

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IVERA MEDICAL CORP.,
Petitioner,

v.

CATHETER CONNECTIONS, INC.,
Patent Owner.

Case IPR2014-01124
Patent 8,647,326 B2

Before JOSIAH C. COCKS, MEREDITH C. PETRAVICK, and
JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Ivera Medical Corp.¹ (“Ivera”) has filed a Petition pursuant to 35 U.S.C. §§ 311–319, seeking *inter partes* review of claims 1–9, 12, and 14–16 of US 8,647,326 (“the ’326 patent”). Paper 2 (“Pet.”). Catheter Connections, Inc.² (“Catheter”) timely filed its Preliminary Response. Paper 9 (“Prelim. Resp.”).

Ivera contends that because the challenged claims are entitled to a priority date of no earlier than January 15, 2008, they are anticipated under 35 U.S.C. § 102(e)(1)³ by an Ivera patent application filed on February 12, 2007. Alternatively, Ivera seeks benefit of an application filed on October 10, 2006. Catheter asks the Board to deny the Petition under 35 U.S.C. § 325(d) because the Petition presents substantially identical arguments, and prior art, as those that were before the Examiner during *ex parte* prosecution.

We have jurisdiction under 35 U.S.C. §§ 6(b) and 314. For the reasons provided below, we grant the Petition to institute *inter partes* review of the challenged claims.

A. Related Matters

The parties declare that the ’326 patent has been asserted in the U.S. District Court of New Jersey in Case No. 1-14-cv-00852, in *Excelsior Medical Corporation v. Ivera Medical Corporation*, filed February 11, 2014. Pet. 1; Paper 5, 3.

¹ Ivera Medical Corporation is the real party-in-interest. Paper 1, 1.

² Catheter Connections, Inc. is the assignee of the ’326 patent and the real party-in-interest. Ex. 1001, 1.

³ Section 3(b) of the Leahy-Smith America Invents Act (“AIA”) revised 35 U.S.C. § 102, Pub. L. No. 112-29, 125 Stat. 284, 296 (2011). Because the ’326 patent has a filing date before September 16, 2012 (effective date), we will refer to the pre-AIA version of § 102.

B. The '326 Patent

The '326 patent relates generally to caps for medical connectors and, more specifically, to caps that can be used to protect the sterility of unconnected medical connectors, such as those that may be used for fluid flow or for fluid delivery systems. Ex. 1001, col. 1, ll. 27–30.

Claims 1 and 16 are independent claims. Claim 1 recites:

1. A system of medical luer⁴ connector caps comprising:

at least two disinfecting caps, each including a receiving portion having (i) a chamber defining an opening in which a medical tubing connector can be received, (ii) an exterior surface extending around the opening for receiving a cover, (iii) a means for engaging threads of luer connectors; and

a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps.

Ex. 1001, col. 29, ll. 33–44.

Claim 16 recites:

16. A system of medical luer connector caps comprising:

a first disinfecting cap, including a first receiving portion having (i) a first chamber defining a first opening in which a medical tubing connector can be received, (ii) a first exterior surface extending around the first opening for receiving a cover, (iii) first means for engaging threads of luer connectors;

⁴ A luer connector is a specific type of connector that uses a conical fitting with a 6% taper to create a seal. Ex. 1002 ¶¶ 30–31. The sealing surfaces of luer connectors are sometimes secured or “locked” in place by threading. *Id.* ¶ 32.

a second disinfecting cap, including a second receiving portion having (i) a second chamber defining a second opening in which a medical tubing connector can be received, (ii) a second exterior surface extending around the second opening for receiving a cover, (iii) second means for engaging threads of luer connectors; and

a cover extending over and solely in contact with the first and second exterior surfaces, so as to seal the first and second chambers.

Id., col. 30, ll. 30–46.

Claims 2–9, 12, and 14–15 all depend from claim 1.

C. References Relied Upon

Ivera relies upon the following references:

Reference	Date	Exhibit No.
US App. No. 2008/0019889 A1 (“Rogers ’889”)	January 24, 2008	1006
US 6,394,983 B1 (“Mayoral”)	May 28, 2002	1021
US 7,282,186 B2 (“Lake”)	October 16, 2007	1019
US App. No. 2007/0112333 (“Hoang”)	May 17, 2007	1018

D. Asserted Grounds of Unpatentability

Ivera challenges the patentability of the ’326 patent on the following grounds:

Ground	Basis	Claims Challenged
1	35 U.S.C. § 102(e)	1, 4–9, 12, 14–16
2	35 U.S.C. § 103(a)	2, 3
3	35 U.S.C. § 103(a)	1, 4–9, 12, 14–16

4	35 U.S.C. § 103(a)	2, 3
5	35 U.S.C. § 103(a)	1, 4–9, 12, 14–16
6	35 U.S.C. § 103(a)	2, 3

