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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK W. ESHOO and CURTIS PHILLIPSON

Appeal 2017-003234
Application 13/340,962
Technology Center 1600

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and as directed to non-statutory subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We Affirm.

STATEMENT OF CASE

According to the Specification, polyadenylate (poly A) is used in the biotechnology industry in various buffers and as a carrier in DNA and RNA extractions. According to the Specification "[c]ommercial preparations of nucleic acid-free preparations of polyadenylic acid are not currently available." Spec. 1.

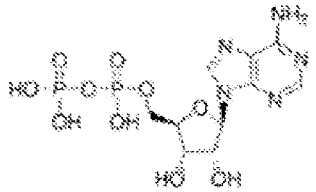
The following claim is representative.

1. A composition comprising or consisting essentially of:
a) polynucleotide phosphorylase;
b) unlabeled adenosine di phosphate (ADP) molecules present at a concentration between 30.0 mM and 100 mM, wherein each of said unlabeled ADP molecules consist of the following structure:

c) a buffering agent with a pH between 7.3 and 8.3; and
d) a divalent metal cation; and
wherein said composition is free of detectable contaminating nucleic acid.

6. The composition of Claim 1, wherein said ADP is present at a concentration between 30.0 mM and 50 mM.

8. A method of making unlabeled polyadenylic acid comprising:
a) combining polynucleotide phosphorylase, adenosine diphosphate (ADP) molecules, a buffering agent with pH between 7.4 and 8.3, and a divalent metal cation, to generate a mixture, wherein said unlabeled ADP molecules are present in said mixture at a concentration between 5.0 mM and 100 mM, wherein each of said ADP molecules consist of the following structure:



; and

b) incubating said mixture under conditions such that a composition comprising unlabeled polyadenylic acid molecules is generated, wherein said unlabeled polyadenylic acid molecules each consist of a plurality of adenylic acid residues, wherein said incubating is conducted for 100 hours to 150 hours at said pH between 7.4 and 8.3, and wherein said composition is free of detectable contaminating nucleic acid.

22. The method of claim 8, wherein said combining comprises a single reaction mixture.

Cited Reference

De Lassauniere	US 4,927,755	May 22, 1990

Grounds of Rejection

1. Claims 1, 3–8, 11, and 14–22 are rejected under pre-AIA 35 U.S.C. § 102(b) as being anticipated by De Lassauniere.
2. Claims 1, 3–8, 11, 12, and 14–22 are rejected under pre-AIA 35 U.S.C. § 101, as directed to a judicial exception without more.

FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Answer at pages 2–8.

PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427

(Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997).

Anticipation Rejection

The Examiner finds that De Lassauniere teaches each element claimed. In particular, the Examiner finds that

> De Lassauniere et al. teach a composition or a system of claims 1, 3-7 and 19-20 comprising or consisting essentially of:
> a) polynucleotide phosphorylase (see col. 3, line 55-59);
> b) unlabelled adenosine diphosphate (ADP) present at a concentration between 30.0 mM and 100 mM (see col. 3, line 61-62, indicating 0.06mM);
> c) a buffering agent with a pH 7.4 -8.3 (see col. 3, line 62-68); and
> d) a divalent cation (MgCh), wherein the composition is free of detectable contaminating nucleic acid (see col. 3, line 66).

Final Act. 4.

Appellants contend that[1]:

1) De Lassauniere does not teach or suggest a method comprising a single reaction mixture of claim 22. App. Br. 9.
2) De Lassauniere does not teach or suggest a method comprising incubation for 100 to 150 hours at a pH between 7.3 and 8.3 (claims 1, 8, and 19). App. Br. 10.

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[1] Emphasis omitted.

3) De Lassauniere does not teach or suggest a composition in which ADP is present at a concentration between 30.0 mM and 50 mM (claim 6). App. Br. 11.
4) De Lassauniere does not teach or suggest compositions, systems or methods of making unlabeled polyadenylic acid that is free of detectable contaminating nucleic acid. App. Br. 12.

The issue is: Does De Lassauniere teach each and every element claimed?

ANALYSIS

We agree with the Examiner's fact finding, statement of the rejection and responses to Appellants' arguments as set forth in the Answer. We find that the Examiner has provided evidence to support a prima facie case of anticipation of all separately argued and rejected claims, except claim 6. We provide the following additional comment to the Examiner's argument set forth in the Final Rejection and Answer.

