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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581336
MINNEAPOLIS, MN 55458-1336

EXAMINER	
KELLER, CHRISTOPHER A	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DANIEL G. ERICSON[1]

Appeal 2015-002998
Application 13/028,819
Technology Center 1600

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims directed to a blood storage and/or rejuvenating composition. Claims 1–7, 10–17, and 38–40 are on appeal as rejected under 35 U.S.C. §§ 101 and 103(a), and under the doctrine of obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] We understand the Real Party in Interest to be Viacell, LLC. App. Br. 1.

STATEMENT OF THE CASE

The appealed claims can be found in the Claims Appendix of the Appeal Brief. Claims 1, 7, and 17 are the independent claims and read as follows:

> 1. A blood storage and/or rejuvenating composition comprising a nucleoside and D-ribose, with the proviso that the nucleoside is not inosine.
>
> 7. A blood storage and/or rejuvenating composition comprising 75 to 1500 mM guanosine and 75 to 1500 mM D-ribose.
>
> 17. A blood storage and/or rejuvenating composition comprising:
>
> 225 mM guanosine;
>
> 300 mM D-ribose;
>
> 300 mM sodium pyruvate; and
>
> 300 mM inorganic phosphate.

App. Br. 14–15 (Claims App'x).

The following rejections are on appeal:

Claims 1–7, 10–17, and 38–40 stand rejected under 35 U.S.C. § 101 as not directed to patent eligible subject matter. Ans. 7.

Claims 1–7, 10–13, 17 and 38–40 stand rejected under 35 U.S.C. § 103(a) over Prankerd,[2] Johnson,[3] and Medical Dictionary.[4] Rejection 3.[5]

Claims 14–16 stand rejected under 35 U.S.C. § 103(a) over Prankerd, Johnson, and Kurauchi.[6] Rejection 6.

Claims 7 and 10–17 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1–6 and 10–16 of '542 Patent,[7] Simon,[8] and Kurauchi. Rejection 7.

DISCUSSION

The rejection of claims 1–7, 10–17, and 38–40 under 35 U.S.C. § 101.

The Examiner determined that "the claims are drawn to a law of nature," or, in other words, "[t]he claimed composition is considered a 'Product of Nature' in accordance with" the Supreme Court's opinions in

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[2] T.A.J. Prankerd M.D., *Revival of Stored Blood with Guanosine*, 267 THE LANCET 469–471 (1956) (hereinafter "Prankerd").
[3] International Patent Application Pub. No. WO 2004/105483 A1 (published Dec. 9, 2004) (hereinafter "Johnson").
[4] *Pyruvate*, The Free Online Medical Dictionary (http:// medical-dictionary.thefreedictionary.com/pyruvate, visited June 26, 2012) (hereinafter "Medical Dictionary") (citing, *inter alia*, JONAS MOSBY'S DICTIONARY OF COMPLEMENTARY AND ALTERNATIVE MEDICINE (2005)).
[5] The appealed office action is the Non-Final Action dated Dec. 4, 2013 (hereinafter "Rejection").
[6] U.S. Patent Application Pub. No. US 2004/0192553 A1 (published Sept. 30, 2004) (hereinafter "Kurauchi").
[7] U.S. Patent No. 8,980,542 B2 (issued Mar. 17, 2015; formerly copending Application No. 13/028,856) (hereinafter "'543 Patent").
[8] E.R. Simon, *Adenine and Purine Nucleosides in Human Red Cell Preservation: A Review*, 7 TRANSFUSION 395–400 (1967) (hereinafter "Simon").

Myriad and *Prometheus*. Ans. 8; *see Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012). The Examiner determined that "all the components of the composition are natural products" and "the use of the compositions [does] not change the structure of the composition such that it differs from a product of nature. *Id.*

On issues of patent eligibility, 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 the 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 *Prometheus*, 132 S. Ct. at 1297–98).

Appellant argues, "[a]lthough both D-ribose and a nucleoside that is not inosine (e.g., guanosine) might arguably be considered as natural products, the Examiner has provided no evidence that a composition comprising both D-ribose and a nucleoside that is not inosine (e.g., guanosine) occurs in nature." Reply Br. 3. Taking up the first step of the Alice-patent-eligibility analysis, we find the claims are directed to a product of nature. As in *Funk Bros.* (and similar to *Myriad*), the claimed invention combines naturally occurring biological chemicals, here a nucleoside and D-ribose, and does not change them in any way other than purification. *See Myriad*, 133 S. Ct. at 2117 (discussing *Funk Bros. Seed Co. v. Kalo*

Inoculant Co., 333 U.S. 127, 130–32 (1948)). For this reason, we are constrained to find the patent-ineligibility exception threshold met.

