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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ELISE CHAMPION, BRUCE MCCONNELL, and GYULA DEKANY

Appeal 2023-003725
Application 16/913,590
Technology Center 1600

Before DONALD E. ADAMS, JOHN G. NEW, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

NEWMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–16, 19–21. *See* Final Act. 3. Through a subsequent amendment canceling certain claims, the pending rejected claims are 1–3, 8, and 16.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as GLYCOM A/S. Appeal Br. 2.

[2] *See* February 2, 2020 Amendment After Notice of Appeal 2, canceling then-pending claims 4–7, 9–15, and 19–21.

STATEMENT OF THE CASE

According to the Specification, human milk oligosaccharides (HMOs) have roles in "numerous biological processes" occurring in humans, and are believed to positively modulate the resident community of microbes in the human digestive track, which "plays a major role in health and disease" and may lead to disease when imbalanced. Spec. 1:12–14; 2:5–10. "[A]t least 130 of these complex oligosaccharides" can be found in mammalian milk. *Id.* at 1:12–14.

The Specification discloses mixtures of three HMOs, 6′-O-sialyllactose (6′-SL), lacto-N-neotetraose (LNnT) and sialyllacto-N-tetraose c (LST c). *Id.* at 2:18–19. This mixture has been "surprisingly discovered [to] possess an anti-infective activity and therefore can be used as an anti-infective composition, e.g.[,] for treating bacterial infections through specific modulation of the microbiome and by preventing binding of pathogens to epithelial cells." *Id.* at 45:17–20.

The mixtures are disclosed in a variety of molar concentration ratios, e.g., "the molar ratio of LST c relative to (6′-SL + LNnT) is at least 1:18, advantageously at least 1:8, more advantageously at least 1:5, even more advantageously at least 1:3." *Id.* at 2:20–22. However, the Specification also discloses that

> [t]he proper dosage of these compositions for a patient can be determined in a conventional manner, based upon factors such as the patient's immune status, body weight and age. In some cases, the dosage will be at a concentration similar to that found for 6′-SL, LNnT and/or LST c in human breast milk.

Id. at 19:9–12.

CLAIMED SUBJECT MATTER

The claims are directed to ternary mixtures of 6′-SL, LNnT and LST c. Claims 1 and 16, reproduced below, illustrate the claimed subject matter:

> 1. A mixture of human milk oligosaccharides (HMOs) consisting essentially of an anti-infective effective amount of 6′-O-sialyllactose (6′-SL), lacto-N-neotetraose (LNnT) and sialyllacto-N-tetraose c (LST c).
>
> 16. An anti-infective composition for treating bacterial infections comprising the mixture of claim 1.

Appeal Br. 13 (Claims App'x.).

REJECTION

The Examiner maintains the following rejection:

Claims 1–16 and 19–21 are rejected under 35 U.S.C. § 101 because "the claimed invention is directed to a judicial exception without significantly more." Final Act. 3.

OPINION

Principles of Law

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. But the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable. *E.g., Alice Corp. v. CLS Bankint'l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) and *Alice*. 573 U.S. at 217–18 (citing *Mayo*, 566 U.S. at 75–77). In accordance with that framework, we first determine what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, i.e., the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappas*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk.").

If the claim is "directed to" a patent ineligible concept, we turn to the second step of the *Alice* and *Mayo* framework, where "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 573 U.S. at 217 (citation omitted).

The United States Patent and Trademark Office ("USPTO" or "the Office") published revised guidance on the application of § 101. USPTO's January 7, 2019, Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance").[3] Under that guidance, we first look to whether the claim recites the following:

(1) any judicial exceptions, including law of natures, natural phenomena, or certain groupings of abstract ideas (i.e., mathematical concepts,

[3] Available at https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf.

certain methods of organizing human interactions such as a fundamental economic practice, or mental processes); and

(2) additional elements that integrate the judicial exception into a practical application (see MPEP § 2106.0S(a)-(c), (e)-(h)).[4]

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

(3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)); or

(4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

Analysis

In the Final Office action, the Examiner rejected all pending claims as directed to ineligible subject matter, finding that the claimed mixture of 6´-O-sialyllactose (6´-SL), lacto-N-neotetraose (LNnT) and sialyllacto-N-tetraose c (LST c) was "a judicial exception not integrated into a practical application" without "additional elements that are sufficient to amount to significantly more than the judicial exception." Final Act. 3–5. The

[4] We acknowledge that some of these considerations may be evaluated properly under Step 2 of *Alice* (Step 2B of the Office Guidance). Solely for purposes of maintaining consistent treatment within the Office, we evaluate this inquiry under Step 1 of *Alice* (Step 2A of the Office Guidance).

