

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT, INC.,
Petitioner,

v.

NOBLE HOUSE GROUP PARTY LTD.,
Patent Owner.

Case IPR2015-00379
Patent 8,777,921 B2

Before JOSIAH C. COCKS, RICHARD E. RICE, and JAMES A. WORTH,
Administrative Patent Judges.

COCKS, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Petitioner, Terumo BCT, Inc. (“Terumo”), filed a revised Petition (Paper 5, “Pet”) requesting *inter partes* review of claims 1–19 of U.S. Patent No. 8,777,921 B2 (“the ’921 patent”). Subsequent to the submission of Terumo’s Petition, Patent Owner, Noble House Group Party Ltd. (“Noble”), filed a paper indicating that claims 1–5, 7–13, 15, and 17–19 had been disclaimed pursuant to 37 C.F.R. § 1.321. Ex. 2001. In light of that filing, we considered Terumo’s Petition requesting *inter partes* review only in connection with claims 6, 14, and 16. Inst. Dec. 2. We issued a Decision to institute an *inter partes* review (Paper 9, “Inst. Dec.”) of the ’921 patent on the ground that claims 6, 14, and 16 are unpatentable under 35 U.S.C. § 103(a) over the SSK Pamphlet¹ and Ishida.² Inst. Dec. 17.

After institution of trial, Noble filed a Patent Owner’s Response (Paper 11, “PO Resp.”), to which Terumo replied (Paper 12). Oral argument was conducted on March 2, 2016. A transcript of that argument has been made of record in this proceeding. Paper 24.

We have jurisdiction under 35 U.S.C. § 318(a). After considering the evidence and arguments of both parties, and for the reasons set forth below, we determine that Terumo met its burden of showing, by a preponderance of the evidence, that claims 6, 14, and 16 of the ’921 patent are unpatentable.

¹ “Inventor disclosed SampLok Sampling Kit Non-Patent Literature” (Ex. 1005). Pet. 3.

² U.S. Patent No. 6,328,726, which issued December 11, 2001 to Ishida et al. (Ex. 1020).

A. The '921 Patent (Ex. 1001)

The '921 patent is titled “Sterile Sampling Methods and Apparatus.” More particularly, the '921 patent describes that:

The present invention provides methods that allow multiple samples of a liquid in a primary container (here called a ‘pouch’) to be taken with minimal danger of contaminating the liquid in the container during the sampling process.

Ex. 1001, 2:12–15. Figure 8 of the '921 patent is reproduced below:

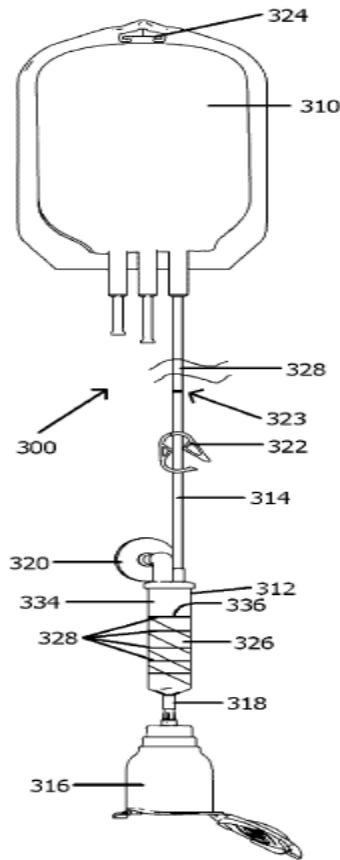


Figure 8 above depicts “assembly 300” according to an embodiment of the invention. Ex. 1001, 8:16–17. As shown in the figure, assembly 300 is composed of “a combined pouch 310 (typically a platelet container), sight

chamber 312 and sampling port 316 arrangement.” *Id.* at 8:17–20. Pouch 310 is connected to sight chamber 312 via tube 314. *Id.* at 8:20–21. Sight chamber 312 includes “graduations 328,” that may be used to measure the amount of fluid 326 in the sight chamber. *Id.* at 8:59–60. Sight chamber 312 also includes filter 320, through which air in the sight chamber may exit, or be vented from, the chamber. *Id.* at 8:60–61. Fluid flow through tube 314 may be controlled via operation of tube clamp 322. *Id.* at 8:39–41. Tube 314 also includes “frangible barrier 323” that initially closes the tube. *Id.* at 8:41–43.