II. BACKGROUND

The '326 patent claims the benefit of a chain of applications, including one provisional application and three continuations-in-part. Pet. 9. The '326 patent issued from US Appl. No. 12/610,033 (the “Solomon '033 application”), which was filed on October 30, 2009. Ex. 1001, 1. The Solomon '033 application claims the priority benefit of, *inter alia*, provisional application No. 60/880,541 (the “Howlett '541 application”) which was filed January 16, 2007. *Id.*

A. Prosecution of the '326 Patent

The original claims of the Solomon '033 application described “a system configured for use with a pair of separated medical connectors,” “wherein the male cap and the female cap are attached to each other and are in a sealed condition when in pre-use configuration.” Pet. 11 (quoting Ex. 1004, 93).

In mid-2011, Catheter canceled the pending claims, and added new claims. Pet. 12 (citing Ex. 1013). The new claims were no longer limited to a “pair” of male and female caps, but instead claimed a system with “at least two disinfecting caps.” *Id.* (citing Ex. 1013, 5–6). The new claims also replaced the “sealed connection” with a “cover extending over the exterior surface of the at least two disinfecting caps.” *Id.*

The Examiner rejected the amended claims as unpatentable over US 7,780,794 (the “Rogers '794 patent”). The Rogers '794 patent issued from US Appl. No. 11/705,805 (the “Rogers '805 application”), which was filed on

February 12, 2007 and published on January 24, 2008 as US Publ. App. No. 2008/0019889 (the “Rogers ’889 publication”). In rejecting the amended claims, the Examiner found that the Rogers ’794 patent disclosed disinfecting caps, each including: (i) a receiving portion having a chamber defining a single opening in which a luer connector can be received; (ii) an exterior surface extending around the opening for receiving a cover; (iii) an absorbent pad having an antiseptic agent disposed in the chamber; and (iv) a means for engaging threads of luer connectors. Ex. 1009, 4. The Examiner also found that “Rogers [’794] teaches that multiple caps may be attached to a single cover ... so as to seal the chamber of each disinfecting cap.” *Id.*

Catheter did not dispute the Examiner’s finding that the Rogers ’794 patent taught the subject matter of the pending claims, but instead argued that the Rogers ’794 patent was not eligible prior art because it was not entitled to the priority dates of its provisional applications “with respect to the disclosure of the seal.” Ex. 1010, 6. Therefore, argued Catheter, the Rogers ’889 publication’s effective filing date was February 12, 2007 (the date the utility application was filed), for subject matter directed to the seal. *Id.* Furthermore, Catheter argued that they were entitled to the benefit of the January 16, 2007 filing date of the Howlett ’541 application. Pet. 14 (citing Ex. 1010, 6).

In response to Catheter’s argument, the Examiner identified another reason the ’326 patent was not entitled to the effective date of the Howlett ’541 application. The Examiner found that the claim term “luer connector” of claims 1 and 16 does not appear in the Specification of the Howlett ’541 application. *Id.* (citing Ex. 1011, 3). Summarizing a subsequent interview between the Examiner and Catheter, the Examiner stated: “The proposed amendment does not provide the claims with the filing date of the provisional application 60/880,541 since the

provisional does not explicitly teach luer connectors. Therefore, Rogers [’794] is still eligible as prior art.” Pet. 15 (citing Ex. 1012, 2). The Examiner then suggested amending the independent claims to replace “luer connector” with terms consistent with the ’541 application, specifically, substituting the limitation “medical tubing connector” for “luer connector.” Catheter subsequently amended the claims in conformance with the Examiner’s recommendation. The claims were then allowed, and the ’326 patent issued on February 11, 2014. Ex. 1001, 1.

III. ANALYSIS

A. *Claim Construction*

The Board construes claims in an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). Claim terms also 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 disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Ivera proposes the following claim constructions for the proposed *inter partes* review:

Claim Term	Proposed Interpretation	Claim(s)
means for engaging threads of luer connectors	threads that mate with the threads of luer connectors, and equivalents thereof	1, 16

means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a female luer connector	threads on the interior of the opening of the cap, that mate with the threads of a female luer connector, to securely connect the cap to the connector, and equivalents thereof	2
means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a male luer connector	threads on the interior of the opening of the cap, that mate with the threads of male luer connector, to securely connect the cap to the connector, and equivalents thereof	4
connection interface	the part of a connector cap that connects with another medical implement or connector cap	9

Catheter does not contest the claim constructions proposed by Ivera, but reserves the right to present positions on claim construction in this or any another proceeding.

As we relate *infra*, during *ex parte* prosecution of the '326 patent, the Examiner determined that the claim term “means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a male luer connector” did not require that the recited means necessarily constitute a luer connector within the cap. We agree with the Examiner’s finding and similarly do not interpret Ivera’s proposed construction of the claim term to require that the “means within the cap for engaging a male luer connector” necessarily constitutes a female luer connector.

