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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NORMAN C. NELSON, KENNETH A. BROWNE, LIZHONG DAI, JAMES RUSSELL, MARK E. FILIPOWSKY, MARGARITA B. KAMINSKY, and DANIEL L. KACIAN

Appeal 2013-002307
Application 11/073,085
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and ULRIKE W. JENKS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to a solution for use in preventing nucleic acids from acting as templates in an amplification reaction. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

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[1] Appellants identify the Real Parties in Interest as Gen-Probe Incorporated (*see* App. Br. 1).

Statement of the Case

Background

"During the steps of an assay or synthesis procedure which includes an amplification procedure, it is possible to contaminate work surfaces or laboratory equipment with nucleic acids. . . . This nucleic acid can then carryover and contaminate future amplification and other nucleic acid assay procedures" (Spec. ¶ 5). "[I]t is an object of the present invention to provide a formulation containing a nucleic acid deactivating agent that is stable in solution, has a tolerable odor, and which is non-corrosive or is substantially less corrosive than a standard 50% bleach solution" (Spec. ¶ 7).

The Claims

Claims 59–72, 116, 118, 119, 121, and 122 are on appeal. Independent claim 59 is representative and reads as follows (italics added):

> 59. A homogenous solution for use in preventing nucleic acids from acting as templates in an amplification reaction when the solution is combined with a nucleic acid deactivating agent, the solution consisting essentially of a corrosion-inhibiting agent, a wetting agent, and a solubilizing agent, each of the agents remaining substantially in solution at 22°C,
>
> wherein the wetting agent and the solubilizing agent are each needed to maintain the other agent substantially in solution in the presence of the corrosion-inhibiting agent,
>
> wherein the amount of each agent is such that, when combined with a nucleic acid deactivating agent in an amount sufficient for the solution to substantially deactivate nucleic acids, the corrosion-inhibiting agent reduces the corrosive properties of the deactivating agent, the wetting agent improves the dispersion properties of the deactivating agent on a solid surface and/or increases the solubility of the deactivating agent and/or other material that may be present on a solid surface or

> in a solution, and the solubilizing agent increases the solubility of at least one of the deactivating agent, the corrosion-inhibiting agent and the wetting agent, and
>
> *wherein the solution does not include a nucleic acid deactivating agent.*

The Issues

A. The Examiner rejected claims 59–70, 72, 118, and 121 under 35 U.S.C. § 103(a) as obvious over Durmowicz[2] (Ans. 5–13).

B. The Examiner rejected claim 71 under 35 U.S.C. § 103(a) as obvious over Durmowicz and Lokkesmoe[3] (Ans. 13–15).

C. The Examiner rejected claims 116, 119, and 122 under 35 U.S.C. § 103(a) as obvious over Durmowicz and DeSimone[4] (Ans. 15–17).

A. 35 U.S.C. § 103(a) over Durmowicz

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Durmowicz renders the claims obvious?

Findings of Fact

1. The Specification teaches that "[c]orrosion-inhibiting agents of the present invention include phosphate, borate, sodium bicarbonate, detergents and other corrosion-inhibiting agents known in the art" (Spec. ¶ 12).

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[2] Durmowicz et al., US 2004/0101881 A1, published May 27, 2004.
[3] Lokkesmoe et al., US 4,911,856, issued Mar. 27, 1990.
[4] DeSimone, R., US 4,113,645, issued Sept. 12, 1978.

2. The Specification teaches that "[d]etergents and surfactants are preferred wetting agents because they reduce surface tension and allow for more complete wetting of surfaces with the deactivating agent" (Spec. ¶ 13).

3. The Specification teaches that the "solubilizing agent may contain, for example, an organic solvent. . . . Organic solvents that may be included in the formulation include . . . isopropanol" (Spec. ¶ 14).

4. The Specification teaches that "[p]referred deactivating agents include bleach, sodium hypochlorite (NaOCl) (or hypochlorous acid (HOCl)" (Spec. ¶ 9).

5. Durmowicz teaches "a solution of a nucleic acid oxidizing agent and a surfactant. It has been found that the use of this solution is more effective to provide nucleic acid decontamination and removal than conventional sodium hypochlorite solutions" (Durmowicz ¶ 5).

6. Durmowicz teaches "a kit containing appropriate amounts of surfactant and oxidizing agent in separate containers for mixing prior to application" (Durmowicz ¶ 52).

