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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREW FRANCIS PAGE and BRECK OLLAND PARKER

Appeal 2019-000231
Application 13/519,391
Technology Center 1600

Before ULRIKE W. JENKS, TIMOTHY G. MAJORS, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from Examiner's decision to reject claims 1–4 and 7–9. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as GE Healthcare Bio-Sciences Corp. Appeal Br. 2.

STATEMENT OF THE CASE

Claims 1–4 and 7–9 are on appeal, and can be found in the Claims Appendix of the Appeal Brief.² Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A solid matrix for storage of purified nucleic acid, wherein the matrix is impregnated with inulin.

Appeal Br. 12

REFERENCE(S)

The prior art relied upon by Examiner is:

Name	Reference	Date
Burgoyne	US 5,496,562	March 5, 1996
Chomczynski	US 2006/0147944 A1	July 6, 2006
Cormier et al. ("Cormier")	WO 2005/042702 A2	May 12, 2005
Kravchenko et al., <i>Preservation of Nucleic Acid Integrity in Guanidine Thiocyanate Lysates of Whole Blood</i> , 32 Russian Journal of Bioorganic Chemistry 547–51 (2006) ("Kravchenko")		

REJECTION(S)

Appellant requests review of the following grounds of rejection made by Examiner:

- I. Claims 1, 3, 8, and 9 under 35 U.S.C. § 103(a) as unpatentable over Burgoyne in view of Kravchenko and Cormier.
- II. Claims 2, 4, and 7 under 35 U.S.C. § 103(a) as unpatentable over Burgoyne, Kravchenko, and Cormier and further in view of Chomczynski.

² In this opinion we refer to the corrected Appeal Brief filed May 2, 2018 ("Appeal Br.").

I. Obviousness over Burgoyne, Kravchenko, and Cormier

The issue is does the preponderance of evidence of record support Examiner’s conclusion that a nucleic acid storage matrix impregnated with inulin is obvious?

Findings of Fact

FF1. Burgoyne teaches:

Transport of blood DNA as dried, purified DNA is most desirable, but it requires a high standard of technical assistance to be available at the places of collection. . . .
Transport of liquid blood involves the need for sterility of collection and . . . [t]he transport of liquid blood or frozen blood also demands temperature control and an appropriate transport system other than the regular postal system.

Burgoyne 1:40–52. “Blood dried onto filter paper is a proven alternative . . . and it has been shown that DNA can be extracted and isolated from dried whole blood spots.” *Id.* at 1:58–60.

FF2. Burgoyne teaches a solid support medium for storage of DNA.

Burgoyne, Abstract. Solid support includes cellulose-based paper or a micromesh of synthetic plastics material. *Id.* at 2:21–23.

FF3. DNA samples applied to Burgoyne’s solid support include blood (*id.* at 4:41–42) as well as plasmids or other viral replicating forms (*id.* at 4:61–62).

FF4. Burgoyne teaches that the solid support contains a DNA-protecting compound that is absorbed onto the solid support. *Id.* at 2:24–25.

Burgoyne teaches that “for long[-]term storage of purified DNA, the DNA-protecting compound or composition comprises uric acid,

- together with a weak base to convert the uric acid to a urate salt and to provide an alkaline pH between 8.0 and 9.5.” *Id.*, *see id.* at 2:65–67.
- FF5. Burgoyne teaches that paper treated with DNA-protecting compound allowed for the recovery of 100% transformationally active DNA. *See id.* at 6:9–20.
- FF6. Cormier teaches “compositions for stabilizing dried nucleic acids with carbohydrates such as non-reducing sugars, polysaccharides, and reducing sugars.” Cormier, Abstract. Cormier teaches “methods for retarding the degradation of dried nucleic acids that comprise mixing the nucleic acid with one or more stabilizing agents and one or more surface active agents and dry coating the mixture onto a solid substrate.” *Id.* ¶ 81.
- FF7. Cormier teaches that the “stabilizing agent is preferably selected from the group consisting of dextran, soluble starch, dextrin, and inulin.” *Id.* ¶ 20, *see also id.* 28, claims 1 and 7.
- FF8. Kravchenko teaches that the use of guanidine thiocyanate allows for the retention of RNA and DNA integrity upon storage. Kravchenko Abstract, *see id.* at 548 (“the samples of whole blood can directly be stored as guanidine thiocyanate lysates . . . and ensures the preservation of RNA and DNA”). Kravchenko teaches that “[g]uanidine thiocyanate is the most potent among known ribonuclease denaturing agents widely used in RNA isolation[.]. Hence, it seemed quite natural to use it for storage of the samples.” Kravchenko 548.
- FF9. Kravchenko teaches storing freshly collected blood in a tube that contains a conserving solution to create a lysate. Kravchenko 550. The