Turing to the second step under *Alice*, we review the claims to ascertain whether the product of nature has been sufficiently transformed, or in the terminology of *Chakrabarty*, ultimately possess "markedly different characteristics from any found in nature," so as to become patent eligible. *See Alice*, 134 S. Ct. at 2355; *see also Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980). "The [Supreme] Court has recognized [] that too broad an interpretation of th[e] exclusionary principle could eviscerate patent law [because] all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Prometheus*, 132 S. Ct. at 1293. The claims here are drawn to a composition and that is the focus of our inquiry.

From the record on appeal, we find neither the Examiner nor Appellant has discussed or identified how the recited D-Ribose or nucleosides function in nature, either independently or in combination. We understand D-Ribose is a carbohydrate and is the naturally-occurring enantiomeric form of ribose, and is a molecule related to deoxyribose, found in DNA. Phosphorylated derivatives of ribose, e.g., ATP and NADH, are involved in metabolism. We understand nucleosides are combinations of a nitrogenous base and 5-carbon sugar molecules, such as ribose or deoxyribose, and can be phosphorylated to produce nucleotides and are, in this way, the molecular foundation of DNA and RNA.

The Examiner determined that the claims do not recite anything markedly different from the naturally occurring components. Ans. 9. We

must agree. The claim language, "[a] blood storage and/or rejuvenating composition," defines how the claimed composition functions, but imposes no structural limitations on the claimed composition. Upon reviewing the appealed claims in view of the Specification, Appellant's invention relates to the recognition that "a pentose carbohydrate (e.g., D-Ribose) [] can serve to aid *de novo* synthesis and metabolic salvage of purine nucleotides including ATP," and that a non-inosine nucleoside can "reduce the breakdown products produced by inosine, and can further enhance RBC ATP content." *See* Spec. 6:29–7:7. Here, the invention is a composition specifically combining these two components, which has the (apparently natural) ability to increase blood's 2,3-DPG value[9] and, thereby, impart improved blood storage and/or blood rejuvenation qualities. *See* Spec. 12:12–17.

There is no evidence of record that the two recited components function differently in the claimed composition than they function, either independently or in combination, in nature. Like the facts of *Funk Bros.* (where the inventor combined naturally occurring and non-cross-inhibiting bacteria for their natural legume inoculation functionality), and unlike the facts of *Chakrabarty* (where the inventor created a genetically modified bacteria capable of breaking down crude oil components), the evidence supports that the inventor here has done nothing more than bring together natural components in an unique package. And *Myriad* expressly teaches

[9] 2,3-DPG stands for the marker 2,3-diphosphoglycerate, which characterizes a storage lesion on red blood cells (RBCs) and is found to decrease after the separation of blood components; this decrease in 2,3-DPG indicates an increase in the production of oxygen free radicals and a change in RBC morphology. Spec. 2:23–26.

that purification "is not an act of invention" and that claims are not necessarily statutory even if isolation "severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Myriad*, 133 S.Ct. at 2117–2118. The inventor has selected and paired natural biological chemicals, but has not changed any characteristic thereof from what they would have been in nature. Thus, the inventor does not claim significantly more than the product of nature and the claims fail under the second *Alice* step.

For the reasons above, we find the preponderance of the evidence supports the Examiner's determination that the claims are patent ineligible and we affirm the rejection.

The rejection of claims 1–7, 10–13, 17 and 38–40 under 35 U.S.C. § 103(a) over Prankerd, Johnson, and Medical Dictionary.

Regarding the obviousness rejections, we adopt the Examiner's findings of fact, reasoning on scope and content of the prior art, and conclusions set out in the Final Action and Answer. The Examiner has established a prima facie case for obviousness and Appellant's arguments have not persuaded us that this case for obviousness is not correct. Any findings of fact set forth below are merely to highlight certain evidence. We address Appellant's arguments below.

Appellant argues the obviousness rejection should be reversed because the Examiner used the language "as evidenced by" when referring to the disclosure of the Medical Dictionary because such language is only appropriate for an anticipation rejection. App. Br. 5. We are not persuaded. Appellant was well apprised of the substance of and rationale for the

obviousness rejection, regardless of the language used. *See* Rejection 3–6. Moreover, Appellant's contention regarding the timing of the cited prior art disclosure and argument that obviousness must be predicated on what was known at the time of invention (App. Br. 5) is also not persuasive because the cited Medical Dictionary disclosure regarding the definition of pyruvate refers to a 2005 reference (*see* fn.4, *supra*) and the definition was known as of the date of invention.