B. Grounds 1–4

A threshold question before us is whether the '326 patent can claim the priority benefit of the Howlett '541 application. If it can, then the Rogers '794 patent is not prior art to the '326 patent, and Ivera likely cannot prevail on Grounds 1–4.

Ivera's arguments that the '326 patent cannot claim the benefit of the Howlett '541 application are based upon two premises: (1) that the specification of the Howlett '541 application does not teach the claim language's use of the term "luer connection"; and (2) that the Howlett '541 application does not teach a "cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps."

Catheter responds that the record of the file history demonstrates that the Examiner deliberated upon the issue of priority with respect to both of these premises on multiple occasions during prosecution, and that Catheter repeatedly addressed the Examiner's findings, to the eventual satisfaction of the Examiner. Prelim. Resp. 12 (citing Ex. 1020, 7).

With respect to premise (1), Ivera argues that, despite Catheter's amendment of claims 1 and 16, the term "luer connectors" remains present elsewhere in the limitations of the claims, and that the '326 patent cannot claim the priority benefit of the Howlett '541 application. Pet. 20 (citing Ex. 1001, claims 1 and 16). According to Ivera, a person of ordinary skill in the art would not have understood the "medical connectors" described in the Howlett '541 application to necessarily mean "luer connectors," which are not explicitly disclosed. *Id.* (citing Ex. 1002 ¶ 311). Ivera argues that there are types of "medical connectors" other than luer connectors that fall within the broad description of the Howlett '541 application, including connectors used in blunt needle systems and blunt cannula systems. *Id.*,

21 (citing Exs. 1022 and 1023). Ivera also points to the specification of the '326 patent, which recognizes that there are medical connectors other than luer connectors; luer connectors are disclosed as only one embodiment of the patented invention. *Id.* (citing Ex. 1001, col. 5, ll. 43–44).

Catheter responds by arguing that the recitation of “luer connectors” within the preamble is not a limitation of the claim. Prelim. Resp. 12. Furthermore, argues Catheter, with respect to the recited function of engaging threads of luer connectors in the means-plus-function language of the claims, the recited structure (means) encompasses threads, and it is this structure, i.e., threads, that is disclosed explicitly by the threaded, screw-on cap disclosed by the Howlett '541 application. *Id.* (citing Ex. 1005, 1, 2, Fig. 4). Catheter also argues that substantially identical structures are presumed to be capable of the same function, and there is no allegation that threads to receive “luer connectors” are structured differently than threads to receive “medical connectors.” *Id.*, 12–13.

With respect to premise (1), we find that the arguments made by Ivera here in connection with the Rogers '889 publication are directed to essentially the same issues considered by the Examiner during the *ex parte* prosecution of the application that issued as the '326 patent. *See* Section II.A., *supra*. Although Ivera disagrees with the Examiner's eventual finding that the Rogers '794 patent (and by extension the Rogers '889 publication) is not prior art, Ivera does not explain persuasively why the Examiner was incorrect in concluding that the specification of the Howlett '541 application provides adequate written description support for the claims of the '326 patent.

In the Final Rejection of claim 1, the Examiner stated:

[T]he [Howlett '541 application] does not teach the claimed feature of “a chamber defining a single opening in which a luer connector can be received.” [The '541 application] only teaches caps suitable for

connection with connectors commonly used in a variety of medical apparatus (e.g. IV tubing sets and needless [sic] injection sites/connectors attached to vascular access devices).

Ex. 1011, 2. The Examiner eventually allowed claim 1 of the '326 patent after Catheter altered the language of claim 1 to read “a chamber defining ~~a single~~ an opening in which a ~~luer~~ medical tubing connector can be received.” Ex. 1020, 2. A similar change was made to the language of independent claim 16. *Id.*

Therefore, the only two remaining uses of the claim term “luer” within the extant language of claim 1 are the recitations of a “system of medical luer connector caps” in the claim preamble and “a means for engaging threads of luer connectors.” The language of a claim preamble does not constitute a limitation of the claim when it simply states a purpose or intended use of the invention, or acts as a mere title for the invention. *See, e.g., Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 868 (Fed. Cir. 1985). Determinations of whether the language of the preamble limits the scope of the claim are made on a case-by-case basis. *See In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987). In this instance, the preamble recites no more than the title and purpose of the claimed invention, i.e., a “system of medical luer connector caps.” In this usage, the term “luer” modifies the word “connector” and not the term “caps” themselves, which are the claimed invention. Put otherwise, the preamble describes a system of caps for luer connectors. As such, the term “luer” in the preamble refers to the nature of the connectors to which the caps are designed to be connected. Consequently, it provides no limitation of the scope of the claimed invention itself, other than that the cap is designed for luer connectors.

