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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHAD AMBORN, GEOFF CLARK, and
RENEE ROBERT

Appeal 2018-003752
Application 13/860,770
Technology Center 3600

Before KEN B. BARRETT, BRANDON J. WARNER, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1, 3–11, 13–20, 22, and 24. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM IN PART.

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 Smiths Medical ASD, Inc. Appeal Br. 3.

I. CLAIMED SUBJECT MATTER

The claims are directed to “connector fittings and more particularly to a filling fitting adapted to be used with medicament infusion systems.”

Spec. ¶ 2. According to the Specification, the disclosed filling fitting “prevents mis-connection among connectors to ensure that the correct medicament is input to the cassette [to be used with a medicament infusion system].” *Id.* ¶ 4. Of the claims on appeal, claims 1, 11, and 22 are independent claims. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A fitting, comprising:
 - a body having a longitudinal portion and a first end and a second end, one through passage in the body connecting the first and second ends, the first end having a conventional luer connector, the second end having an opening to the one through passage;
 - a non-conventional connector including an extension adapted to fit into the opening of the body, an other through passage extending along the non-conventional connector and the extension in longitudinal alignment with the one through passage, the non-conventional connector having a given configuration that prevents it from mating with a counterpart conventional luer connector but matable with a counterpart non-conventional connector having a configuration complementary to the given configuration;
 - at least one wing extending from and longitudinally along at least a part of a main portion of the body, the wing having a longitudinal top edge; and
 - a partition having a surface away from the first end extending circumferentially about the body, the end of the wing facing the first end merging with the surface of the partition with the top edge of the wing align [sic] with an outer circumferential edge of the partition.

Appeal Br. 22 (Claims Appendix).

Independent claim 22 recites, rather than a “non-conventional connector,” “the connector having a given configuration that prevents it from mating with any luer connector but matable with a counterpart connector having a configuration complementary to the given configuration.” *Id.* at 26.

II. REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Guala	US 5,855,230	Jan. 5, 1999
Segal	US 6,402,207 B1	June 11, 2002
Kennard	US 2008/0065023 A1	Mar. 13, 2008
Kyle	US 2011/0230856 A1	Sept. 22, 2011

III. REJECTIONS²

1. Claims 1, 3–11, and 13–20 are rejected under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention;
2. Claims 1, 3–5, 9, 11, 13, 15, 17, 22, and 24 are rejected under 35 U.S.C. § 102(a)(1) as anticipated by Guala;
3. Claims 6, 7, 18, and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Guala and Segal;
4. Claims 10 and 16 are rejected under 35 U.S.C. § 103 as being unpatentable over Guala and Kennard; and

² The application is being examined under the First Inventor to File provisions of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, which was enacted on September 16, 2011. Final Act. 2.

5. Claim 14 is rejected under 35 U.S.C. § 103 as being unpatentable over Guala and Kyle.

IV. OPINION

A. The Indefiniteness Rejection

Independent claims 1 and 11 recite “a conventional luer connector” and “a non-conventional connector . . . , the non-conventional connector having a given configuration that prevents it from mating with a counterpart conventional luer connector but matable with a counterpart non-conventional connector having a configuration complementary to the given configuration.” The Examiner rejected claims 1, 3–11, and 13–20 as being indefinite, maintaining that the terms “conventional” and “non-conventional” fail to impart particular structure to the connectors. *See* Final Act. 2, 10; Ans. 3–5.

Appellant argues that “a person skilled in the art could readily see that, with more than reasonable certainty, ¶¶ 005 and 0021–0023 [of the Specification] amply describe the differences between a ‘conventional’ connector and a ‘non-conventional’ connector.” App. Br. 8. Appellant further argues that the meaning of the disputed terms is made clear through references in the Specification to certain International Standard Organization (ISO) standards and a provisional application incorporated by reference. *Id.* (citing Spec. ¶¶ 21, 23 (as amended by preliminary amendment)); *see id.* (citing but not discussing paragraph 25 of the Specification). Appellant’s proposed construction is that “conventional” luer connectors are “the luer connectors that are defined by ISO 594-1 and 594-2” and, “[b]y extension, a ‘non-conventional’ connector is a connector that is not based on the ISO 584-1 and 594-2 standards.” App. Br. 8.