resulting lysate contains “4 M guanidine thiocyanate, 25 mM sodium citrate (pH 7.5), 0.5% sarcosyl, 13 mM EDTA, and 1.3% 2-mercaptoethanol.” *Id.*

Principle of Law

“If the claim extends to what is obvious, it is invalid under § 103.”

KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007).

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) (citations omitted).

Analysis

Burgoyne teaches a nucleic acid storage matrix that is impregnated with a compound that protects the nucleic acid from degradation. FF1–FF5. Examiner acknowledges that the difference between Burgoyne and the present claims is that the claimed composition contains inulin. Ans. 4. Cormier teaches sugars, such as inulin, as nucleic acid stabilizing agents on solid surfaces. FF6–FF7. Kravchenko teaches that guanidine thiocyanate is a known ribonuclease denaturation agent that can be used to store blood and maintains the integrity of nucleic acids, such as RNA and DNA. FF8–FF9.

Applying the guidance set forth in *KSR* to the facts here, we conclude that the ordinary artisan of ordinary creativity familiar with the teachings of nucleic acid stabilization would have selected known equivalent nucleic acid stabilizing agents of Cormier and applied them to the nucleic acid stabilizing

matrix taught in Burgoyne because such a combination is merely a “predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417. We further conclude that the ordinary artisan would have found it obvious to incorporate guanidine thiocyanate, because this compound is taught in Kravchenko to be a nucleic acid stabilizing agent, into the composition of Burgoyne and Cormier in order to further stabilize the nucleic acids and prevent degradation upon storage.

Appellant contends that the cited art is non-analogous art and therefore there is no reason to combine their teachings. *See* Appeal Br. 5–9; Reply Br. 5–8. Specifically, Appellant contends that there is no overlap between Burgoyne and Cormier, and that Kravchenko does not fill the gaps between the other references. Appeal Br. 6; Reply Br. 5. Appellant contends that “the surprising technical effect of inulin, as demonstrated in Table 1 of Appellant’s specification, is to significantly increase the yield of eluted DNA.” Appeal Br. 9; Reply Br. 8. According to Appellant, both Cormier and Burgoyne are silent about elution yields of DNA. Appeal Br. 9; Reply Br. 9.

After considering the evidence and the arguments, we conclude the weight of the evidence favors Examiner’s conclusion of obviousness. Accordingly, we adopt Examiner’s reasoning (*see* Grounds of Rejection, Ans. 3–6), and agree that Examiner properly found Appellant’s arguments unpersuasive (*see* Response to Argument, Ans. 8–35). We provide the following points for emphasis.

We are not persuaded by Appellant’s non-analogous art argument. “Although § 103 does not, by its terms, define the ‘art to which [the] subject matter [sought to be patented] pertains,’ this determination is frequently

couched in terms of whether the art is analogous or not, *i.e.*, whether the art is ‘too remote to be treated as prior art.’” *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992) (citing *In re Sovish*, 769 F.2d 738, 741 (Fed. Cir. 1985)). “Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Id.* at 658–59. Here, Examiner identified that all “the applied references (Burgoyne, Kravchenko and Cormier) disclose teachings directed to DNA” and its desire to maintain the integrity of nucleic acids upon storage. Ans. 14.