Appellant argues Prankerd does not disclose including sodium pyruvate, inorganic phosphate, or D-ribose in its blood storage/restoring composition. App. Br. 6. Appellant argues that, even if Prankerd did disclose D-ribose, its presence in the composition could not be interpreted as a blood storage and/or rejuvenating composition including D-ribose. *Id.* 6–7. Appellant argues that Prankerd's disclosure of ribose phosphate in its composition is not a D-ribose molecule. *Id.* 8. Appellant argues that Prankerd also does not disclose guanosine in a relevant composition. *Id.*

Moving on to the Johnson reference, Appellant argues that it fails to teach or suggest compositions including a nucleoside such as guanosine, and for this reason, the skilled artisan would not combine it with Prankerd. *Id.* 8–9. Appellant also argues that while Johnson discloses blood storage/rejuvenating compositions including D-ribose, phosphoenolpyruvate (pyruvate), and sodium phosphate buffer, it fails to disclose all three in one composition and, so, cannot be relied upon to modify Prankerd. *Id.* 9. Finally, Appellant argues Johnson teaches away from using D-ribose in the invention because it discloses that ribose can be an energy source and

theoretically regenerates ATP, while Prankerd suggests that adding ATP is not required because of its own inclusion of a nucleoside. *Id.* 9–10.

None of Appellant's arguments are persuasive. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). When determining obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

Here, the combined Prankerd and Johnson references disclose each element of claims 1, 7, and 17, that is a nucleoside (specifically guanosine) and D-Ribose, and in the case of claim 17, also sodium pyruvate and inorganic phosphate, and they each teach that these components are used for the very same purpose as in the appealed claims: "a practical and simple means of increasing the optimal storage time of blood," per Prankerd; and "to extend function [of whole blood or packed red cells] in storage," per Johnson. Prankerd 469 (left col.); Johnson Abstract, 4:26–29, 8:17–22,

8:26–30, 11:11–28. As the Examiner determined, Prankerd also disclosed using ribose to rejuvenate red blood cells. Ans. 13. It would have been obvious to combine the disclosures of Prankerd and Johnson for a blood storage improving composition.

Claims 7 and 17, beyond reciting the components for the blood storage composition, further recite quantities or concentrations thereof. However, this is not a patentable distinction.

"[I]t is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955); *see also In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003). "Only if the 'results of optimizing a variable' are 'unexpectedly good' can a patent be obtained for the claimed critical range." *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (quoting *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977)). "[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). Appellant's arguments fail under these tests. Appellant has not presented persuasive evidence that the quantity/concentration elements of the claims were unexpectedly good or critical and we are not persuaded that they amount to more than routine optimization.

Finally, Johnson does not teach away from the invention or its combination with Prankerd.

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it

> suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.

In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, both Prankerd and Johnson provide the various components recited by the claims to the same end, that is, to support stored blood. Johnson suggests D-ribose is added as a substitute for dextrose, the energy source for blood stored in CPD or CDPA, and may be an energy source for glycolysis and for regeneration of ATP. Johnson 7:18–19. According to Prankerd, ATP is not needed with the ribose of the nucleoside; however, Prankerd does not indicate that an energy source or ATP generation is not needed at all in blood storage or blood rejuvenation. Thus, there is no direct teaching away from the combination of these references.

For the above reasons, we find that the preponderance of evidence of record supports the Examiner's determination that the claims would have been obvious. We affirm the rejection.

The rejection of claims 14–16 under 35 U.S.C. § 103(a) over Prankerd, Johnson, and Kurauchi.

Appellant presents no arguments concerning this rejection different from those presented for the prior rejection, other than Kurauchi "fails to provide that which is missing from Prankerd in view of Johnson." App. Br. 11. For the same reasons set forth above concerning the prior obviousness rejection, we affirm this rejection as well.

The rejection of claims 7 and 10–17 on the ground of nonstatutory obviousness-type double patenting.

Because Appellant presents no arguments pertaining to the Examiner's double patenting rejection (App. Br. 12), we summarily sustain the rejection. *See* MPEP § 1205.02, 9th ed., Rev. 7, Nov. 2015.

SUMMARY

The rejection of claims 1–7, 10–17, and 38–40 under 35 U.S.C. § 101 is affirmed.

The rejection of claims 1–7, 10–13, 17, and 38–40 under 35 U.S.C. § 103(a) over Prankerd, Johnson, and Medical Dictionary is affirmed.

The rejection of claims 14–16 under 35 U.S.C. § 103(a) over Prankerd, Johnson, and Kurauchi is affirmed.

The rejection of claims 7 and 10–17 on the ground of nonstatutory obviousness-type double patenting over claims 1–6 and 10–16 of '542 Patent, Simon, and Kurauchi is affirmed.

The claims were argued as a group, therefore all claims fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

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).

AFFIRMED