B. Illustrative claim

Claim 6 is illustrative of the subject matter of the ’921 patent at issue in this proceeding. Claim 6 depends from claim 1. Claims 1 and 6 are reproduced below:

1. Apparatus for providing at least one sample of a liquid contained in a pouch while mitigating the danger of contaminating the liquid in the pouch, the apparatus comprising:
 - an inlet tube having proximal and distal ends, and comprising a frangible barrier therein, between the proximal and distal ends, the proximal end connected to an inlet of a sterile sight chamber, the chamber comprising:
 - a vent in the chamber wall fitted with a bacterial filter through which air can flow to and from the chamber; and
 - an outlet;
 - the inlet tube comprising a tube clamp thereon, wherein the tube clamp is a sufficient distance from the distal end to permit a sterile fluid connection to be established with the inlet tube at a point distal to the tube clamp;
 - the tube clamp operable to regulate liquid flow through the inlet tube to the chamber when the connection is established and operable to block fluid flow in the absence of the connection;
 - and

a sample port comprising a hollow body with a distal end and a proximal end, wherein the distal end of the sample port is connected to the outlet of the chamber, and the proximal end is opposite the outlet.

6. Apparatus according to claim 1, wherein the chamber is transparent and rigid.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. *See* 37 C.F.R. § 42.100(b) (2013); *see Cuozzo Speed Techs. LLC v. Lee*, No. 15–446, 2016 WL 3369425, at *12 (U.S. June 20, 2016). Under that construction, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Nevertheless, a “claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.” *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

For purposes of our Decision instituting trial in this *inter partes* review, we determined that no terms of the claims of the ’921 patent acquired any special meaning. Thus, all terms were afforded their broadest reasonable meaning as would be understood by a person of ordinary skill in the art in light of the Specification. Inst. Dec. 6. We made explicit that meaning for a single claim term: “frangible barrier.” *Id.* In that regard, we

determined that the ordinary meaning of “frangible barrier” is a “seal that impedes the flow of a fluid until physically broken.” *Id.* Neither party offers an alternative construction for the term “frangible barrier,” and based on the record developed during trial, we do not alter the meaning expressed above.

*B. The Ground of Unpatentability Based
on the SSK Pamphlet and Ishida.*

The sole ground at issue in this *inter partes* review is premised on obviousness. A claim is unpatentable for obviousness under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations.³ See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We also recognize that prior art references must be “considered together with the knowledge of one of ordinary skill in the pertinent art.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (citing *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

³ Here, neither party has presented or discussed any evidence of secondary considerations for evaluation by the panel.

