establish infringement, and that Elysium would be required to show that the prior art disclosed the "isolated" element to establish anticipation or obviousness. Appx2880. *See, e.g., Aventis Pharm Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300-03 (Fed. Cir. 2007) (analyzing obviousness of claim requiring compound to be "substantially free of other isomers"). Indeed, in its summary judgment ruling, the district court underscored the import of ChromaDex's stipulation: "ChromaDex consented to my construction of 'isolated [NR]'… And that construction in no way required that the NR in the claimed composition be stable, bioavailable, sufficiently pure, or have a therapeutic effect." Apppx38-39.

ChromaDex's assertion that it was "denied the opportunity to submit expert testimony" on § 101 patentability is false. Rehearing Pet. at 8. ChromaDex submitted an expert report directed to Elysium's § 101 defense, and ChromaDex proffered the expert's opinion in opposing summary judgment. Appx9686-9687; Appx10174-10180. The district court considered ChromaDex's arguments but

rejected them as contrary to the stipulated claim construction. ChromaDex may disagree with the district court's decision, but there is no merit to its allegation that the court somehow violated its due process rights or that the ruling raises a question of exceptional importance warranting *en banc* review.

III. The Panel Correctly Applied *Alice/Mayo*

While concluding that it "could" end the § 101 inquiry after performing its "markedly different characteristics" analysis of the claimed invention, the panel did not end the inquiry there. In Section III of its opinion, the panel alternatively applied both steps of the *Alice/Mayo* framework to evaluate patentability. It expressly held that "if resort to *Alice/Mayo* is necessary," the claims are unpatentable under that framework as well. Panel Op. at 9-10. ChromaDex's arguments about whether claims directed to natural products should be analyzed under *Alice/Mayo* is not a ground for rehearing, because the panel did analyze the Asserted Claims under that framework and found them invalid.

ChromaDex's assertion that the panel misapplied *Alice/Mayo* step two is wrong as well. At step two, the analysis looks for "an 'inventive concept'—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Alice Corp. Pty Ltd. v. CLS Bank International*, 573 U.S. 208, 217-18 (2014).

The panel addressed each of the two allegedly inventive steps urged by ChromaDex: "[1] recognizing the utility of NR for enhancing health and well-being and [2] the wisdom of *isolating* the NR to provide concentrations higher than what occur naturally." Panel Op. at 10. The panel then explained that neither makes the claims patentable. As to the first, the panel rightly observed that under *Myriad*, "recognizing the utility of NR is nothing more than recognizing a natural phenomenon, which is not inventive." As to the second, *Myriad* likewise forecloses the argument, because "the act of isolating the NR by itself, no matter how difficult or brilliant it may have been (although the specification makes clear that it was conventional), similarly does not turn an otherwise patent-ineligible product of nature into a patentable invention." *Id*.

In its Rehearing Petition, ChromaDex does not specify the "inventive step" that allegedly renders the claims patent eligible. Instead, it argues that the inventor invented "isolated NR" which "was ***not*** available in nature." Rehearing Pet. at 16. The specification of the '807 patent acknowledges, however, that isolation of NR and the formulation of compositions comprising isolated NR involve routine, conventional, and well-understood activities. It states that compositions containing NR "can be prepared by methods… which are well-known in the art." Appx2527 at 29:24-35; *see also* Appx10098. It further explains that "[i]solated extracts of the natural sources can be prepared using standard methods," and that NR alternatively

can "be chemically synthesized using established methods." Appx2526 at 27:45-56, 28:58-61; *see also* Appx10099. ChromaDex's expert conceded that "[i]t is not the specific techniques of isolation that transform the Asserted Claims beyond a law of nature or natural phenomenon." Appx10180 at ¶164; *see also* Appx10099. *See Myriad,* 569 U.S. at 591 (separating a natural molecule from its surrounding material "is not an act of invention").

ChromaDex's reliance on *Rapid Litigation Management v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) is misplaced. There, the Court emphasized that the claims were ***method*** claims that improved an existing technological process for preserving hepatocytes, a type of liver cell, in an unconventional way. *Id.* at 1048-50. Here, by contrast, the claims are composition claims and there is nothing unconventional about them. As the panel appreciated, *Myriad* is dispositive.

At best, the inventor discovered a natural relationship between NR and NAD+ biosynthesis. But discovery of a natural phenomenon does not satisfy § 101. Patent eligibility requires more than "simply stat[ing] the law of nature while adding the words 'apply it.'" *Mayo*, 566 U.S. at 72. As the panel correctly held, the Asserted Claims are unpatentable.

CONCLUSION

For all the foregoing reasons, the Rehearing Petition should be denied.

Respectfully submitted,

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Dated: April 24, 2023

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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