With respect to the limitation reciting “a means for engaging threads of luer connectors,” the Examiner found, in allowing the claim, that the recited means-

plus-function language should be interpreted under 35 U.S.C § 112 (sixth paragraph) because it uses the generic placeholder “means for” coupled with functional language “engaging threads of luer connectors.” Notice of Allowance, October 3, 2013, 2. The Examiner consequently interpreted the term to cover the corresponding structure described in the Specification that achieves the claimed function. *Id.* The Examiner found that the Specification disclosed “threads that mate with the threads of luer connectors,” which corresponded to the means-plus-function language of the claim.

We agree with the Examiner and Catheter that the Howlett ’541 application discloses “threads that mate with the threads of luer connectors.” The Howlett ’541 application explicitly discloses “protective caps for both male and female screw-together connections” that have “helical screw threads on the inside” of a “hollow cylindrical housing.” Ex. 1005, 8. These threads are designed to cap the ends of exposed complementary medical screw-on connectors, including, potentially, luer connectors, which were well-known in the contemporary art. *Id.*, 7. We consequently agree with the Examiner’s finding that the “threads” which are integral to the language of the limitation are disclosed by the Howlett ’541 application and that the ’326 patent can claim the priority benefit of the Howlett ’541 application. Ivera next argues, with respect to premise (2) (*viz.*, the Howlett ’541 application does not support a “cover extending over ... at least two disinfecting caps”), that the Howlett ’541 application describes only: (1) a nested pair of male and female caps with a “wrap-around seal”; or (2) a “cover” over a single female cap embodiment (the same as in Ivera’s Provisional Appl. No. 60/850,438 (the “Rogers ’438 application”)). Pet. 22 (citing Ex. 1005; Ex. 1002 ¶ 86). Ivera argues that Catheter cannot point to the “seal” in the Howlett ’541 application as support for the claimed “cover.” *Id.* Ivera contends that the “seal”

shown in the Howlett '541 application could not be used with anything other than a pair of exactly two — and not “at least two” as claimed — disinfecting caps, and does not support this claim limitation. *Id.* (citing Ex. 1002 ¶¶ 87–88, 90).

Catheter responds that the distinction proposed by Ivera is artificial, because a claim which comprises, for example, a structure is essentially the same as a claim that comprises “at least” that structure. Prelim. Resp. 13 (citing, e.g., *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000)). Catheter argues that although the device can provide for nesting, nesting is not required, and it can be “a female cap only.” *Id.* (citing Ex. 1005, 1, 2, Fig. 4 (teaching both that a “cover or seal” can be used for a female cap and that a cover can be provided for two caps)). Catheter contends that this argument was sufficient to overcome the Examiner’s rejection during prosecution. *See* Ex. 1011.

We find that Ivera’s arguments with respect to premise (2) are directed to essentially the same issue considered by the Examiner during *ex parte* prosecution of the application that issued as the '326 patent. The Examiner initially found that the Rogers '794 patent disclosed the disputed limitation and rejected Catheter’s claims as anticipated under 35 U.S.C § 102(e). Ex. 1009, 4. Catheter amended the limitation and responded that:

[A]pplicants are entitled to their provisional filing date of January 16, 2007 [of the Howlett '541 application] as it discloses an embodiment of the claims, that is two caps with a “cover extending over the exterior surface of the at least two disinfecting caps, so as to seal the chamber of each disinfecting cap”.

Ex. 1010, 6. Specifically, Catheter stated:

On page 1, in the middle of the 3rd paragraph the text of the provisional refers to “the two caps are tightened, a seal is formed A second wrap-around, adhesive seal (e.g., foil leaf) may be added to maintain integrity of this seal during transport or storage.

And on page 1, last paragraph, "... the same nested and sealed male and female caps ..."

Id.

This argument evidently overcame the Examiner's rejection on this ground, for the Examiner's Final Rejection of the claims does not address this issue. *See* Ex. 1011. We cannot discern, nor does Ivera raise, any substantive difference between the argument made by Ivera in its Petition and the issue raised by the Examiner and overcome by Catheter during *ex parte* prosecution. We agree with the Examiner's reasoning during *ex parte* prosecution, and based on the present record are not persuaded that the Examiner made the wrong determination in that respect.

Finally, Ivera argues that, even if the '326 patent can claim the benefit accorded the Howlett '541 application, the Rogers '794 patent still qualifies as prior art because it is entitled to the effective filing date of the Rogers '438 application, of October 10, 2006, which antedates the filing date of the Howlett '541 application. Pet. 23. According to Ivera, the Rogers '438 application makes the same relevant disclosure as the Rogers '889 publication, except that — like Catheter's Howlett '541 application — Ivera's Rogers '438 application shows the "cover" element only in relation to a single disinfecting cap. *Id.* (citing Ex. 1017, Fig. 2; Ex. 1002 ¶ 173). Therefore, argues Ivera, if the '326 patent may claim the effective date of the Howlett '541 application, based on a finding that the description of a cover over a single cap is sufficient, then the Rogers '794 patent should likewise be prior art as of date of the Rogers '438 application for this concept, which is earlier still. *Id.*, 22–23. In such an eventuality, the Rogers '794 patent would anticipate the '326 patent as in Ground 1.