Single reaction mixture

With respect to Appellants' argument 1 concerning the single reaction mixture of claim 22, the Examiner found Appellants' arguments unpersuasive because

> adding additional components to the initial reaction mixture do not exclude any component of the reaction mixture in the final reaction mixture and the *final reaction mixture represents a single reaction mixture.* Further, the claim 22 is in 'comprising' open language format and according to MPEP 2111.03 any unrecited additional steps or elements are within the scope of the claims. Thus the additional steps of adding the components to the same reaction

> mixture as taught by De Lassauniere are within the scope of the claim 22.

Ans. 7; emphasis added.

On pages 9–10 of the Brief, Appellants reproduce the method of De Lassauniere, highlighting its multiple steps. A similar step highlighting treatment is applied below to the description of Appellants' method, as reproduced from pages 3–4 of the Specification, Example 1. (Emphasis added).

> This Example describes an exemplary method for making polyadenylic acid using an IV bag. First, each lg vial of ADP used is reconstituted with 4ml of water to bring it up to a 250mg/ml solution. Next, the following amounts of **reagents are injected into a 500ml IV bag** to produce a reaction buffer: 20ml of250mg/ml ADP, 25ml of IM Tris, pH 8.0, 5ml of IM MgCb, and 450ml of Water. The solution is **then gently mixed** by swir 1 ing the bag. The solution can then be **passed through a filter** (e.g., a 0.2 um filter) and **transferred to a new IV bag**, while **discarding the first 50 ml of the filtrate**. A syringe is then used to **inject an amount of polynucleotide phosphorylase equivalent to 189Us**. The solution is then **mixed gently on a rocker** for about one hour at room temperature. The solution is then **incubated at 42C** for about 120 hours. The solution is **mixed daily** by gently inverting the bag three times. This method will generate polyadenylic acid that is free from contaminating nucleic acid. The polyadenylic acid generated may be tested and recovered as follows. A small amount of the final solution (e.g., 0.5 ml) may be **run on a 1 % agarose gel** to ensure that the reaction has gone to completion. Next, obtain 2 **Amicon filters and to each one add 15,000 ul of2M KCL Centrifuge tubes** for 10 minutes at 3000 rpm. Carefully pool KCl filtrate into a fresh, UV-treated 50 ml conical tube. Using a syringe, remove approximately 22.7 ml of poly-A solution from the IV bag and pour into a UV-treat 50ml conical tube. **Repeat until all of the solution has been dispensed into conical tubes.** Add 2.5 ml of filtered KCl to each tube of a poly-A solution, and 22.5 ml of 100% isopropanol. **Cap each tube and mix by**

> **inversion**. **Centrifuge tubes** at 3000 rpm for 10 minutes. Carefully remove supernatant by pouring off. Let sit right side up for 2 minutes, then pipette out any remaining isopropanol. Let sit inverted on a kimwipe or blotting paper equivalent for 2-3 minutes to generate a dried pellet. **The dried pellet from each tube may be resuspended** in 2 ml dilution buffer and then all the samples may be pooled.

Appellants have not explained why adding additional components to the initial reaction mixture in multiple steps in De Lassauniere does not disclose a single reaction mixture, as claimed. The rejection of claim 22 is affirmed for the reasons of record.

pH

Claim 1 requires the presence of a *buffering agent* with a pH between 7.3 and 8.3. No other pH is recited in claim 1. Appellants also argues that De Lassauniere does not teach or suggest a method comprising incubation for 100 to 150 hours at a pH between 7.3 and 8.3 (claims 1, 8, and 19). App. Br. 10.

We are not persuaded by Appellants' arguments. De Lassauniere discloses at lines 60-65 the preparation of ADP polymers using Tris HCl pH 8.3 and EDTA pH 8.0. Thus, De Lassauniere discloses a buffering agent with a pH, as claimed. Furthermore, De Lassauniere discloses optimal conditions for polynucleotide polymerization are pH 8.0 to 8.3. Col. 4, ll. 32–33.

