



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/345,297	01/06/2012	Paul Jeffrey Haney	TF9380US1-NAT	1046
52059	7590	01/31/2020	EXAMINER	
LIFE TECHNOLOGIES CORPORATION			MENON, KRISHNAN S	
Attn: IP Department			ART UNIT	
5823 Newton Drive			PAPER NUMBER	
Carlsbad, CA 92008			1777	
			NOTIFICATION DATE	
			DELIVERY MODE	
			01/31/2020	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentDocketing@thermofisher.com
pair_thermofisher@firsttofile.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL JEFFREY HANEY, BRIAN L. WEBB,
NAVID REZA HAGHDOOST, RIZWAN FAROOQUI, and
ATUL MADHUKAR DESHPANDE

Appeal 2019-002433
Application 13/345,297
Technology Center 1700

Before CATHERINE Q. TIMM, BRIAN D. RANGE, and
MICHAEL G. McMANUS, *Administrative Patent Judges*.

McMANUS, *Administrative Patent Judge*.

DECISION ON APPEAL

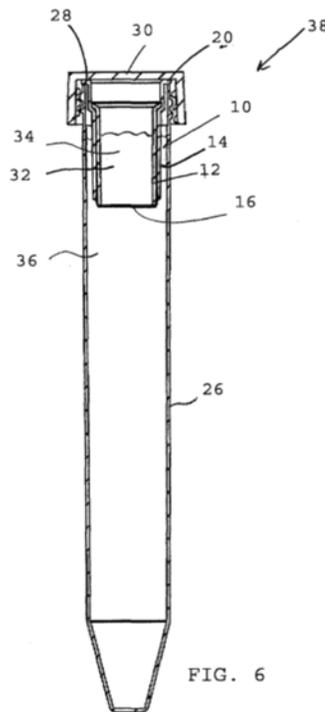
Pursuant to 35 U.S.C. § 134(a), Appellant¹ seeks review of the Examiner's decision to reject claims 1–10, 21, and 22. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Pierce Biotechnology, Inc. Appeal Br. 3.

CLAIMED SUBJECT MATTER

The present application generally relates to a dialysis system for enabling the diffusion of small molecules. Spec.² 1. The Specification teaches an embodiment where “a generally sealed device [is] configured to receive both a buffer and a dialysis chamber, where positioning the dialysis chamber seals the device.” *Id.* The Specification further teaches that “[t]he device is configured to receive a sample to enable dialysis of the sample with respect to the buffer across the membrane.” *Id.* The described embodiment is shown in Figure 6, reproduced below.



² Specification dated Jan. 6, 2012 (hereinafter “Spec.”).

Figure 6 shows a side cross section of a dialysis device 10, vessel 26, and cap 30. Spec. 1. The Specification teaches as follows with regard to Figure 6:

In use, a sample 32 (FIG. 6) containing small molecules which are desired to be removed is placed in the inner cavity 34 of the dialysis device 10/inner member 12 such as by a pipette or the like. A buffer solution or dialysate fluid 36 (i.e. containing a relatively low concentration of small molecules) is positioned in the tube 26. The dialysis device 10 is then inserted into the tube 26 such that the membrane 16 is submerged below the fluid level of the buffer 36, as shown in FIG. 6. Because the sample 32 is in contact with the membrane 16, and the membrane 16 is, in turn, in contact with the buffer 36, dialysis occurs across the membrane 16 as the smaller molecules of the sample 32 diffuse across the semi-permeable membrane 16 into the buffer solution 36.

Spec. 3.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below with certain limitations bolded for emphasis:

1. A dialysis system comprising:
 - a sealable device comprising:
 - a vessel defining a first inner cavity configured to receive a dialysis buffer;
 - the vessel having an open end defined by an annular lip and a closed end;
 - a dialysis device positioned in the first inner cavity of the vessel defining a second inner cavity located in the dialysis device;
 - the second inner cavity configured to receive a sample to be dialyzed;
 - the dialysis device having:

an inner member including an open upper end and an open lower end;

an outer member including a radially outwardly-extending flange configured to overlies the annular lip of the vessel when the dialysis device is positioned in the vessel; and

a dialysis membrane trapped between the inner and the outer members and extending across the open lower end of the inner member,

where, the dialysis membrane is in contact with the dialysis buffer and the sample to be dialyzed and where positioning the dialysis device in the first inner cavity of the vessel seals the device such that the dialysis buffer is fluidly isolated from the sample; and

a cap configured to engage the vessel adjacent the open end thereof, when the radially outwardly-extending flange of the dialysis device is positioned between the cap and the annular lip of the vessel so that the cap and the radially outwardly-extending flange of the dialysis device cooperate to seal both the first inner cavity of the vessel wherein the dialysis buffer is located and the second inner cavity of the dialysis device wherein the sample to be dialyzed is located.