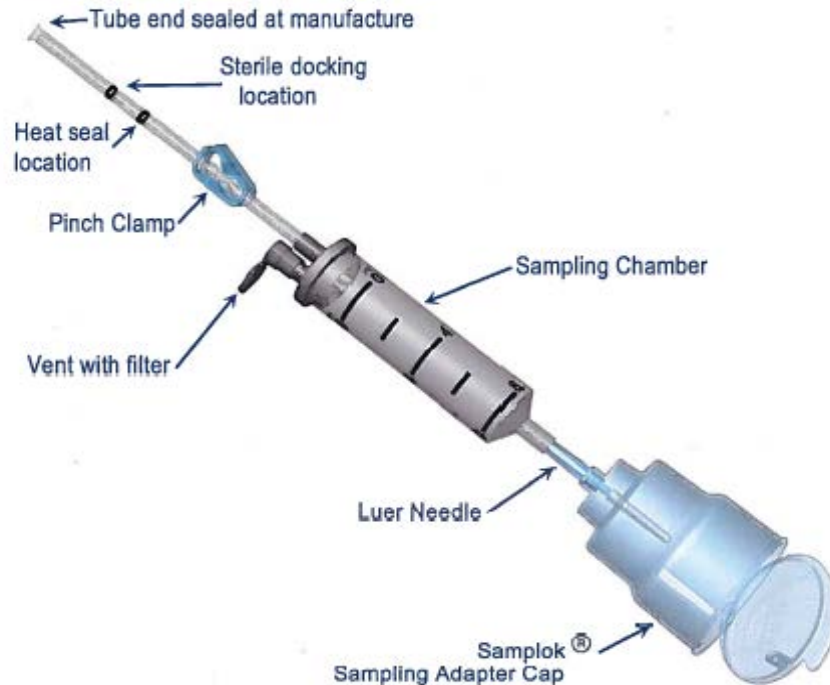
1. Overview of the Prior Art

a. The SSK Pamphlet⁴

The SSK Pamphlet is a document described as being directed to “Bacterial Detection Ancillaries,” and discloses a “SampLok Sampling Kit (SSK)” and a “Platelet transfer kit.” Ex. 1005. A portion of the SSK Pamphlet is reproduced below:

SampLok Sampling Kit provides:

- Accurate sample measurement
- Ability to streamline procedures with few steps to collect and transfer samples
- Minimal platelet waste
- Minimal biohazard waste



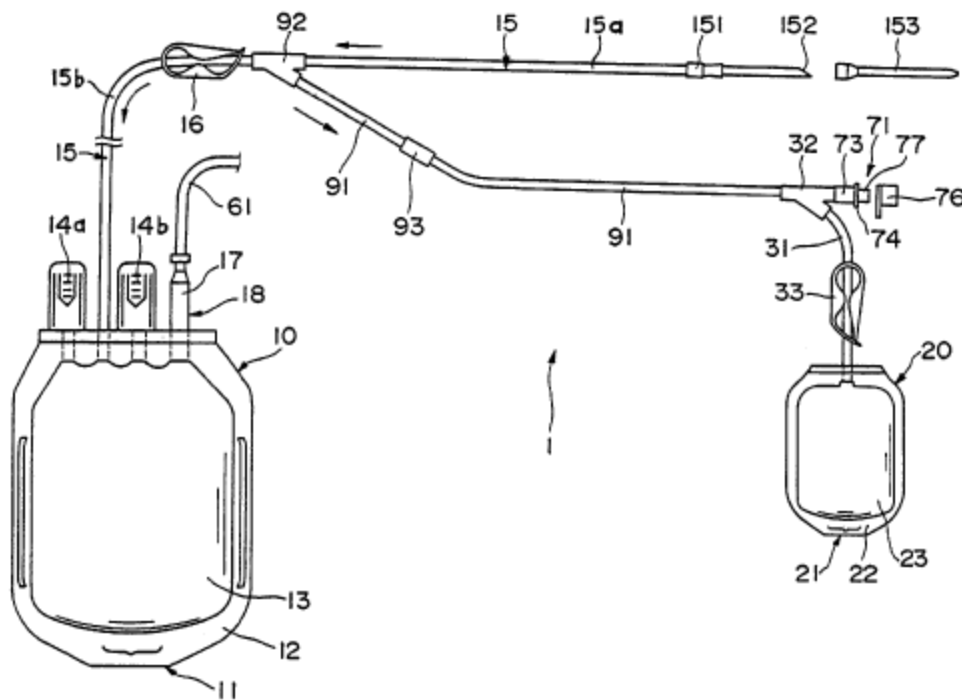
⁴ In instituting trial, we were satisfied, on the record that was before us, that the SSK Pamphlet constituted prior art. Inst. Dec. 10–11. Noble does not challenge that determination in its Patent Owner Response. Neither does the record, as developed during trial, give reason to revisit that determination in connection with this Final Written Decision. Accordingly, we regard the SSK Pamphlet as prior art to the '921 patent.