Catheter responds that Ivera does not, in its Petition, allege that the Rogers '438 provisional discloses a cover for "at least two disinfecting caps." Prelim.

Resp. 14. Therefore, argues Catheter, it can not only be said that the Examiner considered the issue of priority, but also that Ivera does not credibly allege that there is a disclosure of a cover for at least two caps in the Rogers '438 application. *Id.*, 15.

We agree with Catheter. Ivera does not point to any teaching that the Rogers '438 application teaches a “cover extending over ... at least two disinfecting caps,” nor can we find any such teaching. Consequently, we are not persuaded that the Rogers '438 application teaches this limitation. Nor did the Examiner find that the Rogers '438 application (which is a parent to the Rogers '805 application, which issued as the Rogers '794 parent) disclosed a “cover extending over” “at least two disinfecting caps.”

On the record before us, then, we are not persuaded that the Examiner erred in finding that the specification of the Howlett '541 application discloses the limitations “medical connectors” and a “cover extending over ... at least two disinfecting caps” recited in the independent claims. We therefore conclude that the '326 patent properly receives the benefit accorded the Howlett '541 application, which removes the Rogers '794 patent as prior art. Accordingly, and for the foregoing reasons, we are not persuaded that Ivera's Petition has shown a reasonable likelihood or prevailing on its proposed Grounds 1–4, and we consequently deny institution upon those Grounds.

B. Grounds 5 and 6

Ivera also seeks institution of *inter partes* review on the ground that claims 1, 4–9, 12, and 14–16 are invalid under 35 U.S.C. § 103(a) over the combination of Hoang and Lake (Ground 5), and on the ground that claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over the combination of Hoang, Lake, and Mayoral

(Ground 6). It is not disputed by the parties that: (1) Hoang is prior art to the '326 patent under 35 U.S.C. § 102(e)(1) because it was filed on November 17, 2005; (2) Lake is prior art to the '326 patent under 35 U.S.C. § 102(e)(1) because it was filed on June 20, 2003; and (3) Mayoral is prior art to the '326 patent under 35 U.S.C. § 102(b) because it issued on May 28, 2002.

1. Ground 5: Obviousness of claims 1, 4–9, 12, and 14–16 over the combination of Hoang and Lake

Ivera argues that Hoang teaches caps for fluid line access valves. Pet. 49. (citing Ex. 1018; Ex. 1002 ¶ 210). According to Ivera, the device in Hoang is a “cap/cleaner,” with the cap [10] at one end and cleaning end [16] at the other, as shown in Figure 4 of Hoang. *Id.* (citing Ex. 1002 ¶ 211). Figure 4 of Hoang is reproduced below:

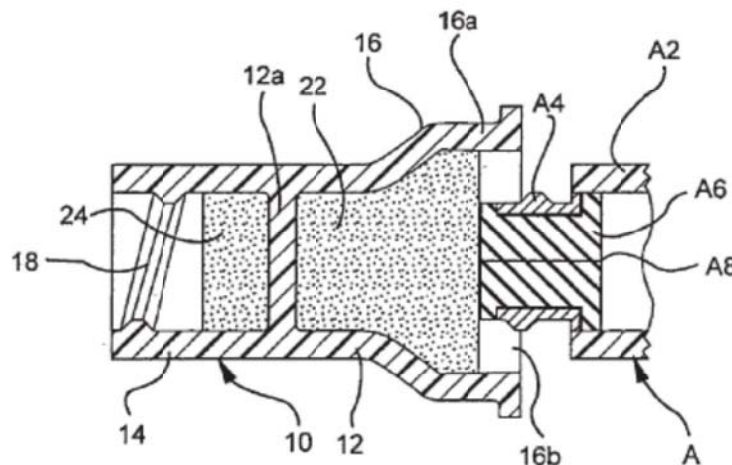


Figure 4 depicts a cross-sectional side view of the claimed cap/cleaner device cleaning a patient fluid line access valve.

Ivera quotes Hoang as stating that both “[c]ap [10] and cleaning [16] devices antiseptically maintain patient fluid line access valves to minimize the risk of

infection via catheters.” *Id.* (quoting Ex. 1018, Abstract).

Ivera also points to Figure 10B of Hoang, which is reproduced below:

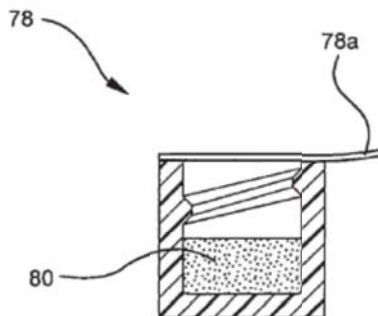


Figure 10B depicts a cross-sectional view of a capping device.