With respect to the claimed incubation times, Examiner further finds that

> De Lassauniere disclosure discloses pH ranges between *7.4 and 8.6* and duration of incubation as 3 to 6 days (*72 hrs to 144 hrs*) (see at least col. 2, line 15-25 and claims 1-2 on col. 6), which is within the scope of the instant claims. With reference to adjusting pH of the reaction mixture it is noted that the pH drops to 8.3 after 24 hours, however, *the pH is thereafter maintained at 8.0 to 8.3* by the addition of 5N. NH_4OH. With reference to the incubation period of 3 to 4 days the cited portion teaches that at the end of 3-4 days 80-90% polymerization rate occurs, as opposed to the actual incubation period (3 to 6 days). The rejection is based on the entire disclosure of *De Lassauniere and as discussed above the disclosure teaches pH range 7.4 to 8.6* and the duration of incubation range from 3 to 6 days (72 hours to 144 hours), which are within the scope of the instant claims as presented. With reference to the arguments to the claim 6, drawn to no teaching of the concentration of ADP, the arguments were found unpersuasive. De Lassauniere teaches ADP concentration as 100g in the total reaction mixture, which is within the range of the concentration of ADP claimed (between 30mM and 50mM).

Ans. 7–8; emphasis added. In addition, anticipation has been found even when a prior art range "does not exactly correspond to [the] claimed range," but the prior art "range entirely encompasses, and does not significantly deviate from, [the] claimed ranges." *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (court found that a claimed range of 0.025 to 5% did not significantly deviate from a prior art range of 0.01 to 20%).

In the present case, we find, as did the Examiner, that De Lassauniere discloses a buffering agent with a similar pH in a similar composition, and incubation times, as claimed. We note that claim 1 does not include a limitation for any particular incubation times. The anticipation rejection of claim 1 is affirmed.

With respect to the incubation pH of claim 8, De Lassauniere discloses optimal conditions for polymerisation are pH 8.0 to 8.3. Col. 4, ll. 32–33. The anticipation rejection of claim 8 is also affirmed.

Concentration - claim 6

Appellants contend that De Lassauniere does not teach or suggest a composition in which ADP is present at a concentration between 30.0 mM and 50 mM (claim 6). App. Br. 11. Appellants state that the lowest ADP concentration described by De Lassauniere is 60 mM. App. Br. 11. The Examiner finds that De Lassauniere discloses unlabelled adenosine diphosphate (ADP) present at a concentration between 30.0 mM and 100mM (*see* col. 3, ll. 61–62, indicating 0.06mM). We do not find that the Examiner has provided anticipatory evidence of a concentration between 30.0 mM and 50 mM (claim 6).[2]

The anticipation rejection of claim 6 is reversed.

[2] We note that the Examiner did not address this claim using an obviousness analysis.

Free of contaminants

Appellants contend that De Lassauniere does not teach or suggest compositions, systems or methods of making unlabeled polyadenylic acid that is free of detectable contaminating nucleic acid. App. Br. 12. Appellants argue that, "De Lassauniere provides a process that expressly comprises contaminating 'traces of substances'." (De Lassauniere, col. 1, line 67 - Col. 2, line 2.) App. Br. 13.

The Examiner finds that

> The disclosure of De Lassauniere teach toxicity testing or pyrogenecity of the polynucleotides in rats and found fully negative results. Further, on col. 5, line 27-34, De Lassauniere teaches that the polymers (poly A or poly U) and copolymers (polyA-polyU complex) made are substantially purified products. For all the above the disclosure of De Lassauniere anticipates the claims.

Ans. 9. We find that the Examiner has provided prima facie anticipatory evidence of the claimed product free of contaminants. While Appellants argue that De Lassauniere products contain contaminating trace substances, Appellants provide no evidence to support this argument. Attorney argument cannot take the place of evidence. *In re DeBlauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

Moreover, De Lassauniere specifically states that the trace contaminants are "devoid of action on the further polymerisation process." Col. 1, l. 67-col. 2, l. 2. Appellants have not shown with appropriate evidence, that any trace contaminants in the compositions of De Lassauniere affect the purity or function of the final product. De Lassauniere's method of preparing the polyA composition is conducted at similar temperatures for similar incubation times. Appellants have not shown that any differences in

the method of preparing the claimed composition result in a different product.

> Where, as here, the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977). Appellants have not satisfied their burden to rebut the Examiner's finding with evidence on this record.

The anticipation rejection is affirmed for the reasons of record.