For the reasons that follow, we affirm the Examiner's indefiniteness rejection.

As mentioned, Appellant directs our attention to, *inter alia*, paragraphs 5 and 25 of the Specification. *See* App. Br. 8. Paragraph 5, in discussing "[t]he inventive filling fitting," states that "[t]he non-conventional connectors are disclosed in the [then co-pending provisional application No. 61/457,879] and may be referred to as CorrectInject® (CI) connectors." Spec. ¶ 5. Similarly, paragraph 25 along with paragraph 27 describe Figure 6 as "a cross-sectional view of *the fitting 100 of the instant invention* showing the non-conventional male connector . . . [where] filling fitting 100 has . . . a non-conventional connector 112 in the form of a male CI connector at its other or second end." Spec. ¶¶ 25, 27 (emphasis added). From this, a person of ordinary skill in the art might understand that the non-conventional connectors of the claimed invention are limited to the specific CI connectors disclosed in the cited provisional application or to that shown in Figure 6 of the instant Specification,³ and are not, as Appellant urges, merely anything other than the particular luer connector of the ISO standards. *Cf.* Reply Br. 4 n.2 (Appellant, in attempting to distinguish the prior art, arguing that, "[i]n the claims, the recited 'non-conventional connector' is clearly shown in the drawings and explained in the specification.").

The preliminary amendment to paragraph 21 inserted the following language: "As disclosed in the aforementioned incorporated by reference [provisional] application 61/457,879 (now 13/517,782), standard or

³ It is not clear whether the CorrectInject® (CI) connectors of the cited provisional application and as shown in the figures of the instant Specification are the same.

conventional luer connectors are manufactured in accordance with the current ISO (International Standard Organization) Standards 594-1 and 594-2.” Prelim. Amend. (6/30/14) ¶ 21 (underlining omitted). In response to the Examiner’s concern regarding the practice of defining claim limitations using standards that can change over time, Appellant represented that the cited ISO Standards issued in 1986 and 1998, respectively, and that those two standards do not change, and further asserts that those “have been replaced by ISO standard 80369-7 published in 2016.” Reply Br. 2.⁴

After the Preliminary Amendment, paragraph 23 provides, with underlining showing inserted language:

The non-conventional male connector, as a standalone component 112, is shown in Fig. 4. The particulars of the non-conventional male connector, which may be referred to as a male CorrectInject[®] (CI) connector as noted above, is described in greater detail in the aforementioned ’879 (now ’782) application, where non-conventional connectors are defined to be designed such that they are incompatible with the luer connectors that are manufactured in accordance with the current ISO (International Standard Organization) Standards 594-1 and 594-2.^[5] As

⁴ The Examiner requested that Appellant submit copies of the cited standards. Final Act. 10. Appellant responded as follows: “Appellant submits that the examiner is wrong in requiring that copies of the ISO standard be submitted. As pointed out above, the ISO standard 594-1 was published in 1986 and the ISO 594-2 in 1998. Therefore, each of those standards is publicly available and well known to persons who practice in the medical field.” Reply Br. 3.

⁵ To be precise, paragraph 5 of the provisional application refers not to a definition of “non-conventional connectors” generally, as the language of the Preliminary Amendment might suggest, but rather characterizes the design of the particular connector disclosed in that provisional application. Appl. No. 61/457,879, Spec. ¶ 5 (“*The connectors for the various conduits of the drug delivery system of the instant invention are designed such that they are incompatible with the standard or conventional connectors such as*

shown, non-conventional male connector 112 has a connector end represented by male CI connector 113 and a neck extension 114. . . .