The portion of the SSK Pamphlet shown above depicts a “Tube end sealed at manufacture,” a “Heat seal location,” a “Pinch clamp,” a “Sampling Chamber,” a “Vent with filter,” a “Sampling Chamber,” a “Luer Needle,” and a “Samplok® Sampling Adapter Cap.”

b. Ishida

Ishida is directed to a “blood collecting apparatus.” Ex. 1020, Abstract. Ishida’s Figure 1 is reproduced below:

FIG. 1



Ishida’s Figure 1 above depicts blood collecting apparatus 1 including clamp assembly 33 (*id.* at 6:5–8), and “sealing member 93,” which includes “thin and frail breakable portion 933” (not shown) that is intended to be “broken” such that “sealing member 93 is opened” (*id.* at 8:4–21).

2. Level of Ordinary Skill in the Art

Terumo contends the following in connection with a person of ordinary skill in the art:

TBCT submits that a person having ordinary skill in the relevant art would be: a medical device designer with a Bachelor of Science degree in engineering, such as mechanical, industrial, biomedical engineering, or an equivalent technical degree with at least 5-7 years of experience in the field; or a person with an advanced degree in bio-medical engineering, with fewer years of experience, but at least some years of experience in the field; or a person who has worked in the field for at least 15 years. (Ex. 1007, ¶¶ 13-17.)

Pet. 4.

Noble does not express any disagreement with Terumo's contention in that respect. Accordingly, we accept Terumo's assessment as to the level of ordinary skill in the art. *See* 37 CFR 42.23(a) (material facts not specifically denied may be considered admitted).

3. Terumo's Position

Terumo contends that the SSK Pamphlet discloses all the features required by claims 6, 14, and 16, with the exception of a "frangible barrier." Pet. 37–44. We agree. With respect to the "transparent" (claims 6 and 16) and "rigid" (claims 6, 14, and 16) features added by those claims, Terumo represents that the SSK Pamphlet discloses a chamber that is "transparent" and a "syringe" of suitable rigidity. Pet. 41–43.

In accounting for the "frangible barrier" requirement of the claims, Terumo relies on Ishida. Pet. 37. In that regard, Terumo characterizes Ishida's sealing member 93 as being a frangible barrier with breakable portion 933. *Id.* at 37–38. Terumo also reasons the following:

It would have been obvious for one of ordinary skill in the art to combine the familiar elements of a platelet sampling device of the SSK Pamphlet with the breakable seal of Ishida to perform the functions those elements are known to perform in order to yield what would be expected from such an arrangement. *See KSR*, 550 U.S. at 415–417.

Id. at 38.

4. Noble’s Position

Noble generally disputes that a person of ordinary skill in the art would have combined the teachings of the SSK Pamphlet and Ishida to arrive at the invention of claims 6, 14, and 16. In advancing those arguments, Noble theorizes that: (1) it makes “no sense” to incorporate a frangible barrier as a part of the SSK Pamphlet’s blood sampling device (PO Resp. 6–10.); (2) the record does not establish recognition in the art that sampling devices may include both a clamp for closing off an inlet tube as well as a second sealing component for initially sealing the tube (*id.* at 11–15); and (3) the prior art did not recognize that a frangible barrier serves as a “failsafe against user error” in the manner contemplated by the ’921 patent (*id.* at 16–18).

5. Discussion

In reviewing both the SSK Pamphlet and Ishida, it is apparent that blood collecting or sampling devices are understood in the art as incorporating a clamp assembly operable to close off an inlet tube during the operation of the device, in conjunction with additional tube sealing components. Indeed, the SSK Pamphlet contemplates two such additional seals, namely: (1) a seal at the tube end formed “at manufacture”; and (2) a heat seal applied at some time at the position designated “heat seal location.”