7. Durmowicz teaches an embodiment with "the kit comprising a separate container consisting essentially of a higher fatty acid alkali metal soap, organic builder salts and a separate container consisting essentially of oxidizing agent" (Durmowicz ¶ 54).

8. Durmowicz teaches "[w]ater-soluble salts of the higher fatty acids, i.e., 'soaps,' are useful surfactants in the blends of solution disclosed herein" (Durmowicz ¶ 26).

9. Durmowicz teaches "[i]norganic detergency builders useful herein include, for example, water-soluble salts of phosphates,

pyrophosphates, orthophosphates, polyphosphates, phosphonates, carbonates, bicarbonates . . . Other preferred non-phosphorous building material . . . include . . . sodium bicarbonate" (Durmowicz ¶¶ 37, 40).

10. Durmowicz teaches that "[o]ther preferred non-phosphorous builder materials (both organic and inorganic) herein include sodium carbonate, sodium bicarbonate" (Durmowicz ¶ 40).

11. Durmowicz teaches:

> Preferably, the blend is solvated in an aqueous solution, however, other solvents are contemplated as useful for the present invention. For example alcohols, such as ethanol, methanol, propanol, isopropyl alcohol, butanol and the like can be used. Such non-water solvents can serve as the sole solvent, or if miscible, can be combined with water.

(Durmowicz ¶ 41).

12. Durmowicz teaches that the term 'solution' or 'non-particulate solution' and grammatical variations thereof, herein means an essentially single-phase liquid system" (Durmowicz ¶ 15).

13. Durmowicz teaches "to use common laboratory surfactants and detergents to practice the instant invention such as, but not limited to, the Tween series, the octylphenol series (Triton), tergitol detergents (NP series), sodium laureth sulfide (SDS), Brij detergents and niaproff anionic detergents" (Durmowicz ¶ 36).

14. Durmowicz teaches that:

> The term "detergent" and grammatical variations thereof, herein means an ***emulsifying agent*** or surface active agent made usually by action of alkali on fat or fatty acids and consisting essentially of sodium or potassium salts of such acids. In a related embodiment, the term may include any of

> numerous synthetic water-soluble or liquid organic preparations that are chemically different from soaps but are able to emulsify oils, hold dirt in suspension, and act as wetting agents.

(Durmowicz ¶ 18; emphasis added).

15. Durmowicz teaches "pre-packaging may facilitate dissolving of the surfactant, oxidizing agent or both into solution" (Durmowicz ¶ 52).

Principles of Law

"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). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Ans. 5–13; FF 1–15).

Claim 59

We begin with claim interpretation because before a claim is properly interpreted, its scope cannot be compared to the prior art. Claim 59 is drawn to a solution composed of three elements, "a corrosion-inhibiting agent, a wetting agent, and a solubilizing agent" and excludes a "nucleic acid deactivating agent."

We interpret the claims in light of the Specification which teaches that "corrosion-inhibiting agents" include phosphates and bicarbonates (FF 1), that "wetting agents" include detergents and surfactants (FF 2), that "solubilizing agents" include organic solvents such as isopropanol (FF 3), and that "nucleic acid deactivating agents" include bleach (FF 4).

Durmowicz teaches solutions (FF 12) in kits with the nucleic acid deactivating reagents split into two separate containers, one containing bleach (FF 5–6), and the second container containing organic builder salts and a higher fatty acid alkali metal soap (FF 7). Durmowicz teaches that organic builder salts include phosphates and carbonates (FF 9) and that the metal soap is a surfactant (FF 8).

Durmowicz further suggests that the blend of detergency builders and surfactants may be solvated in organic solvents including isopropyl alcohol (i.e. isopropanol) alone or in combination with water (FF 11)

Thus, Durmowicz expressly suggests a kit comprising two tubes, a first with bleach, and a second containing a mixture of: phosphates and bicarbonates ("corrosion-inhibiting agents" in the lexicon of the Specification); surfactants including metal soaps ("wetting agents" in the lexicon of the Specification); and organic solvents including isopropanol ("solubilizing agents" in the lexicon of the Specification). Therefore, we agree with the Examiner that Durmowicz expressly suggests the homogenous solution required by claim 59 wherein the solution does not include a nucleic acid deactivating agent (*see* Ans. 20).

Appellants contend that the Examiner cited "portions of Durmowicz discuss detergent builders and provide no information about whether these compositions are, or are analogous to, the corrosion-inhibiting agents of the present claims" (App. Br. 7).