Prelim. Amend. (6/30/14) ¶ 23 (underlining in original). Thus, a “non-conventional connector” could be understood to be: 1) that shown in Figure 4 of the instant Specification, 2) the CI connector described in the provisional application, or 3) any connector that is incompatible with a luer connector manufactured in accordance with one of two older ISO Standards. As to the latter and Appellant’s proposed construction—where a non-conventional connection is anything not based on the referenced ISO standards (App. Br. 8)—the incorporated provisional application suggests that luer connectors were, at that time, not the only type of known “standard or conventional connectors.” Appl. No. 61/457,879, Spec. ¶ 5 (referring to “the standard or *conventional connectors such as* luer connectors that are manufactured in accordance with the ISO (International Standard Organization) Standards 594-1 and 594-2.”) (emphasis added). If that is a correct proposition, Appellant’s term “non-conventional” confusingly would encompass a non-luer fitting that was regarded in the art as conventional at the time of the invention.

Additionally, the Examiner notes that “essential material,” which includes material necessary for claim definiteness, only may be incorporated by reference to a U.S. patent or U.S. patent application publication which does not itself incorporate by reference essential material. Ans. 4–5 (quoting

luer connectors that are manufactured in accordance with the ISO (International Standard Organization) Standards 594-1 and 594-2, but are compatible only with specially designed counterpart complementary connectors.”).

37 C.F.R. § 1.57(d)). Appellant responds, *inter alia*, with the assertion that, “to allege that the terms ‘conventional’ and ‘non-conventional’ are ‘essential material’ and therefore the claim is indefinite is *non sequitur*.” Reply Br. 3. The Examiner has the better position. The cited ISO standards are “essential material” because Appellant relies on them to define the claim terms “conventional” and “non-conventional.” Therefore, we agree with the Examiner that the incorporation by reference of the standards is improper, whether they are incorporated directly in the instant Specification or through a patent application publication that is incorporated in the instant Specification.

On the record of this appeal, the meaning of the terms “conventional” and “non-conventional” are sufficiently unclear to render indefinite the rejected claims. *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). Accordingly, we affirm the Examiner’s indefiniteness rejection under § 112(b) of claims 1, 3–5, 9, 11, 13, 15, 17, 22, and 24.

B. The Anticipation Rejection—Guala

Claims 1, 3–5, 9, 11, 13, 15, 17, 22, and 24 are rejected as anticipated by Guala. As discussed above, independent claims 1 and 11 recite “a non-conventional connector.” App. Br. 22, 23–24 (claims appendix). Independent claim 22 recites “a connector . . . having a given configuration that prevents it from mating with any luer connector but matable with a counterpart connector having a configuration complementary to the given configuration.” *Id.* at 26.

The Examiner found that Guala’s cap 8 is the recited non-conventional connector of claims 1 and 11 and the non-luer connector of claim 22. Final Act. 3, 5, 10; Ans. 5. Appellant disagrees, arguing that

component 8 is a protection cap, not a non-conventional connector. App. Br. 9.

Figure 1 of Guala is reproduced below:

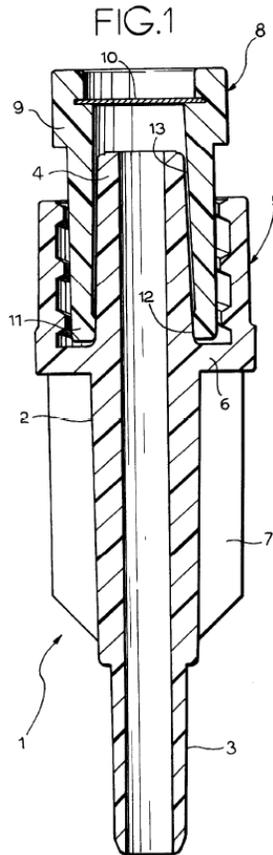


Figure 1 depicts “a diagrammatic axially sectioned view of a Luer-Lock fitting for medical infusion/transfusion lines.” Guala, 1:50–51. Shown is “a Luer-Lock fitting [element number 1] . . . comprising . . . a first outer Luer cone connector 3, intended to be coupled within the terminal end of a flexible hose . . . and defining at the other end a second outer Luer cone connector 4.” Guala, 1:54–60. “Reference numeral 8 indicates a protection cap sealingly fitted axially over the Luer cone connector 4.” *Id.*, 2:1–2.