Appeal Br.³ 22–23 (Claims App.) (emphasis added).

REFERENCES

The Examiner relies upon the following prior art:

Name	Reference	Date
Sklar et al. (“Sklar”)	US 5,601,711	Feb. 11, 1997
Sykaluk	US 6,039,871	Mar. 21, 2000

³ Amended Appeal Brief dated Nov. 15, 2018 (“Appeal Br.”).

REJECTIONS

The Examiner maintains the following rejections:

1. Claims 1–10, 21, and 22 are rejected under 35 U.S.C. § 112, ¶ 2 (pre-AIA) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Final Act. 2.⁴
2. Claims 1–10, 21, and 22 are rejected under 35 U.S.C. § 103(a) (pre-AIA) as being unpatentable over Sykaluk in view of Sklar. *Id.* at 2–6.

DISCUSSION

Rejection 1. The Examiner rejects claims 1–10, 21, and 22 as indefinite. *Id.* at 2. The Examiner determines that the limitation “where positioning the dialysis device in the first inner cavity of the vessel seals the device such that the dialysis buffer is fluidly isolated from the sample” renders the claim indefinite. *Id.*

On appeal, Appellant does not present argument against the rejection. Appeal Br. 18. Rather, Appellant states an intent to amend claim 1 so as to remove the limitation at issue. *Id.* In view of the absence of argument disputing the Examiner’s rejection, we summarily affirm. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2012); *see also* Manual of Patent Examining Procedure (MPEP) § 1205.02 (8th ed., Rev. 8, July 2010) (“If a ground of rejection stated by the examiner is not addressed in the appellant’s brief, that ground of rejection will be summarily sustained by the Board”).

⁴ Final Office Action, dated May 22, 2018 (hereinafter “Final Act.”).

Rejection 2. The Examiner rejects claims 1–10, 21, and 22 as obvious over Sykaluk in view of Sklar. Final Act. 3–6. In support of the rejection, the Examiner finds that Sykaluk teaches a dialysis device (including an inner member, outer member, and membrane) similar to that which is claimed. The Examiner further finds that Sykaluk does not teach an external vessel or a cap that cooperates with the flange of the outer member of the dialysis device to seal the vessel. Final Act. 4; Examiner’s Answer dated Nov. 30, 2018 (“Answer”), 4, 6. Figures 1 and 2 of Sykaluk are reproduced side-by-side below.

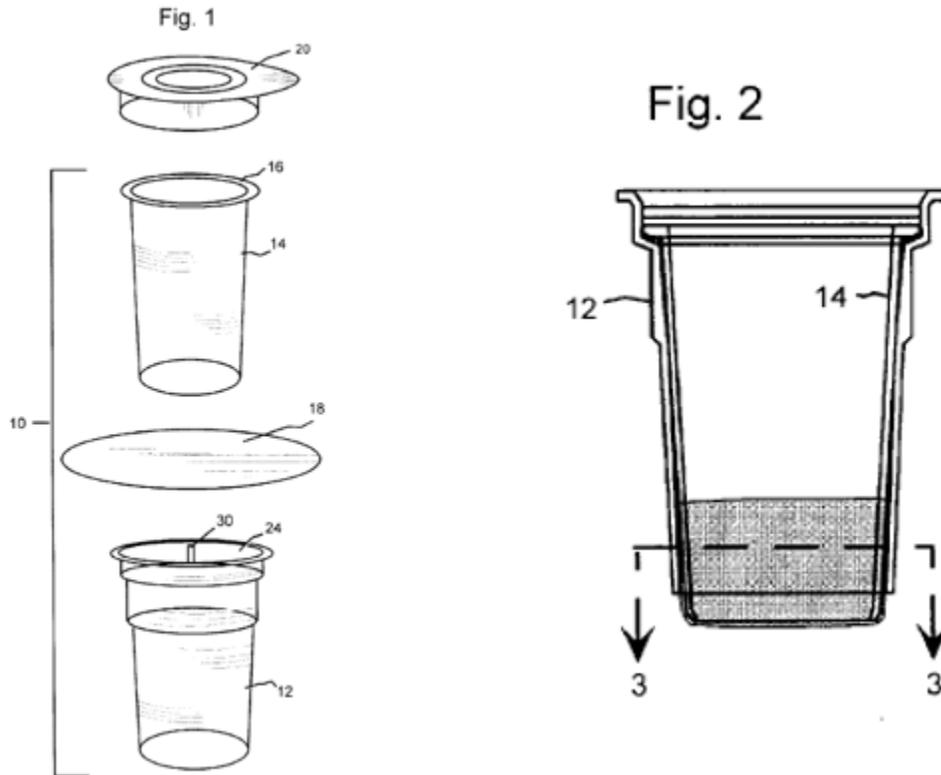
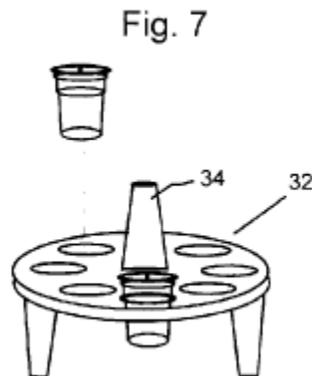