According to Ivera, Figure 10B depicts a “stand-alone” cap that contains a pad [80] with antimicrobial agent that comes into contact with the line when inserted therein. Pet. 49 (citing Ex. 1018 ¶¶ 17, 22; Ex. 1002 ¶ 212). Ivera asserts that the cap shown in Hoang has threads that can be attached to a medical connector, including a “luer” connector. *Id.* (citing Ex. 1018 ¶ 22; Ex. 1002 ¶ 215). Ivera also argue that Hoang discloses a cover 78a that extends over an open end of the cap. *Id.* (citing Ex. 1018 ¶ 43; Ex. 1002 ¶ 213).

Ivera argues further that Lake teaches a method of packaging wherein multiple disinfecting caps are connected to another under a single cover. Pet. 43 (citing Ex. 1019, Fig. 4, col. 3, ll. 59–65; Ex. 1002 ¶ 183). Ivera quotes Lake as relating that:

The invention can be packaged in many different ways. There is shown in FIG. 4 an embodiment in which several decontamination devices 10 are joined at edges 58. The edges 58 are perforated, scored, or otherwise construed to permit the detachment of the decontamination devices from one other. Covers 62 can then be removed by peeling or otherwise removing the covers 62 from housings 64.

Id. (quoting Ex. 1019, col. 3, ll. 59–65); *see also* Ex. 1002 ¶ 183. Figure 4 of Lake is reproduced below:

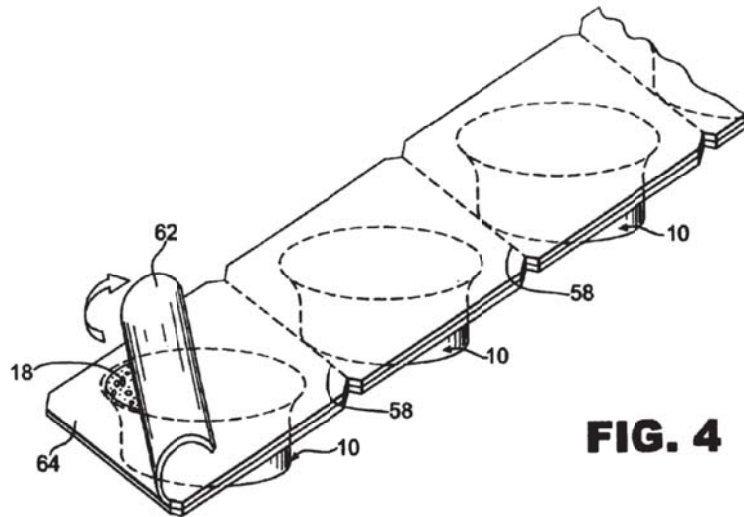


Figure 4 of Lake depicts a perspective view, partially in phantom, illustrating a packaging system in which several decontamination devices are engaged together.

Ivera contends that it would have been obvious to one of ordinary skill in the art to use the packaging system of Lake with the system for disinfecting caps described in Hoang; this would involve the extension of the Hoang cover across two or more caps. Pet. 50 (citing Ex. 1002 ¶¶ 219–220).

As an initial matter, because we have denied Ivera’s Petition to institute trial on Grounds 1–4, Catheter’s argument with respect to the horizontal redundancy of the cited prior art references, specifically the Rogers ’889 publication and Hoang, cited in support of Ground 5, is now moot.

Claim 1 of the ’326 patent has two principal limitations: (1) at least two disinfecting caps, each including a receiving portion having (1a) a chamber defining an opening in which a medical tubing connector can be received, (1b) an exterior surface extending around the opening for receiving a cover, (1c) a means

for engaging threads of luer connectors; and (2) a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps.

With respect to limitation (1), Hoang teaches (1a) “a chamber defining an opening in which a medical tubing connector can be received” and (1b) “an exterior surface extending around the opening for receiving a cover.” Hoang teaches that:

[C]ap end **14** of cap/cleaner **10** is placed over access portion **A10** such that access portion **A10** is within cavity **14b** of cap end **14**. Cap/cleaner **10** may be attached either prior to or after placement of valve A for the patient. As shown in **FIG. 3**, valve A includes thread **A4**. By rotating cap/cleaner **10** or valve A relative to one another, threads **A4** and **18** (of cap/cleaner **10**) interlock to provide a secured attachment.

Ex. 1018 ¶ 24. Hoang thus teaches a “cavity” into which the “access portion⁵” is inserted, corresponding to claim 1’s “chamber defining an opening in which a medical tubing connector can be received.”