In similar fashion, Ishida conveys that, in addition to clamping components such as clamp 33, sealing member 93 is employed for inhibiting flow within blood collecting apparatus 1. Thus, the prior art unmistakably conveys that clamps operating together with additional types of seals were known in blood collecting/sampling devices. Noble's contradictory position does not reflect appropriate consideration of how a person of ordinary skill in the art would have viewed the teachings of the prior art. In that respect, Noble does not reconcile its position to the contrary with the clear and unambiguous teachings of the prior art.

We also do not discern that the record fails to convey adequate reasoning for combining the teachings of the SSK Pamphlet and Ishida. A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR*, 550 U.S. at 416. Indeed, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at 417. Here, the prior art, in particular Ishida, sets forth readily that frangible barriers were a known type of sealing component in blood sampling devices. Each of Ishida and the SSK pamphlet demonstrates that, in such devices, use of additional sealing components beyond simply a clamp was commonplace. There also is no suggestion that implementation of a known and viable type of seal, i.e., a seal recognizable as a frangible barrier, into a given blood sampling device was somehow beyond the skill of one of ordinary skill in the art. The incorporation of a known frangible barrier as a sealing component in lieu of other sealing components, such as the tube end seal or heat seal of the SSK

pamphlet, is not the product of invention, but is, instead, the exercise of routine skill based on knowledge readily conveyed by the prior art.

Furthermore, even assuming that Noble's contention is correct, i.e., that the prior art did not recognize the same benefit of a frangible barrier as did the '921 patent (i.e., acting as a "failsafe for user error"), that does not conclude the obviousness inquiry. To that end, such inquiry does not require that the proffered reason to combine prior art references must be the same as that of a particular patentee. *See In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996) ("Although the motivation to combine here differs from that of the applicant, the motivation in the prior art to combine the references does not have to be identical to that of the applicant to establish obviousness."). Here, a skilled artisan would have had good reason to use a known type of seal, acting as one would expect of a seal, at a location in which such a seal is recognized as desired, irrespective of whether the reason is one regarded as being a "failsafe for user error."

Moreover, it is evident that the SSK Pamphlet contemplates the application of an initial seal of the end of the tube of its blood sampling assembly which is implemented "at manufacture." Ex. 1005. In that respect, it is self-evident that the seal must ultimately be breached or removed by a user to allow for the passage of fluid during operation of the sampling assembly. To the extent that such a seal, which must be removed or broken, is not, itself, regarded reasonably as a frangible barrier, Noble does not articulate suitably why a seal that is a frangible barrier, i.e., Ishida's sealing member 93 with its breakable portion 933, would not have been a logical and practical selection for such a seal.

With respect to the “transparent” and “rigid” features added by claims 6, 14, and 16, we note that, although the SSK Pamphlet does not characterize expressly its sampling chamber as “transparent” or “rigid,” Noble does not dispute that the SSK Pamphlet discloses a chamber that is transparent and rigid in the manner required. We also observe that Mr. Leinsing testifies that the SSK Pamphlet would be understood as disclosing a syringe chamber that is both transparent and rigid. *See* Ex. 1007 ¶ 82. We are mindful that a reference stands for all of its specific teachings, as well as the inferences one of ordinary skill in the art reasonably would have been expected to draw therefrom. *See In re Fritch*, 972 F.2d 1260, 1264–65 (Fed. Cir. 1992); *see also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (“hold[ing] that while an analysis of obviousness always depends on evidence that supports the required Graham factual findings, it also may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily require explication in any reference or expert opinion”). On the record before us, we are satisfied that a skilled artisan would have inferred reasonably that the sampling chamber depicted in the SSK Pamphlet has a level of transparency and rigidity adequate to account for the features introduced by claims 6, 14, and 16.

III. CONCLUSION

We have considered the record before us, including the Petition, its underlying evidentiary support, and Noble’s Patent Owner Response. For the foregoing reasons, we conclude that the record establishes that claims 6, 14, and 16 of the ’921 patent have been shown to be unpatentable by a preponderance of the evidence.

IV. ORDERS

It is

ORDERED that claims 6, 14, and 16 of the '921 patent are held unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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