Figure 1, which is reproduced on the left above, is an exploded perspective view showing the dialysis device of Sykaluk in a disassembled state.

Sykaluk, col. 2, ll. 23–24, 41–43. Figure 1 depicts outer sleeve 12, inner sleeve 14, and dialysis membrane 18. *Id.* at col. 2, ll. 41–48. Figure 2, which is reproduced on the right above, shows the device of Sykaluk as assembled. *Id.* at col. 2, l. 59. Sykaluk teaches that “as assembled, the bottom 22⁵ of the inner sleeve 14 extends below the bottom of the outer sleeve 12 and is covered by the membrane 18.” *Id.* at col. 2, ll. 59–61. Sykaluk teaches that dialysis is performed by partially submerging the dialysis device in dialysate. This is partly shown in Figure 7 of Sykaluk, reproduced below.

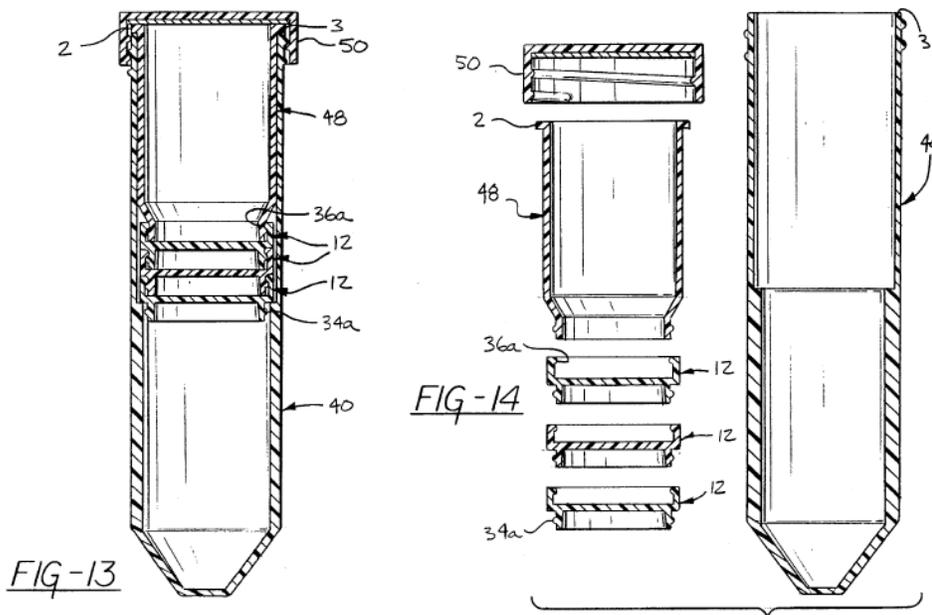


Sykaluk teaches that Figure 7 “illustrates a manner in which the devices of this invention can be used to accomplish dialysis of a sample or simultaneously accomplish dialysis of multiple samples.” Sykaluk col. 4, ll. 1–3. Sykaluk further teaches that “floatation device 32 containing a handle 34 is used. The lower end of the dialysis device containing the membrane

⁵ The figures do not include a reference numeral 22, but the location of the bottom of inner sleeve 14 is evident from Figures 1 and 2 as the lower most portion of inner sleeve 14.

extends through the openings in the float and into the dialysate.” *Id.* at col. 4, ll. 5–7.