35 U.S.C. § 101

The Examiner finds that

> The claims set forth[,] recite a *composition* comprising or essentially consisting of polynucleotide phosphorylase and unlabeled adenosine diphosphate, as written, represent [a] law of nature (judicial exception). The claims, as a whole is [sic] analyzed to determine whether any element or a combination of elements, is sufficient to ensure that the claims amount to significantly more than the exception and the claims do not particularly point out any non-naturally occurring differences between the claimed composition and the law of nature. The additional components as presented do not recite "significantly more" than a law of nature. The additional elements or steps (buffering agent, pH, $Mgcl_2$,) are not themselves law of nature, but neither are they sufficient to transform the nature of the claims because they consist of well-understood, routine, conventional activity already engaged in by the scientific community. The additional elements consist of well-understood, routine, conventional activity already engaged in by the scientific community. The additional

> elements or steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Final Act. 6; emphasis added.

Appellants contend that

> because polynucleotide phosphorylase, unlabeled adenosine diphosphate, a buffering agent with a pH between 7.3 and 8.3, and a divalent metal cation do not occur together in nature, and do not occur in nature where a composition or system is free of detectable contaminating nucleic acid, there is no naturally occurring counterpart mixture for comparison. Moreover, mixing these components clearly changes the structure of the components, for example, from ADP to polyadenylic acid. As well, a chemical reaction clearly occurs between the claimed components with a changed structure and property that is different from the mere sum of the components. The altered structure and properties of polyadenylic acid are marked differences in characteristics from the claimed components. Thus, the claimed compositions and systems are not a "law of nature" or "product of nature" exception. Because the claimed compositions and systems are not a "law of nature" or "product of nature" exception, there is no need to evaluate the "significantly more" considerations for the claims.

App. Br. 16.

We find that the Examiner has established a prima facie case for lack of patentable eligible subject matter for composition claim 1 and system claim 19. We do not find that, on balance, the Examiner has provided sufficient evidence to support a prima facie case of lack of patentable eligible subject matter for method claim 8 and its dependent claims.

It has been established that "while a claim drawn to a fundamental principle"—i.e., a law of nature, natural phenomenon, or abstract idea—"is unpatentable, 'an application of a law of nature or mathematical formula to a

known structure or process may well be deserving of patent protection.'" *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008) (quoting *Diehr*, 450 U.S. at 187). The key issue for patentability, then, at least on the present facts, is whether a claim is drawn to a fundamental principle or an application of a fundamental principle. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1342 (Fed. Cir. 2009). The Supreme Court has also made clear that the patent eligibility of a claim as a whole should not be based on whether selected limitations constitute patent-eligible subject matter. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010), (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

In analyzing patent eligibility questions under 35 U.S.C. § 101, the Supreme Court instructs us to "first determine whether the claims at issue are directed to a patent-ineligible concept." *Alice Corp. Pty Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). If this threshold is met, we move to a second step of the inquiry and "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012); *see also* "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products," (Guidance) issued by the U.S. Patent and Trademark Office, March 2014.

Claims 1, 19 - *Step One*

Taking up the first step of the patent-eligibility analysis, we find that the Examiner has established that claim 1 is directed to a law of nature or

natural phenomenon. Looking to the Specification to enlighten us as to the claimed invention, as did the Federal Circuit in *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016), we find that the Specification discloses composition and system claims 1 and 19 which are directed to a composition or mixture of polynucleotide phosphorylase; unlabeled adenosine diphosphate (ADP) molecules, a buffering agent and a divalent metal cation, wherein the composition is free of detectable contaminating nucleic acid. Spec. 1. The Examiner finds that, the claims recite a composition which is essentially polynucleotide phosphorylase and unlabeled adenosine diphosphate, and, as written, represent law of nature or natural phenomenon (judicial exception), without significantly more. Final Act. 6.

We are not persuaded by Appellants' argument that the claims recite a mixture not found in nature. For example, nucleotide polymers (DNA, RNA, mRNA) are well known in the art. It is also well known that polynucleotide phosphorylase synthesizes long, highly heteropolymeric tails in vivo. Polynucleotide phosphorylase accounts for all of the observed residual polyadenylation in strains of *Escherichia coli* missing the normal polyadenylation enzyme.[3] Thus, it is well known to those of ordinary skill in the art that polyadenylation occurs in vivo in nature (in *E. Coli*) through the action of a mixture of a nucleotide and polynucleotide phosphorylase. The Examiner further finds that the additional elements in claims 1 and 19, that is the

(buffering agent, pH, Mgcl2,) are not themselves law[s] of nature, but

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[3] https://en.wikipedia.org/wiki/Polynucleotide_phosphorylase

> neither are they sufficient to transform the nature of the claims because they consist of well understood, routine, conventional activity already engaged in by the scientific community. The additional elements consist of well-understood, routine, conventional activity already engaged in by the scientific community.