With respect to limitation (1b), Hoang teaches that:

FIG. 10B shows a representative embodiment of cap device **78** with lid **78a** and pad **80**. Cap device **78** is a stand-alone device where pad **80** may either be a wet pad or a dry pad. Where pad **80** is a dry pad, cap device **78** is used as described above for cap end **14**.

Id. ¶ 43.

Hoang also teaches “valve A includes thread **A4**. By rotating cap/cleaner **10** or valve A relative to one another, threads **A4** and **18** (of cap/cleaner **10**) interlock to provide a secured attachment” corresponding to limitation (1c)’s “a means for engaging threads of luer connectors.” *Id.* ¶ 24.

⁵ Of a “patient fluid line access valve,” i.e. a “medical tubing connector.” See Ex. 1018 ¶ 5.

Figure 10B depicts the lid 78a attached only to the outer surface of the cap 78 surrounding the opening of the cavity, corresponding to limitation 1B's "a cover extending over and solely in contact with the exterior surface" of the cap.

Hoang also teaches:

However, upon withdrawal after accessing the patient fluid line, access portion A10 of valve A may either be immediately capped or cleaned again prior to capping. If immediately capped, a new, second cap/cleaner 10a is obtained and removed from its package. This is represented by step 40 [of FIG. 5].

Id. ¶ 35. Hoang's teaching of "a new, second cap/cleaner" corresponds to limitation (1)'s and claim 16's common requirement of "at least two disinfecting caps."

Lake teaches: "Packaging for the decontamination device can be provided. A removable cover can be provided for the housing. At least two of the decontamination devices can be detachably engaged." Ex. 1019, col. 2, ll. 1-41. Claim 6 of Lake recites: "[t]he decontamination device of claim 1, wherein at least two of said housings are detachably engaged." *Id.* Furthermore, Figure 4 of Lake shows a connected strip of at least three decontamination devices, i.e., "disinfecting caps" that are joined at their edges, each covered by a removable cover 62. *Id.*, Fig. 4. This, in combination with Hoang's teaching of a sealing cover, *supra*, corresponds to limitation (2)'s requirement of "a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps." Furthermore, Lake also teaches that: "the cover 30 is then secured to flange 52 by a suitable adhesive so as to be removable" corresponding to dependent claim 6's recitation of: a "system according to claim 1 wherein the cover comprises an adhesive." *Id.*, col. 3, ll. 56-58.

On this record, we find that the combination of Hoang and Lake teaches all of the limitations of independent claims 1 and 16. Ivera also has provided detailed claims charts indicating where all the features of dependent claims 4–9, 12, 14, and 15 are found in either Hoang or Lake. *See* Pet. 54–59. Furthermore, Ivera contends that:

One of ordinary skill in the art at the time of the invention would have been motivated to modify the system of Hoang by providing the plurality of cleaning devices attached to a strip of the flexible material, as in Lake, in order to maintain an orderly arrangement of multiple cleaning caps which are readily accessible for use.

Pet. 51 (quoting Ex. 1027, 8–9).

Ivera also cites to the testimony of its declarant, Karl Leinsing, in support of its obviousness position. *Id.*, 50 (citing Ex. 1002 ¶¶ 185–193, 219–220). Mr. Leinsing, who has extensive experience in the field of medical IV-line related products, declares that “the combination represents the incorporation of a known method for packaging a decontamination device [Lake] with a known Luer connector cap [Hoang/Rogers ’889 publication].”⁶ Ex. 1002 ¶¶ 2–3, 192, 220. Catheter does not dispute this contention. Ivera has thus reasonably set forth uncontested arguments as to why the combined prior art references teach the limitations of claim 1, as well as why one of ordinary skill in the art would be motivated to combine the references. On this record, we are satisfied that Ivera has articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). We therefore conclude that Ivera has a reasonable likelihood of prevailing on ground 5.

⁶ In arguing obviousness over the combination of Hoang and Lake, Dr. Leinsing repeats his arguments with respect to the obviousness of the invention over the Rogers ’889 publication and Lake.

2. Ground 6: Obviousness of claims 2 and 3 over the combination of Hoang, Lake, and Mayoral.

Claim 2 of the '326 patent recites, a “system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed on an exterior wall of the cap so as to engage a male luer connector.” Claim 3 depends from claim 2, and recites a “system according to claim 2, wherein the means for engaging threads includes a helical thread.”

Ivera repeats its contentions *supra* with respect to the teachings of Hoang and Lake. Pet. 60. Ivera argues that disinfecting caps with threads on an exterior wall to engage a male luer connector are taught by Mayoral. *Id.* (citing Ex. 1002 ¶ 198). Ivera contends that it would have been obvious to combine the teachings of Mayoral with Hoang and Lake for the same reasons that it would have been obvious to combine the teachings of Mayoral with Rogers '889 and Lake. *Id.* (citing Ex. 1002 ¶ 268). Ivera quotes Mayoral as reciting:

The present invention relates to a system for covering a portion of a fitting or connector on a medical device or other apparatus through which fluid is transferred. The present invention is especially suitable as a cap and male Luer lock connector combination for a Luer lock type of fluid transfer device such as a hypodermic needle.