For example, Burgoyne disclose a solid medium for storage of DNA, including blood DNA, comprising a solid matrix having a compound or composition which protects against degradation of DNA incorporated into or absorbed on the matrix. And, Kravchenko et al. disclose or suggest that DNA can be preserved and/or stabilized (*i.e.*; retain its integrity) when guanidine thiocyanate (a denaturant). . . . Cormier et al. disclose or suggest that inulin (a preferable polysaccharide) can be used for stabilizing (*e.g.*, retarding the degradation of the nucleic acid) dried nucleic acids (which includes DNA).

Ans. 14; *see* FF1–FF9.

We agree with Examiner’s finding that the cited references are from the same field of endeavor in this case nucleic acid preservation and prevention of degradation of the nucleic acid product. Accordingly, we are not persuaded by Appellant’s contention that the cited art is not analogous.

We are also not persuaded by Appellant’s surprising technical effects argument. *See* Appeal Br. 9; Reply Br. 9. Specifically, Appellant contends that the Specification demonstrates that the use of inulin “significantly

increase[s] the yield of eluted DNA.” Reply Br. 8. Examiner counters that inulin’s effect on increasing yield is expected rather than surprising. *See* Ans. 34. Specifically, Examiner explains that based on the teachings of Cormier,

one of ordinary skill in the art would expect that inulin, the preferred polysaccharide which stabilizes DNA, would significantly increase the yield of eluted DNA since less DNA would be degraded, destabilized or disintegrated and thus more will be present which would result in an increase yield and would therefore also cause or provide an improved storage matrix that increases the percentage of the applied DNA that can be eluted from the solid matrix.

Id. By “stabilizing nucleic acid (which includes DNA) would also significantly increase the collection or yield of eluted DNA and thus the amount or percent of DNA applied.” *Id.* We agree with Examiner that there are at least two ways to increase yield of DNA. One way is to ensure that all DNA that is bound to the solid matrix is also able to elute from the solid matrix. The other way it to prevent DNA from degrading while bound to the solid matrix in order to provide higher yield when it is eluted from the matrix. Thus, the record supports Examiner’s determination that a skilled artisan would expect increased yield of eluted DNA by employing inulin as DNA stabilizing agent as taught in Cormier. FF7.

Insofar that Appellant’s surprising technical effects argument is an unexpected results argument we are also not persuaded. The burden of demonstrating unexpected results rests on the party asserting them. *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). That burden has not been carried here because Appellant has not established that the results achieved using the recited matrix impregnated with inulin were unexpectedly superior compared to the closest prior art, which are compositions disclosed by

Burgoyne. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Here, Burgoyne teaches that paper treated with the DNA-protecting compound uric acid allowed for the recovery of 100% transformationally active DNA, while the recovery of DNA from untreated matrix was only 10%. Burgoyne 6:18–20; FF5.

We conclude that the evidence cited by Examiner supports a prima facie case of obviousness with respect to claim 1, and Appellant has not provided sufficient rebuttal evidence or sufficient evidence of secondary considerations that outweighs the evidence supporting Examiner’s conclusion of obviousness. As Appellant does not argue the claims separately, claims 3, 8, and 9 fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

II. Obviousness over Burgoyne, Kravchenko, Cormier, and Chomczynski

Examiner has rejected claim 2, 4, and 7 as obvious based Burgoyne, Kravchenko, Cormier, and Chomczynski. Ans. 6–8; Final Act. 6–8. Appellant’s only argument with respect to this rejection is that Chomczynski “does not teach or suggest impregnating a matrix with inulin, and thus does not cure the deficiencies of Burgoyne, Kravchenko, and Cormier.” Appeal Br. 10. This argument is not persuasive because, as discussed above, we conclude that Burgoyne, Kravchenko, and Cormier discloses or would have made obvious a matrix impregnated with a nucleic acid stabilizing agent. We affirm the rejection of claim 2, 4, and 7 for the reasons given by Examiner.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3, 8, 9	103	Burgoyne, Kravchenko, Cormier	1, 3, 8, 9	
2, 4, 7	103	Burgoyne, Kravchenko, Cormier Chomczynski	2, 4, 7	
Overall Outcome			1-4, 7-9	

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