Final Act. 6. "Laws of nature and natural phenomena, as identified by the courts, include naturally occurring principles/substances and substances that do not have markedly different characteristics compared to what occurs in nature."[4] "When there is no naturally occurring counterpart to the nature based product, the comparison should be made [by the Examiner] to the closest naturally occurring counterpart. In the case of a nature-based combination, the closest counterpart may be the individual nature-based components that form the combination, i.e., the characteristics of the claimed nature-based combination are compared to the characteristics of the components in their natural state."[5] "In accordance with this analysis, a product that is purified or isolated, for example, will be [patent] eligible when there is a *resultant change in characteristics sufficient to show a marked difference* from the product's naturally occurring counterpart."[6] Emphasis added.

In the present case, Appellants have not shown that the purity of the claimed mixture results in a change in characteristics sufficient to show a marked difference in structure or function from the product's naturally

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[4] 2014 Interim Guidance On Patent Subject Matter Eligibility, 70 Federal Register 74618 (December 16, 2014), at 74622 § (I)(2).
[5] 2014 Interim Guidance On Patent Subject Matter Eligibility, 70 Federal Register 74618 (December 16, 2014), at 74623 § (I)(3)(b).
[6] *Id.*

occurring counterpart. Nor have Appellants shown that the additional claim limitations are not well-understood, routine and conventional in the field. A claim that recites a law of nature or natural correlation, with additional elements that involve well-understood, routine, conventional activity previously engaged in by researchers in the field is not patent-eligible, regardless of whether the steps result in a transformation. See, *Mayo Collaborative Services v. Prometheus Laboratories*, Inc., 132 S.Ct. 1289, 1290 (2012). De Lassauniere evidences that the additional components are conventional purification ingredients. Final Act. 4.

We also do not find any principled difference between the claim to an isolated nucleic acid encoding the BRCA1 polypeptide in *Myriad* and the instant claim 1 drawn to an isolated ADP with buffers in particular amounts. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2113, 2117 (2013). As in *Myriad*, Appellants did not create or alter the ADP molecules, and the ADP molecules existed in nature before Appellants' isolated them. At best, Appellants' contribution was obtaining this natural product. However, claims 1 and 19 are not drawn to methods of making ADP, but rather are drawn to the ADP product itself.

Like *Myriad* and *Funk Brothers*, and unlike *Chakrabarty*, the ADP composition of claim 1 was not a creation of Appellants, but rather a product of nature. And there is nothing markedly different between the ADP composition of claim 1 and the natural product other than purification and mixture with buffers. But separating the ADP from the natural source is not an act of invention. *See Myriad*, 133 S.Ct. at 2117; *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

The rejection of claims 1 and 19 for lack of patent-eligible subject matter is affirmed.

Claim 8

Method claim 8 is included in the lack of patent eligible subject matter rejection. The Examiner does not separately or specifically reference the separately argued (App. Br. 17) method claim 8 limitations. Claim 8 is directed to a method of making unlabeled polyadenylic acid. The Examiner has the burden, in the first instance of establishing a prima facie case of lack of patent eligible subject matter. We find that the Examiner has not established a prima facie case that method claim 8, falls within a judicial exception to patentable subject matter.

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," citing *Diehr*, 450 U.S. at 188). *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1298 (2012). We find that the Examiner has not established that the method steps within the scope of method claim 8, when read as a whole, ordered combination, is directed to patent ineligible subject matter. The lack of patent eligible subject matter rejection of claim 8 is reversed.

CONCLUSION OF LAW

The cited reference supports the Examiner's anticipation rejection of claims 1, 3-5, 7-8, 11, and 14-22 is affirmed. The anticipation rejection of claim 6 is reversed. The lack of patent eligible subject matter rejection of

composition claim 1 and system claim 19 is affirmed. Claims 3-7 and 18-21 fall with claims 1 and 19. The lack of patent eligible subject matter rejection of method claim 8 is reversed.

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

AFFIRMED