Id., 40 (quoting Ex. 1021, col. 1, ll. 5–10).

Ivera argues that the combination of Hoang and Mayoral represents the incorporation of the known cap for a male luer connector (Mayoral) with the known disinfecting luer connector cap (described in Hoang), each without change of their known functions, and without unpredictable results. *Id.*, 60 (citing Ex. 1002 ¶ 172). According to Ivera, it would have been obvious to combine the teachings of Mayoral with Hoang because a person of ordinary skill in the art would know that male threads complement female threads, and *vice versa*. *Id.*

Catheter responds to Ivera's arguments with respect to both Grounds 5 and 6 (Catheter's "Group C") by arguing that Ivera has failed to provide sufficient rationale to overcome the horizontal redundancy with respect to the references in Grounds 1–4. According to Catheter, Ivera has replaced Rogers '889 in Grounds 1–4 (Catheter's Groups A (Grounds 1 and 2) and B (Grounds 3 and 4), respectively) with a two reference combination of Hoang and Lake, without adequately explaining the relative weaknesses of Grounds 5 and 6 that rely on Hoang and Lake, as compared with Grounds 1–4 that rely on Rogers '889.

As we found with respect to Catheter's arguments with respect to Ground 5 *supra*, because we have denied Ivera's Petition to institute trial on Grounds 1–4, Catheter's argument with respect to the horizontal redundancy of the cited prior art references, specifically the Rogers '889 application and Hoang, cited in support of Ground 6, is also moot.

Mayoral teaches:

[A] system for covering a portion of a fitting or connector on a medical device or other apparatus through which fluid is transferred. The present invention is especially suitable as a cap and male Luer lock connector combination for a Luer lock type of fluid transfer device such as a hypodermic syringe.

Ex. 1021, col. 1, ll. 5–10.

Specifically, Figure 2 of Mayoral depicts an embodiment of the claimed device. Figure 2 of Mayoral is reproduced below:

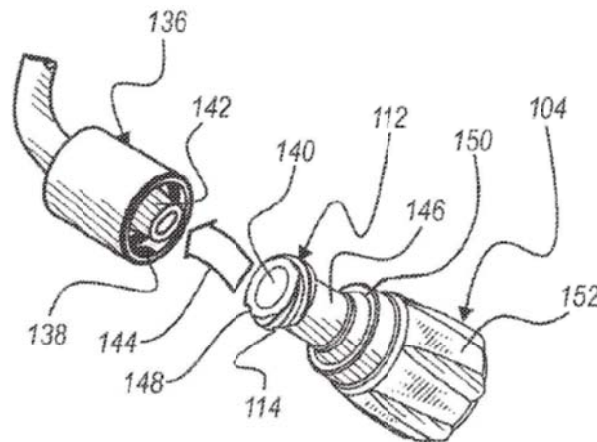


Figure 5

Figure 5 of the '326 patent depicts a cap and luer lock connector to which the male cap may be affixed.

The specification of the '326 patent describes Figure 5 as depicting “threads **114** of cap **104** are of a size and pitch to engage threads **138** of a male luer lock connector **136**.” Ex. 1001, col. 5, ll. 43–44.

We find that Hoang, Lake, and Mayoral all teach that male and female luer connections and caps were well-known in the prior art at the time of invention and that Mayoral explicitly teaches a male luer connector. Combining this finding with our findings *supra* with respect to Ground 5, on this record, we find that the combination of Hoang, Lake, and Mayoral teach all of the limits of claims 2 and 3, and we conclude that Ivera therefore has a reasonable likelihood of prevailing on Ground 6.

IV. CONCLUSION

For the foregoing reasons, we determine that the evidence and arguments presented in the Petition establish that there is a reasonable likelihood that Ivera would prevail in showing the unpatentability of claims 1–9, 12, and 14–16 on Ivera’s Grounds 5 and 6. We are not persuaded that Ivera’s Petition establishes a

reasonable likelihood in showing the unpatentability of claims 1–9, 12, and 14–16 on Grounds 1–4. The Board has not made a final determination as to the patentability of any challenged claim.

V. ORDER

Accordingly, it is

ORDERED pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the following grounds of unpatentability:

Claims 1, 4–9, 12, and 14–16 as unpatentable under 35 U.S.C.

§ 103(a) over the combination of Hoang and Lake: and

Claims 2 and 3 as unpatentable under 35 U.S.C. § 103(a) over the combination of Hoang, Lake, and Mayoral;

FURTHER ORDERED that no other grounds are authorized for this *inter partes* review as to claims 1–9, 12, and 14–16; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this Decision.

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