We find this argument unpersuasive because the Specification teaches that "[c]orrosion-inhibiting agents of the present invention include phosphate, borate, sodium bicarbonate, detergents and other corrosion-

inhibiting agents known in the art" (FF 1). Thus, the components identified by the Specification as "corrosion-inhibiting agents" are identical to the phosphate and bicarbonate components taught by Durmowicz as builder salts (FF 9). "Products of identical chemical composition can not have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Appellants have provided no evidence showing that the phosphate or bicarbonate components of Durmowicz would not function as "corrosion-inhibiting agents" as required by claim 59.

Appellants contend that "Durmowicz fails to teach or suggest a homogenous solution that lacks a deactivating agent. For example, Durmowicz states that 'the present invention comprises a solution of a nucleic acid oxidizing agent and a surfactant,' and '[t]he composition of interest also contains a nucleic acid oxidizing agent'" (App. Br. 7 (emphasis omitted)).

We are not persuaded. Just as claim 59 contemplates mixing together two solutions, one being a nucleic acid deactivating agent and one being the claimed homogenous solution without nucleic acid deactivating agent, in order to form the final solution, Durmowicz also teaches "a kit containing appropriate amounts of surfactant and oxidizing agent in separate containers for mixing prior to application" (FF 6). Durmowicz further explains an alternative embodiment with surfactant and organic builder salts such as phosphates or bicarbonates in one tube and the oxidizing (i.e. nucleic acid deactivating agent) in another tube (FF 4, 7, 9).

Durmowicz's solution with surfactant, organic builder salts such as phosphates and bicarbonates (FF 7) and optionally organic solvents such as

isopropanol (FF 11) reasonably renders the solution of claim 59 obvious when formulated in the first tube that will later be mixed with a second tube containing the nucleic acid deactivating agent (FF 6).

Appellants contend that "those of skill in the art would have expected particulate formation if a corrosion-inhibiting agent, wetting agent, and solubilizing agent were combined in the absence of an oxidizing agent" (App. Br. 10).

We are not persuaded because Appellants simply make this argument without evidence. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.") Appellants do not identify any teaching in Durmowicz suggesting that the combination of components necessarily results in particulate formation, and indeed, Durmowicz teaches "a non-particulate solution" (*see* Durmowicz ¶ 53).

Claims 65, 67, 118, and 121

Appellants contend that "Durmowicz does not teach or suggest the limitations of claims 65, 67, 118–119, or 121 since it does not teach or suggest the incorporation of sodium dodecyl sulfate or lithium lauryl sulfate in any solutions" (App. Br. 11).

We are not persuaded. Durmowicz expressly teaches the use of "common laboratory surfactants and detergents" (FF 13), a class including sodium dodecyl sulfate. We recognize that Durmowicz states "sodium

laureth sulfide (SDS)" (FF 13) and note that sodium lauryl sulfate is a well-known alternative name for sodium dodecyl sulfate.[5]

Claim 66

Appellants contend that "Durmowicz does not teach or suggest each element of claim 66 since it does not teach an emulsifier as a solvent in its solutions" (App. Br. 12).

We find this argument persuasive. While the Examiner correctly notes that Durmowicz teaches the use of detergents as emulsifying agents (FF 14), the Examiner does not explain how Durmowicz suggests the use of two different components where the "wetting agent" is a detergent and the "solubilizing agent" is an emulsifying agent as required by claim 66. The use of two different terms in claim 66 is reasonably interpreted as requiring two different components. *See CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co.*, 224 F.3d 1308, 1317 (Fed.Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of . . . different terms in the claims connotes different meanings.").

Claim 68

Appellants contend that "the teachings of Durmowicz relied on here by the Examiner are in-connection with the same agent, not two different agents as required in claim 68" (App. Br. 12).

We are not persuaded. As we discussed in our analysis of claim 59 above, Durmowicz expressly suggests teaches a kit comprising two tubes, a first with bleach, and a second containing a mixture of: phosphates and bicarbonates ("corrosion-inhibiting agents" in the lexicon of the

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[5] *See* http://pubchem.ncbi.nlm.nih.gov/compound/ Sodium_dodecyl_sulfate

Specification); surfactants including metal soaps ("wetting agents" in the lexicon of the Specification); and organic solvents including isopropanol ("solubilizing agents" in the lexicon of the Specification). That second tube uses different corrosion-inhibiting and wetting agents as required by claim 68.