In making the finding that Guala’s cap 8 is a non-conventional, non-luer connector, the Examiner reiterates the position that

“non-conventional connector” is indefinite and therefore “all that can be used to define” it are the remaining structural limitations recited in the claim. Ans. 5; *see also* Final Act. 10 (“In response to applicant’s argument that the connector 8 of Guala is not ‘non-conventional’, there is nothing in claim 1 that prevents this connector from being considered a ‘non-conventional connector’. If applicant wishes to further structurally define what constitutes a ‘non-conventional’ connector, then the claim should be amended accordingly.”). According to the Examiner,

Under broadest reasonable interpretation, the connector 8 can be considered a “non-conventional connector” since it contains an extension (11) and a through passage in longitudinal alignment with a through passage of the body as required by claim 1. Further, since cap 8 has an inner diameter too large to successfully mate with the outer diameter of a counterpart conventional connector “3”, the cap 8 of Guala is a “non-conventional connector” as defined by claim 1.

Ans. 5; *see also id.* at 7–8 (similarly addressing independent claim 11), 9 (addressing independent claim 22).

Although we recognize that Guala’s cap connects to the luer cone connector, we fail to see how the cap itself is a connector. *See* Guala, 1:43–47 (“According to a variant of the invention, said outer surface of the Luer cone connector is formed with an outer annular enlarged portion for the forced coupling into the inner end of the cap.”). Guala’s description of the various components of the overall fitting repeatedly refers to a “cap” and a “connector” in the same sentence and as two different types of components and impliedly distinguishes their respective functions of protecting and connecting. *See, e.g., id.*, 1:43–47, 2:1–2 (“Reference numeral 8 indicates a protection cap sealingly fitted axially over the Luer cone connector 4.”).

Regardless as to the meaning of “non-conventional,” the Examiner has not explained adequately why a person of ordinary skill would have considered the cap to be a “connector” within the meaning of the rejected claims. Accordingly, we determine that the Examiner has attributed an unreasonably broad construction to the term “connector.” We cannot find that a person of ordinary skill in the art would have understood Guala’s cap 8 to be the recited “connector.”

In light of the above, we cannot sustain the anticipation rejection of the independent claims, or of the rejected dependent claims which necessarily contain the same limitation.

C. The Obviousness Rejections—Guala and Segal, Guala and Kennard, and Guala and Kyle

The Examiner determined that several dependent claims would have been obvious in light of Guala in combination with one of three secondary references. Final Act. 6–9. The Examiner relies on Segal for, among other things, the relationship between the fluid source, the fluid store, and the fitting interposed therebetween as recited in dependent claim 6. *Id.* at 6. The Examiner relies on Kennard for the orange color of dependent claims 10 and 16, and relies on Kyle for providing indicia on a member as recited in dependent claim 14. *Id.* at 7–8, 9. The three obviousness rejections all are based on the anticipation rejection of the independent claims as discussed above and, specifically, are premised on the Examiner’s finding that Guala’s cap is the claimed non-conventional connector. *See id.* at 6, 7, 9. In light of our disposition of the underlying anticipation rejection, we cannot sustain the obviousness rejections of claims 6, 7, 18, and 19 over Guala and Segal,

claims 10 and 16 over Guala and Kennard, and claim 14 over Guala and Kyle.

V. CONCLUSION

The Examiner's indefiniteness rejection is affirmed. The Examiner's anticipation and obviousness rejections are reversed.

VI. DECISION SUMMARY

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3-11, 13-20	112(b)	Indefiniteness	1, 3-11, 13-20	
1, 3-5, 9, 11, 13, 15, 17, 22, 24	102(a)(1)	Guala		1, 3-5, 9, 11, 13, 15, 17, 22, 24
6, 7, 18, 19	103	Guala, Segal		6, 7, 18, 19
10, 16	103	Guala, Kennard		10, 16
Overall Outcome			1, 3-11, 13-20	22, 24

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED IN PART