Examiner rejected Appellant's argument that the exclusion of other active biomolecules naturally present in breast milk, e.g., the isolation of the three claimed HMOs from other elements, was not a product of nature, finding that isolation of the HMOs had not altered their structure or function. *Id.* at 4. The Examiner also rejected Applicant's argument that the isolated HMOs had a different effect than they had in nature for lack of evidence of a change in effect. *Id.*

Following the Final Action and an Examiner interview, Applicant amended claim 1 to recite that the claimed mixture is "an anti-infective effective amount". *See* September 13, 2022, Response After Final Action, 2.

In an Advisory Action, the Examiner indicated that the amendment would not overcome the rejection because

> Office policy remains that an "effective amount" is essentially an amount of a natural product that has been isolated, which typically does not change the structure or function thereof. The fact that isolating the compound makes it more useful for a pharmaceutical use is an incidental change in the characteristic.

October 6, 2022, Advisory Action, 2.

After appealing, Appellant canceled then-pending claims 4–7, 9–15, and 19–21 in response to a January 10, 2023, Notice of Defective Appeal Brief. *See* February 2, 2020, Amendment After Notice of Appeal, 2.

On appeal, Appellant acknowledges that the claimed subject matter recites a composition of matter that satisfies step 1 of the Guidance as discussed above. Appeal Br. 5. We agree.

With regard to step 2A, in which we must determine if the claims are directed to an unpatentable judicial exception, Appellant acknowledges that the claimed HMOs can be found in nature. Appeal Br. 7. Appellant argues that

> Allowance of the appealed claims will not preclude utilization of the natural product (e.g., infants from breastfeeding) because, at least, the instant claims (1) require an "an anti-infective effective amount" and (2) the use of the transition phrase "consisting essentially of" excludes other HMOs and potentially biologically active molecules in the natural product.

Id. Appellant argues that Step 2A, prong 1 thus does not establish patent ineligibility, and continues its analysis to Step 2A, prong 2. *Id. See also* Reply 2 (asserting that the Examiner's discussion of markedly different characteristics is "inapposite to the issue raised by the instant appeal – whether the appealed claims recite judicial exception under Step 2A, Prong 2"). We agree with the Examiner that the issue of patentability in Step 2A, prong 1 is dispositive.

Appellant's alleged invention is a mixture of human milk oligosaccharides (HMOs) isolated from breastmilk, i.e., a product of nature. Whether the HMOs are isolated or subsequently replicated outside the human is irrelevant to whether they are found in nature. *University of Utah Research Foundation v. Ambry Genetics*, 774 F.3d 755, 760 (Fed. Cir. 2014). To avoid patent ineligibility as being directed to a judicial exception, a patent applicant must show that the product of nature possesses markedly different characteristics from any naturally occurring counterpart. *See* MPEP § 2106.04(c).

On this issue, Appellant argues that its claimed HMOs have "novel properties and biological activities" apart from human milk because they have anti-infective activity and can be used as an anti-infective composition. Reply 2 (citing Spec. 3:9–10, 18:5–7 "Surprisingly, the HMO mixtures containing 6´-SL, LNnT and LST are anti-infective compositions, therefore

they can be advantageously used for treating viral and/or bacterial infections, especially infections of the respiratory tract.").