Claims 69 and 70

Appellants contend that "since Durmowicz fails to teach or suggest the homogenous solution of claim 59 (which lacks an oxidizing agent), it similarly fails to teach kits comprising this solution" (App. Br. 12).

We find this argument unpersuasive for the reasons give above, specifically because Durmowicz teaches the solution of claim 59 as discussed as well as kits as required by claims 69 and 70 (FF 6–7).

Claim 72

Appellants contend that "one of skill in the art would be inclined to avoid the inclusion of nucleic acid amplification reagents in a kit with solutions meant to destroy nucleic acids due to the potential of inadvertent adulteration of the sanitizing solution or the destruction of the amplification reagents" (App. Br. 13).

We are not persuaded. As the Examiner notes, Example 1 teaches the efficacy of the inventive solution on decontaminating a region by use of a decontaminating solution and the BDProbeTec™ ET nucleic acid amplification test kit (*see* Durmowicz 57; Ans. 11). We agree with the Examiner that the ordinary artisan, interested in verifying the effectiveness of the nucleic acid decontamination solution, would have formed a single kit with the decontamination solutions and the nucleic acid amplification test kit

for ease of use in replicating the result demonstrated by Example 1 of Durmowicz.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Durmowicz renders claims 59, 65, 67–70, 72, 118, and 121 obvious.

The evidence of record does not support the Examiner's conclusion that Durmowicz renders claim 66 obvious.

B. 35 U.S.C. § 103(a) over Durmowicz and Lokkesmoe

Appellants contend that "the Durmowicz 'kit' disclosure provides no suggestion to alter the essential order of addition of the Durmowicz reagents, which requires mixing the oxidizing agent and the surfactant as an initial step" (App. Br. 13).

We find that the Examiner has the better position. Claim 71 simply requires that the dried nucleic acid deactivating composition in the kit is in tablet form. As the Examiner points out, Durmowicz teaches "pre-packaging may facilitate dissolving of the surfactant, oxidizing agent or both into solution" (FF 15; Ans. 10). Durmowicz's teaching that the oxidizing agent (i.e. nucleic acid deactivating composition) must be dissolved reasonably suggests that the oxidizing agent in "pre-packaging" is in a dried form. Lokkesmoe evidences that tablets are a known format for dried storage.

Because the claim is drawn to a product, specifically a kit, the order of addition of components is not relevant. Any order of addition represents an intended use of the kit and imposes no structural limitations on the kit itself.

It is "well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

C. 35 U.S.C. § 103(a) over Durmowicz and DeSimone

Appellants contend that "DiSimone, therefore, attempts to teach how to disperse a perfume in an aqueous solution containing bleach, not to use the perfume as a solubilizing agent." In contrast, the fragrance of claims 116, 119, or 122 *comprises* the solubilizing agent" (App. Br. 14; reference omitted).

We do not find this argument persuasive. While Appellants are correct that claims 116, 119, and 122 recite a fragrance as a solubilizing agent, the claims are open to the inclusion of additional agents including the isopropanol solubilizing agent taught by Durmowicz (FF 3, 11). *See PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). ("By using the term 'consisting essentially of' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.")

The Examiner reasonably relies upon DeSimone to suggest the inclusion of perfume "to mask the unpleasant chlorine odor which is characteristic of [bleach] solutions" (DeSimone, col. 1, ll. 6–7). We agree with the Examiner that the ordinary artisan would have found it obvious to incorporate a perfume into the obvious composition of Durmowicz "to prepare a solution where the unpleasant odor of the alkali metal hypochlorite (nucleic acid deactivating agent of instant claims) is masked by use of different fragrances" (Ans. 17).

Appellants also reiterate the argument regarding SDS for claim 122 that we found unpersuasive for claims 65, 67, 118, and 121 for the reasons already given.

SUMMARY

In summary, we affirm the rejection of claims 59, 65, 67–70, 72, and 118, and 121 under 35 U.S.C. § 103(a) as obvious over Durmowicz. Claims 60–64 fall with claim 59, as they were not separately argued.

We reverse the rejection of claim 66 under 35 U.S.C. § 103(a) as obvious over Durmowicz.

We affirm the rejection of claim 71 under 35 U.S.C. § 103(a) as obvious over Durmowicz and Lokkesmoe.

We affirm the rejection of claims 116, 119, and 122 under 35 U.S.C. § 103(a) as obvious over Durmowicz and DeSimone.

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-IN-PART

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