The Examiner finds that the secondary reference, Sklar, teaches a device similar to that of the claims but which employs an external vessel (outer container 40) and a screw cap (50) design. Final Act. 5 (citing Sklar Figs. 13 and 14); Answer 6. Referring to Figures 13 and 14, the Examiner finds that “[i]nner member 48 has a flange that goes over the lip of the outer container 40; the screw cap 50 seals them all together.” *Id.* Figures 13 and 14 are reproduced side-by-side below.



Sklar teaches that Figure 13, which is reproduced on the left above, “is a side view in diametral section of a train of filter media modules and a sample reservoir having snap lock connections with compression fittings, assembled and inserted in a centrifuge tube, for selective separation of materials.” Sklar col. 3, ll. 1–5. Sklar teaches that Figure 14, which is

reproduced on the right above, “is an exploded view of the same elements.”
Id. at col. 3, l. 6.

The Examiner determines that “[i]t would have been obvious to combine the teachings of these references to arrive at appellant’s invention because the combination would [result in] a leak-proof device in Sykaluk as taught by Sklar, particularly for processing a single sample[].” Answer 5. The Examiner further determines that “having the dialysis device of Sykaluk in a container like that of Sklar would have been obvious for the single sample situation and also for making the system leak proof for handling.”
Id. at 6.

Appellant argues that the rejection should be reversed for several reasons. Appeal Br. 14–18. First, Appellant argues that the combination of Sykaluk and Sklar does not teach all elements of claim 1 as follows:

Appellants respectfully submit that the combination of Sykaluk and Sklar do [sic] not teach, suggest or provide motivation for at least the following aspects of independent claim 1 . . . including at least: “a sealable device comprising: a vessel ; a dialysis device positioned in the first inner cavity of the vessel . . . a dialysis membrane trapped between the inner and the outer members and extending across the open lower end of the inner member,” “where, the dialysis membrane is in contact with the dialysis buffer and the sample to be dialyzed;” and “a cap configured to engage the vessel adjacent the open end thereof, when the radially outwardly-extending flange of the dialysis device is positioned between the cap and the annular lip of the vessel so that the cap and the radially outwardly-extending flange of the dialysis device cooperate to seal both the first inner cavity of the vessel wherein the dialysis buffer is located and the second inner cavity of the dialysis device wherein the sample to be dialyzed is located.”

Id. at 14. In support of this argument Appellant asserts that in order for Sklar’s device to be effective, it requires an empty chamber below the filter media 14 “so that filtrate can pass through the filter media and drain centrally along the drain channels and then enter and pass through the through passage channels 28 to a container in a centrifuge insert” *Id.* at 15 (citing Sklar col. 7, ll. 17–21). As a consequence, Appellant reasons, a device embodying the Examiner’s hypothetical combination would have only an “empty container” in contact with the dialysis membrane. *Id.* Accordingly, Appellant argues that the limitation requiring that “the dialysis membrane is in contact with the dialysis buffer” would not be taught. *Id.*; *see also* Declaration of Paul Jeffrey Haney under 37 C.F.R. § 1.132, dated May 15, 2017⁶ ¶¶ 12–15.

In the Answer, the Examiner determines that “[e]ven if the dialysis solution is considered as part of the structure, Sykaluk does teach dialysis buffer (dialysate) and the membrane in contact with it in col. 4 line 5–7, under ‘fig. 7’. It is also the intended use of the Sykaluk system, and thus obvious.” Answer 6.

We find the Examiner’s reasoning persuasive. The Examiner’s proposed combination relies on Sklar only for its teaching of a screw cap and external vessel to permit dialysis in a sealed environment. Final Act 4. The rejection relies on Sykaluk as teaching a dialysis device in contact with a dialysis buffer. Sykaluk teaches that “[t]he lower end of the dialysis device containing the membrane extends through the openings in the float and into the dialysate.” Sykaluk col. 4, ll. 5–7. It is apparent that dialysis

⁶ Hereinafter referred to as the “Haney Declaration.”

cannot occur absent contact between the sample and the dialysate (dialysis buffer). Haney Declaration ¶ 7. Although Sklar does not teach a sample in fluid contact with the dialysate, the Examiner’s proposed combination would have such feature given the teachings of Sykaluk. “The test for combining references is not what the individual references themselves suggest but rather what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art.” *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). Accordingly, the proposed combination would embody a device having the membrane and sample in fluid contact with the dialysate and Appellant has not shown error in this regard.

Second, Appellant argues that the proposed combination lacks an adequate explanation as to why the Examiner proposes to adopt some teachings of Sklar but not others. Appeal Br. 15–16. Appellant further argues that, when one considers all teachings of the Sklar reference, “Sklar’s empty container must be present if Sklar is to be combined with Sykaluk, which would not result in a dialysis system.” Appeal Br. 15–16. This does not show error in the rejection. The Examiner determines that dialysis is “the intended use of the Sykaluk system” and that “having the dialysis device of Sykaluk in a container like that of Sklar would have been obvious for the single sample situation and also for making the system leak proof for handling.” Answer 6. This is a reasoned basis for modification of the primary reference and Appellant has not shown error in the Examiner’s reasoning.

Third, Appellant argues that the Sklar reference teaches away from the claims. Appeal Br. 16. “[M]ere disclosure of alternative designs does not teach away.” *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). “A

reference does not teach away, however, if it merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). Rather, teaching away requires “clear discouragement” from implementing a technical feature. *In re Ethicon, Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017). “A reference teaches away when 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.” *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) (quotations omitted)). Here, Appellant cites to certain teachings of Sklar that concern an alternative design but not to any portion of Sklar that expressly criticizes the notion of a dialysis membrane in contact with a dialysis buffer.

Fourth, Appellant argues that the proposed combination would “render the prior art invention being modified unsatisfactory for its intended purpose.” Appeal Br. 16–17. Appellant again argues that the proposed combination would result in a device where a dialysis membrane is in contact with an empty chamber, thereby preventing the dialysis of Sykaluk. *Id.* at 16. As we have not adopted Appellant’s reasoning regarding the dialysis membrane being in contact with an empty chamber, we do not find this persuasive. Further, a device for dialysis of a single sample in a single vessel (as claimed) has the same or similar intended purpose as the dialysis taught by Sykaluk. *See* Sykaluk col. 4, ll. 1–7; Fig. 7.

Appellant further argues that if Sklar were to be modified by addition of a dialysis buffer to its chamber then the Sklar device would be rendered unsatisfactory for its intended purpose of filtration. This is not persuasive.

“The relevant question is not whether the secondary reference [Sklar] would be rendered unsatisfactory for its intended purpose, but rather whether the primary reference [Sykaluk] would be rendered unsatisfactory by being modified with the teaching of the secondary reference.” *Ex Parte Jan Weber*, Appeal No. 2012-004946, at 6 (PTAB Oct. 9, 2014)⁷ (citing *Application of Ratti*, 270 F.2d 810 (CCPA 1959)). Accordingly, Appellant has not shown the absence of a reason to combine based on a cited prior art reference being rendered unsatisfactory for its intended purpose.

Fifth, Appellant asserts that the Examiner did not give adequate weight to the evidence and arguments provided in the Haney Declaration. Appeal Br. 17–18. We disagree. The Examiner’s discussion in the Answer indicates that the Examiner considered Haney’s statements in the Declaration. Ans. 9–10. Haney’s Declaration includes statements regarding the dialysis process, the teachings of the references, and why those teachings fail to support a conclusion of obviousness. Statements by one of the inventors on the ultimate legal question of obviousness are not evidence. *In re Lindell*, 385 F.2d 453, 456 (1967). Although some weight is given to statements from an ordinary artisan on what was not obvious to them at the time of the invention, those statements must be persuasively supported with corroborating evidence. *Id.* Here, after considering the Declaration, the Examiner concluded that the facts weighed in favor of a conclusion of obviousness. This was not error. *See In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) (“[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants

⁷ 2014 WL 5144544, at *3

discounting the opinions expressed in the declarations.”); *see also Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (“In giving more weight to prior publications than to subsequent conclusory statements by experts, the Board acted well within [its] discretion.”); *see also Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (The Board has discretion to give more weight to one item of evidence over another “unless no reasonable trier of fact could have done so”). Like the Board, the Examiner is entitled to assign proper weight to the various pieces of evidence in the record when considering the question of obviousness.

In view of all of the foregoing, we determine that Appellant has not shown reversible error in the rejection of claims 1–10, 21, and 22 as obvious.

CONCLUSION

The Examiner’s rejections are affirmed.

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–10, 21, 22	112 ¶ 2	Indefiniteness	1–10, 21, 22	
1–10, 21, 22	103(a)	Sykaluk, Sklar	1–10, 21, 22	
Overall Outcome			1–10, 21, 22	

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