Additionally, Appellant cites data from Soyyilmaz et al.[5] that "the claimed HMOs (6´-SL, LNnT and LST c) are found (in mean amounts) of 0.40, 0.37 and 0.17 g/L, respectively, in the colostrum [of human breast milk]. This represents 3.63%, 3.35% and 1.53% of the total HMO content" of total human breast milk HMOs. Appeal Br. 8. Petitioner argues that Soyyilmaz discloses that HMO "biological function is primarily driven by molar concentration." *Id.* (citing Soyyilmaz, 15). Appellant contrasts the HMO levels in colostrum as too low to be anti-infective as compared to the anti-effective amount in its Specification, which Appellant argues "would be on the order of **40x** (40 mg/mL vs. 0.94 g/L) what occurs in nature." *Id.* at 9. Appellant cites *Natural Alternatives Int'l v. Creative Compounds*, LLC, 918 F.3d 1338 (Fed. Cir. 2019) for the proposition that when the claimed invention improves on the natural function of a natural product, the claimed invention is eligible for patenting. Appeal Br. 9 (also citing PTAB cases reversing rejections under the reasoning in *Natural Alternatives*).

We are not persuaded. In our view, this case is more similar to *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, 130 (1948), in which the Supreme Court examined the patentability of a mixed culture of Rhizobia bacteria used to enhance nitrogen fixation in leguminous plants. The Supreme Court found that neither the discovery of the ability to mix the species and retain their original function or the aggregation of select isolated

[5] Soyyilmaz et al., *The Mean of Milk: A Review of Human Milk Oligosaccharide Concentrations throughout Lactation,* NUTRIENTS 13(8): 2737 (August 9, 2021).

strains of the bacteria made the mixture patentable. *Id.* at 131. The Supreme Court reasoned that the mixture was "an advance in the packing of the inoculants" and that none of the species acquired a different character or function by way of this packaging. *Id.*

The instant case is similar to *Funk Bros*. Appellant has isolated for reproduction and combination three HMOs made naturally in breast milk, and the claims recite these HMOs in an "anti-infective effective amount." While we acknowledge the statement in Soyyilmaz that molar concentration drives function, the claims provide no ranges or specify any concentration of the HMOs, leaving the claims subject to the broadest interpretation in light of the Specification. And as the Examiner noted, the Specification discloses that

> [t]he proper dosage of these compositions for a patient can be determined in a conventional manner, based upon factors such as the patient's immune status, body weight and age. *In some cases, the dosage will be at a concentration similar to that found for 6′-SL, LNnT and/or LST c in human breast milk.*

Spec. 19:9–12 (italics added). The broadest interpretation of the claims in light of the Specification indicates that the dosage of an anti-effective concentration is not required to be 40x of the natural amount, but could be as low as the levels of HMOs found in natural breast milk. *Id.* Without limitations reciting specific differences from the levels of HMOs found in natural breast milk, the claims recite subject matter not markedly different from what is found in nature. *See In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1337–1388 (Fed. Cir. 2014) (finding that sheep cloned from existing sheep were exact genetic replicas of the donors and thus did not possess markedly different characteristics despite that some physical shape,

size, and behavior differences existed in the cloned sheet because these identified differences were not claimed).

Appellant also cites *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995) for the proposition that a specification's teaching of a surprising effect in the obviousness context was credited by the Federal Circuit absent evidence to the contrary. Reply 2. We are not persuaded. *In re Soni* regarded obviousness, not patentability. *Id.* at 749. To overcome the *prima facie* case of obviousness, the *In re Soni* appellant introduced what the Federal Circuit characterized as "*substantially* improved results" of "specific data indicating improved properties." *Id.* at 750–751. While similar data of substantially improved results might suffice to show markedly different characteristics, in this case, Appellant has pointed us only to statements in the Specification that the results are "surprising," without any support for what type of increase in function over baseline is observed, much less data commensurate with the broad scope of the claims. *See, e.g.*, Reply 2, citing Spec. 18:5–7. These statements are not persuasive and do not meet Appellant's burden to show a markedly different characteristic warranting patentability.

Appellant further argues that claim 16 is separately patentable as it recites "[a]n anti-infective composition for treating bacterial infections comprising the mixture of claim 1." Appeal Br. 13, 1 (Claims App'x.). Petitioner argues that *Natural Alternatives* holds that natural products "directed to specific treatment formulations that incorporate natural products" are patentable. *Id.* at 11. We are not persuaded. As observed by the Examiner, claim 16 recites an intended use for treating bacterial infections, but lacks any limitation to distinguish it from claim 1 such as a concentration level of the respective HMOs.

CONCLUSION

The Examiner's rejection is AFFIRMED.

DECISION SUMMARY

The following table summarizes our decision:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1–3, 8, 16	101	Eligibility	1–3, 8, 16	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED