Case: 17-1389 Document: 1-2 Page: 7 Filed: 12/21/2016 (8 of 35)

### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOLOGIC, INC.
Requester, Respondent

V.

SMITH & NEPHEW, INC.<sup>1</sup> Patent Owner, Appellant

Appeal 2016-006894

Inter partes Reexamination Control 95/002,058
Patent US 8,061,539 B2<sup>2</sup>
Technology Center 3900

Before DANIEL S. SONG, MICHAEL L. HOELTER, and BRETT C. MARTIN, Administrative Patent Judges.

SONG, Administrative Patent Judge

### **DECISION ON APPEAL**

Smith & Nanhay Ina

<sup>&</sup>lt;sup>1</sup> Smith & Nephew, Inc. is the Patent Owner and the real party in interest (Appeal Brief of Patent Owner (hereinafter "App. Br.")). Covidien LP is also said to be a real party in interest (Updated Mandatory Notices Regarding Real Party-In-Interest, filed August 25, 2016).

<sup>&</sup>lt;sup>2</sup> Patent US 8,061,359 B2 (hereinafter "the '359 patent") issued November 22, 2011 to Emanuel.

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

### STATEMENT OF THE CASE

Claims 1–3 and 5–7 of the '359 patent are subject to reexamination, and stand rejected, while claims 4 and 8 have been canceled (Right of Appeal Notice<sup>3</sup> (hereinafter "RAN") 4). The Patent Owner appeals under 35 U.S.C. §§ 134(b) and 315 from the Examiner's rejections with respect to all of the rejected claims (App. Br. 7). We have jurisdiction under 35 U.S.C. §§ 134(b) and 315.

In addition to its Appeal Brief and Rebuttal Brief, the Patent Owner relies on declarations of Messrs. Apley, Isaacson and Chinnock, and evidence submitted therewith, in support of its appeal. In addition to its Respondent Brief, the Requester relies on declarations of Messrs. Dominicis and Walbrink, and evidence submitted therewith, in support of the Examiner's rejection.

The '359 patent was involved in the legal action *Smith & Nephew, Inc. v. Interlace Medical, Inc. & Hologic, Inc.*, Civil Action No. 10-10951-RWZ (D. Mass.), the court having issued a decision in *Smith & Nephew, Inc. v. Interlace Medical, Inc.*, 955 F.Supp. 2d 69, 71–72 (D. Mass. 2013), with further proceedings relative to damages having been stayed pending outcome of the present reexamination proceeding (App. Br. 6; Resp. Br. 18, Appendix — Related Proceedings; Order, dated May 14, 2015; Memorandum of Decision, dated June 27, 2013).

An oral hearing with the representatives of the Patent Owner and the Requester was held before the Patent Trial and Appeal Board on September

2

<sup>&</sup>lt;sup>3</sup> The Examiner's Answer incorporates the RAN by reference. Hence we cite to the RAN herein.

Case: 17-1389 Document: 1-2 Page: 9 Filed: 12/21/2016 (10 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

22, 2016, and a transcript of the hearing will be entered into the record in due course.

We REVERSE the Examiner's rejection.

### **INVENTION**

The '359 patent is directed to a method for removing tissue from a uterus (App. Br. 43, Claims App.). Representative independent claim 1 reads as follows (*id.*, italics added):

1. A method for removal of tissue from a uterus, comprising:

inserting a distal region of an endoscope into said uterus, the endoscope including a valve and an elongated member defining discrete first and second channels extending from a proximal region of the elongated member to the distal region, the second channel having a proximal end in communication with the valve such that fluid from the valve is able to flow into and through the second channel to the uterus, and *the first channel having a light guide permanently affixed therein* and being sealed from the second channel to prevent fluid from the valve from entering the uterus through the first channel; followed by:

inserting a motor driven cutter into the second channel such that a distal cutting region of the cutter extends distally beyond the endoscope in the uterus;

delivering fluid into the uterus through the valve and the second channel to distend the uterus;

energizing an electric motor to drive the cutter to cut tissue within the uterus; and

aspirating cut tissue and fluid from the uterus and the endoscope through the cutter.

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

The Examiner rejects claims 1–3 and 5–7 under 35 U.S.C. § 103(a) as being unpatentable over Emanuel PCT<sup>4</sup> in view of Bonnet.<sup>5</sup>

### **ISSUE**

The dispositive issue raised in the present appeal is whether Emanuel PCT provides written descriptive support for the claims of the '359 patent, so that the '359 patent is entitled to claim priority to Emanuel PCT, and Emanuel PCT is not prior art.

### PRINCIPLES OF LAW

It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.

PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299 (Fed. Cir. 2008) (citation omitted).

4

<sup>&</sup>lt;sup>4</sup> PCT International Publication No. WO 99/11184, published March 11, 1999. The '359 patent is a continuation of an application that issued as U.S. Patent No. 7,249,602, which in turn, claims priority to Emanuel PCT. Some of the declaration evidence of record refers to the '602 patent rather than Emanuel PCT, which serves as the basis of the Examiner's rejection. However, this distinction is substantively immaterial as the disclosures of the '602 patent is the same as Emanuel PCT from which it claims priority. Correspondingly, for the purposes of this Decision, we refer to Emanuel PCT, even with respect to specific statements in the declaration evidence that refer to the '602 patent.

<sup>&</sup>lt;sup>5</sup> U.S. Patent No. 4,606,330, issued August 19, 1986.

Case: 17-1389 Document: 1-2 Page: 11 Filed: 12/21/2016 (12 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

The test for sufficiency of written description is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Id.

Compliance with the written description requirement is a question of fact, which must be resolved on a case-by-case basis. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). In that regard:

whether a patent complies with the written description requirement will necessarily vary depending on the context. Capon v. Eshhar, 418 F.3d 1349, 1357–58 (Fed.Cir.2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. Id. For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." Id. at 1359.

Ariad Pharm., 598 F.3d at 1351.

Moreover,

it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that the specification recite the Case: 17-1389 Document: 1-2 Page: 12 Filed: 12/21/2016 (13 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

claimed invention in *haec verba*, description that merely renders the invention obvious does not satisfy the requirement. *Id.* at 1352 (citations omitted).

#### **ANALYSIS**

The dispositive issue noted above is raised in the present appeal due to the claim limitation reciting "the first channel having a light guide permanently affixed therein." The Specification of the '359 patent claims priority to Emanuel PCT, but the Specification of the '359 patent differs from that of Emanuel PCT in that the Specification of the '359 patent was amended to state:

A connection 8 for a light source is also present, for connection to <u>a light guide</u>, such as a fibre optics bundle, which provides for lighting at the end of lens 13.

(Col. 3, 11. 56–58, amended material bolded and underlined).

The Examiner finds that "[t]he limitation 'a light guide permanently affixed therein' has two components that are not supported [under 35 U.S.C. § 112, 1st paragraph] by the priority documents, i) light guide and ii) the light guide permanently affixed in the first channel." (RAN 8; *see also id.* at 31). In this regard, the Examiner further finds that:

The priority documents do not even show an optical guide means or even the fiber optic guide disclosed in the specification. Furthermore, there is no indication in the priority documents that the fiber optic guide is located in the first channel.

(RAN 27).

Accordingly, the Examiner finds that:

Case: 17-1389 Document: 1-2 Page: 13 Filed: 12/21/2016

(14 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

The '359 patent is not entitled to the benefit of a priority date of '602 patent, the PCT application and the Dutch patent. It has been determined that the claims are not entitled to benefit of the prior filed applications and are not entitled to claim priority before July 20, 2007; therefore the Emanuel PCT publication, which was published on March 11, 1999, is available prior art to the '359 patent claims.

(RAN 9).

In view of the priority determination, the Examiner rejects claims 1–3 and 5–7 of the '359 patent, finding that Emanuel PCT discloses all of the recited limitations "except the limitation that the light guide is permanently affixed to the first channel," and relying on Bonnet for disclosing an endoscope having a "permanent optical guide means." (RAN 10; *see also* Bonnet, Claim 1). The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to permanently affix the light guide of the Emanuel PCT in the first channel in view of the teachings of Bonnet, in order to protect the light guide." (RAN 10; *see also* RAN 29–30).

The Patent Owner argues that because Emanuel PCT provides written description for the limitation at issue, the '359 patent is entitled to claim priority to Emanuel PCT, so that Emanuel PCT is not prior art, and the Examiner's rejection based thereon is erroneous. We generally agree with the Patent Owner, and address the arguments of the parties *infra*. While we have considered the entirety of the appeal record, we cite to specific portions thereof *infra* in addressing the various issues raised.

Case: 17-1389 Document: 1-2 Page: 14 Filed: 12/21/2016

(15 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

### Written Description Requirement

The Patent Owner argues that in the proper written description evaluation, "[t]he operative question is how a POSA [person of ordinary skill in the art] would understand disclosures against the backdrop of the experience and knowledge that the artisan would have possessed." (App. Br. 32). The Patent Owner argues that the Federal Circuit and the Board's jurisprudence establish that *implicit disclosures* may provide written description support, and that this is "black-letter law." (App. Br. 11–12; *see also* App. Br. 5 and 29–33).

For example, the Patent Owner refers to Vas-Cath and asserts that the court found figures of a priority design patent implicitly disclosed claim limitations (pertaining to a range of a lumen's diameter in relation to the diameter of another cylindrical portion) of a subsequently filed utility application such that the drawings showed inventor's possession of the claimed invention to a person of ordinary skill in the art (App. Br. 29–33, citing Vas-Cath, 935 F.2d 1566; see also App. Br. 31, citing Pozen Inc. v. Par Pharmaceutical, Inc., 696 F.3d 1151, 1166–68 (Fed. Cir. 2012) (claims to a "therapeutic package" for dispensing a pharmaceutical had written description support even though not explicitly disclosed in the specification)). The Patent Owner also argues that descriptions of wellknown subject matter are to be omitted so that the patents are concise statements of what is new (App. Br. 11, citing EnOcean GmbH v. Face Int'l Corp., 742 F.3d 955, 962 (Fed. Cir. 2014)). The Patent Owner further relies on the Patent Office's Manual of Patent Examining Procedure (hereinafter "MPEP"), which states in the context of new or amended claims, "newly

Case: 17-1389 Document: 1-2 Page: 15 Filed: 12/21/2016 (16 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

added claim limitations must be supported in the specification through express, *implicit*, or inherent disclosure." MPEP § 2163(I)(B) (emphasis added).

The Examiner disagrees with the Patent Owner's argument that the law establishes implicit disclosure, and instead, agrees with the Requester's position that the specification *actually or inherently disclose* the recited claim element (RAN 27). In this regard, the Requester relies on numerous Federal Circuit cases in support:

Thus, the Federal Circuit has held that the specification must "actually or inherently disclose the claim PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306-07 (Fed. Cir. 2008); see also TurboCare, 264 F.3d at 1118–20 (holding that written description must be express or "inherent" in the original application) (quoting Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000) ("The fundamental inquiry is whether the material added by amendment was inherently contained in the original application.")); Katz Interactive Call Processing Patent Litig. v. Am. Airlines, Inc., 639 F.3d 1303 (Fed. Cir. 2011) ("the patentee must show that 'the application <u>necessarily discloses</u> that particular device.'") (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998) ("it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.")); Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure.") (followed by *PowerOasis*).

(Resp. Br. 5).

As to the actual articulation of the law, we disagree with the Patent Owner. We do not find, nor does the Patent Owner, direct us to binding precedent, that utilizes the term "implicit disclosure" to satisfy the written Case: 17-1389 Document: 1-2 Page: 16 Filed: 12/21/2016

(17 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

disclosure requirement, or that such a standard is "black letter law." Instead, the Federal Circuit's en banc decision makes clear that the test for sufficiency of written description is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Ariad, 598 F.3d at 1351. In addition, while the MPEP states that "implicit" disclosure provides sufficient written description, the MPEP merely gives an indication of "the presumptions under which the PTO operates," and does not have the force of law. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997). Furthermore, while numerous Board decisions have been cited by the Patent Owner in support of its assertion, none of these Board decisions is precedential so as to be binding on this panel. Moreover, while the Requester's cited cases from the Federal Circuit as set forth above do state that the disclosure must be explicit or inherent, we understand the articulation regarding sufficiency of written description through "inherent" disclosure as having been clarified and/or encompassed within *Ariad*'s articulation set forth above.

Nevertheless, based on the specific facts of this case, we do not agree with the Examiner and the Requester, and while this present case is a close call, the preponderance of the evidence indicates that the disclosure of Emanuel PCT "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351.

Case: 17-1389 Document: 1-2 Page: 17 Filed: 12/21/2016

(18 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

# Permanently Affixed

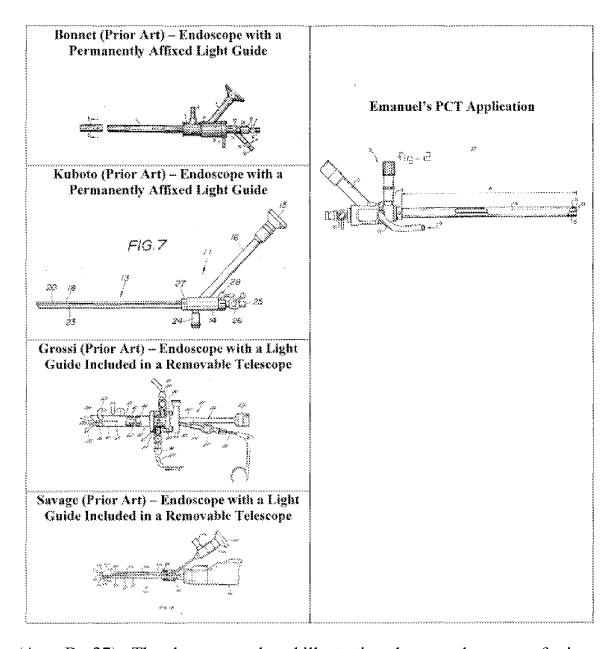
The Patent Owner does not dispute that Emanuel PCT does not explicitly disclose permanent affixation of the light guide. However, the Patent Owner argues that a person of ordinary skill in the art would have viewed the figures shown in Emanuel PCT as depicting a surgical endoscopic cutting device with a conventional endoscope, which is a single unitary instrument without removable components, and thus, the figures would have conveyed to one of ordinary skill that the inventor was in possession of a light guide that is "permanently affixed." (App. Br. 20–22). In this regard, the Patent Owner observes that Emanuel PCT discusses various components of the invention as being removable, but never suggests that the endoscope is anything other than unitary in construction (App. Br. 32).

The Patent Owner also relies on Declaration of Isaacson and Declaration of Apley, both declarants testifying that Figures 2 and 3 of the Emanuel PCT closely resemble drawings from various prior art references of record that show endoscopes typically having fixed light guides, such as in Bonnet and Kuboto, and that these endoscopes visually differ from endoscopes having removable light guides referred to in the art as "telescopes" such as in Grossi and Savage (App. Br. 22–28; Decl. Isaacson ¶¶ 19–20; Decl. Apley ¶¶ 6 and 8–11). The comparison of pertinent figures of the prior art and Figure 2 of Emanuel PCT set forth in the declarations are reproduced in summary in the Appeal Brief as follows:

Case: 17-1389 Document: 1-2 Page: 18 Filed: 12/21/2016

(19 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2



(App. Br. 27). The above reproduced illustration shows endoscopes of prior art references Bonnet, Kuboto, Grossi, and Savage on the left side, and Figure 2 of Emanuel PCT on the right side.

The Patent Owner also argues that the Specification of Emanuel PCT supports the fact that a person of ordinary skill in the art would understand the illustrated endoscope as being of unitary construction considering that it

Case: 17-1389 Document: 1-2 Page: 19 Filed: 12/21/2016 (20 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

discusses removable components of the disclosed surgical cutting device, but does not provide any such disclosure with respect to the disclosed endoscope used therein (App. Br. 20–21).

The Patent Owner further argues that because the light guide and permanent affixing in the first channel are not the focus of the *method* claims, there is no need for disclosure of the details of a well-known, conventional endoscope (App. Br. 5, 11–12, 33–34). Specifically, the Patent Owner argues that:

The extent of description required depends on "the scientific and technical knowledge already in existence" along with the "nature of the claims and the complexity of the technology." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (citing the "well-known" nature of the applicable technology and affirming summary judgment dismissing defendant's written description defense); *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) (vacating Board's decision rejecting claims for lack of written description support). This approach "enables patents to remain concise statements of what is new, not cumbersome repetitions of what is already known and readily provided by reference." *EnOcean GmbH v. Face Int'l Corp.*, 742 F.3d 955, 962 (Fed. Cir. 2014) (vacating Board's decision and holding that claims were entitled to PCT application's filing date).

(App. Br. 11).

In further support, the Patent Owner argues that Bonnet added "permanent" to its claim limitation reciting "optical guide means" without explicit disclosure in its drawings or Specification that its light guide is permanently affixed without objection or comment from the Examiner that examined Bonnet (App. Br. 25, fn. 10). The Patent Owner argues that, similarly, the text of the reexamined '359 patent was amended upon

Case: 17-1389 Document: 1-2 Page: 20 Filed: 12/21/2016

(21 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

suggestion and approval by the original Examiner who stated that there appears to be support for the amendment (App. Br. 14, citing Interview Summary, dated January 5, 2011).

We are ultimately persuaded by the evidence of record and the Patent Owner's arguments that the Examiner erred in finding that Emanuel PCT lacks written descriptive support for the claims at issue in the '359 patent. As noted *supra*, compliance with the written description requirement is a question of fact, which must be resolved on a case-by-case basis. *See Vas-Cath*, 935 F.2d at 1563. Moreover, drawings alone may provide adequate written description. *Id.* at 1565. There is no material dispute between the parties that a person of ordinary skill in the art is a "degreed engineer having at least 5 years of experience designing and developing devices used in minimally invasive surgery (endoscopes, resectoscopes, shavers, tissue removal devices, etc.)." (App. Br. 19; Dominicis Decl. ¶ 21).

The preponderance of the above-noted prior art and declaration evidence indicates that such a person of ordinary skill in the art would have known of the visual and functional differences between endoscopes having fixed light guides, and endoscopes having removable light guides. Indeed, there does not appear to be a material factual dispute that endoscopes having fixed light guides were well-known in the art (*see*, *e.g.*, RAN 29). We also find by preponderance of the evidence that a person of ordinary skill in the art, in reviewing Emanuel PCT with its drawings, would have known that the surgical endoscopic cutting device includes an endoscope having fixed light guide, like that of Bonnet and Kuboto, instead of an endoscope having a removable light guide, like that of Grossi and Savage, so that it would have

Case: 17-1389 Document: 1-2 Page: 21 Filed: 12/21/2016 (22 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

been evident to one of ordinary skill in the art that the inventor of Emanuel PCT was in possession of the claimed device wherein the light guide is permanently affixed.

The Examiner relies on the Requester's argument that Emanuel PCT does not inherently disclose the limitation at issue because it does not disclose that its endoscope necessarily has a permanently fixed light guide, but rather, it could have a removable light guide (Resp. Br. 5–6; RAN 27). In this regard, the Requester argues that the Patent Owner's claim to priority is based "only on the *possibility* of disclosure that is neither express nor inherent." (Resp. Br. 5). The Requester relies on its declarant's testimony that there are various ways that the endoscope disclosed in Emanuel PCT could have included a removable light guide (*id.* at 5–6; 2<sup>nd</sup> Decl. Dominicis ¶ 11; Decl. Walbrink ¶¶ 11, 13, 18). The Requester also notes that a description that merely renders the invention obvious does not satisfy the written description requirement (Resp. Br. 5–6).

In our view, the Examiner and Requester misapplies the law, which requires the inquiry to be focused upon what the disclosure reasonably conveys to those skilled in the art as of the filing date. *Ariad*, 598 F.3d at 1351. Emanuel PCT should be viewed from the perspective of a person of ordinary skill in the art. *Id.*; *see also LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed.Cir.2005)

[T]he patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before . . . . Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the

Case: 17-1389 Document: 1-2 Page: 22 Filed: 12/21/2016

(23 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

invention and to enable such a person to make and use the invention without undue experimentation.

## As the Patent Owner argues:

Requester's witnesses are . . . silent as to how a POSA [person of ordinary skill in the art] would have understood the [Emanuel] PCT application in view of "the scientific and technical knowledge already in existence." Capon, 418 F.3d at 1357 (holding that Board "erred in refusing to consider the state of the scientific knowledge"). They focus instead on whether one could theoretically construct an endoscope that is consistent with Dr. Emanuel's disclosure while featuring a removable light guide. (Second Dominicis Decl. ¶ 11; Walbrink Decl. ¶ 10–11). That is not the relevant inquiry under the law.

(App. Br. 28).

Specifically, neither the Requester and its declarants, nor the Examiner, sufficiently address what the disclosure of Emanuel PCT reasonably conveys to those in the art, but instead, focuses on the lack of explicit disclosure (which is not in dispute), or that the light guide of Emanuel PCT is not necessarily permanently affixed such that it could have included a removable light guide. Neither the Requester and its declarants, nor the Examiner, persuasively rebut the evidence and argument of the Patent Owner that the illustrated endoscope of Emanuel PCT closely resembles the endoscopes of Bonnet and Kuboto, that these endoscopes have permanently affixed light guides, and that this fact would have been readily apparent to those of ordinary skill in the art, so that such a person would have understood Emanuel PCT has having a permanently affixed light guide. For example, while seemingly asserted, the Requester fails to provide any persuasive evidence that endoscopes constructed in the manner discussed

Case: 17-1389 Document: 1-2 Page: 23 Filed: 12/21/2016

(24 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

and shown in Emanuel PCT, Bonnet, or Kuboto, but having a removable light guide exist, or that their existence would have been known by those of ordinary skill.

By focusing on possible ways that the endoscope of Emanuel PCT could have included a removable light guide instead of focusing on how a person of ordinary skill in the art would have understood the disclosure of Emanuel PCT, the Requester is improperly requiring the Emanuel PCT to necessarily exclude possible ways in which the disclosed endoscope may be constructed to include a removable light guide. That is not the proper inquiry. Vas-Cath, 935 F.2d at 1565–66 (rejecting the district court's reasoning that "[the claims] contain limitations that did not follow ineluctably [i.e., inevitably] from the diagrams," because the district court essentially required the drawings of the parent design patent to "necessarily exclude" all diameters other than those within the claimed range.). The proper inquiry as to drawings is "whether the drawings conveyed with reasonable clarity to those of ordinary skill that [the inventor] had in fact invented [the claimed device]," and it is the "[c]onsideration of what the drawings conveyed to persons of ordinary skill [that] is essential." Vas-Cath, 935 F.2d at 1566.

The fact that the priority document in *Vas-Cath* was a design patent is not lost in our consideration. In *Vas-Cath*, the lumens were shown in the drawings of the priority document, whereas in the present appeal, Emanuel PCT does not illustrate a light guide in its drawings. In this regard, as the Examiner notes, even though Bonnet's claim was amended to specifically recite that its optical guide is "permanent," Bonnet also specifically

Case: 17-1389 Document: 1-2 Page: 24 Filed: 12/21/2016 (25 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

identifies the optical guide means in the specification and drawings (RAN 26–27). However, there is no dispute that the Specification of Emanuel PCT discloses "a fibre optics bundle which provides for lighting at the end of lens 13." (Emanuel PCT, pg. 4, 11. 35–36). Again, Emanuel PCT should be viewed from the perspective of a person of ordinary skill in the art who has knowledge of what has come before. LizardTech, 424 F.3d at 1345. Accordingly, the omission of the fiber optics bundle in the drawings of Emanuel PCT does not materially alter the analysis as to what the totality of Emanuel PCT discloses to those of ordinary skill in the art.

The Examiner further notes that during the prosecution of the patent application that ultimately issued as the '359 patent, the Patent Owner distinguished the prior art applied in the rejections based on permanently affixed limitation so it cannot be reasonably argued that this feature is not the focus of the claims (RAN 27–28; see also Resp. Br. 10). However, as the Patent Owner argues (App. Br. 34–35), we find nothing improper about overcoming a rejection by distinguishing the claimed invention over the actual prior art applied by pointing to the deficiencies of the prior art.

The Requester also argues that if the endoscope of Figures 2 and 3 of the '359 patent was, in fact, conventional, then these figures should have been indicated as "prior art." (Resp. Br. 9). However, as the Patent Owner persuasively argues (Reb. Br. 13), there is no requirement for such markings for every subcomponent of a new device, and the disclosed invention is not directed to an endoscope, but rather, "a method for removal of tissue from a

<sup>&</sup>lt;sup>6</sup> We address the issue of whether a disclosure of "a fibre optics bundle" is sufficient to provide written descriptive support for the claimed "light guide" infra.

Case: 17-1389 Document: 1-2 Page: 25 Filed: 12/21/2016

(26 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

uterus," which uses a surgical endoscopic cutting device (Title), and includes an endoscope. In such a situation, like the Examiner during the original prosecution who did not object to the drawings, we do not understand the drawing requirements as necessitating designation of a subcomponent to be "prior art."

The Requester further asserts that the Patent Owner's own declarant testified that a person of ordinary skill would not have had experience with hysteroscopes with a permanently fixed light guide (Resp. Br. 9, quoting Deposition of Isaacson on May 2, 2012 at pg. 179, 11. 2–8). However, the relevance of this is not entirely clear because the testimony at issue pertains to hysteroscopes which is apparently a special type of endoscope used in the uterus (Reb. Br. 15). The testimony is not relevant as to what the entirety of Emanuel PCT would have conveyed to those of ordinary skill in the art. Moreover, as the Patent Owner explains, "[s]ince no one before Dr. Emanuel had operated in the uterus using endoscopes with permanently fixed light guides, Dr. Isaacson rightly testified that POSAs [persons of ordinary skill in the art] lacked experience with 'hysteroscopes' (i.e., endoscopes used in uterine treatment) having a permanently affixed light guide." (Reb. Br. 15). The Requester's apparent argument that this testimony contradicts the assertion that the Emanuel PCT would have conveyed to a person of ordinary skill in the art that the inventor was in possession of an endoscope having a permanently fixed light guide is unpersuasive.

In view of the above, we are persuaded that when a person of ordinary skill in the art considers the '359 patent in its entirety, its text and drawings would have reasonably conveyed to those skilled in the art that the inventor

Case: 17-1389 Document: 1-2 Page: 26 Filed: 12/21/2016

(27 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

had possession of an endoscopic cutting device including an endoscope wherein the fiber optics bundle is permanent and not removable.

### In the First Channel

As noted, the Examiner finds that because Emanuel PCT does not show a fiber optic guide, it lacks written descriptive support for having the fiber optic guide located in the first channel as recited by the claims (RAN 27; *see also id.* at 8, 31). The Examiner relies on the Requester's argument that Emanuel PCT does not inherently disclose the limitation at issue because it does not disclose the fiber optic guide, much less the location of the fiber optic guide (Resp. Br. 12–13; RAN 27). In this regard, the Requester's declarant testifies that a fiber optical guide could have been located in the first channel or the second channel, or even outside the channels, and is not necessarily in the first channel (Decl. Walbrink ¶¶ 11, 18, 19).

The Patent Owner disagrees and argues that the Requester's evidence and arguments as to where the light guide could be within the working channel applies an improper legal standard, and that the pertinent limitation is disclosed implicitly (App. Br. 37–38). The Patent Owner also argues that the light guide is recited in the claims as being in a first channel, which need not be the viewing channel as asserted by the Examiner, but merely must be a channel that is sealed and separate from the second channel through which the fluid may be delivered such as a working channel (App. Br. 35, citing RAN 31). The Patent Owner further argues that a person of ordinary skill in the art would have known that the light guide would be located in a channel

Case: 17-1389 Document: 1-2 Page: 27 Filed: 12/21/2016

(28 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

different from the working channel, and permanently affixed and sealed due to practical considerations and common sense (App. Br. 36). In this regard, the Patent Owner argues that "the undisputed impracticality of placing the light guide in the same channel as the cutting instrument confirms the [Emanuel] PCT application's implicit support for requiring that the light guide be in a channel separate from the working channel." (App. Br. 37).

Notwithstanding our disagreement with the Patent Owner with respect to "implicit" disclosure for the reasons already discussed *supra*, we are persuaded by the preponderance of the evidence that the disclosure of Emanuel PCT "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter" for reasons similar to those discussed *supra* relative to permanently affixed light guide. In particular, whereas the Patent Owner focuses on what Emanuel PCT reasonably conveys to those in the art, the Requester's arguments and testimonial evidence relied upon by the Examiner focus on the potential location of the light guide in Emanuel PCT, which again misapplies the law. As discussed *supra*, the proper inquiry as to whether Emanuel PCT supports the present limitation is not whether the endoscope described and illustrated therein could have positioned the light guide in the working channel or elsewhere, but rather, whether its disclosure reasonably conveys possession of this limitation to those of ordinary skill.

Thus, under the facts of this case, the inquiry is whether a person of ordinary skill would have understood that the endoscope disclosed in Emanuel PCT had a light guide that is positioned within a channel, which differs from the channel used for conveyance of fluid and for insertion of

Case: 17-1389 Document: 1-2 Page: 28 Filed: 12/21/2016

(29 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

other components. The preponderance of the evidence indicates that endoscopes of the type illustrated in Figures 2 and 3 of Emanuel PCT, such as the endoscope of Bonnet, are provided with a light guide in a channel (i.e., a first channel) that differs from a channel where other components of the endoscope are inserted and removed (Bonnet, col. 2, 11. 32–40; Fig. 2). Neither the Requester nor the Examiner persuasively rebuts the evidence and argument of the Patent Owner that the endoscopes of the type illustrated in Emanuel PCT have light guides in a channel separate from that used by other components, or that this fact would not have been readily apparent to those of ordinary skill in the art. In this regard, the manner in which the device of Emanuel PCT is disclosed as being used makes it reasonably clear to those of ordinary skill that the light guide would not be in the working channel, but rather, in a different channel. Thus, ased on the preponderance of the evidence, we find that Emanuel PCT reasonably conveys to those of ordinary skill in the art, possession of a light guide located in a channel, which is separate from a channel used by other components. In this regard, we note that

the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before.... Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed.Cir.2005).

Case: 17-1389 Document: 1-2 Page: 29 Filed: 12/21/2016 (30 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

## Light Guide

As noted, the Examiner rejects the claims finding that Emanuel PCT also does not support the limitation "light guide" because it merely discloses a "fibre optics bundle." (RAN 8). The Patent Owner argues that the disclosure of the species "fibre optics bundle" supports the claimed genus of "light guides" because a fibre optics bundle is an example of a light guide (App. Br. 14; *see also* App. Br. 15–17, and 19). In this regard, the Patent Owner argues that:

Given the predictability of the field and the fact that endoscopes with light guides were well known to a POSA [person of ordinary skill in the art] in 1998, Dr. Emanuel's disclosure of a "fibre optics bundle" species is more than sufficient to support claims to the "light guide" genus. The original examiner reached this conclusion when noting that the "drawings and the specification appear to have support for the limitation 'light guide'" and subsequently approving a "minor amendment" to the specification to recite "a light guide, such as a fibre optics bundle." (9/3/2010 Interview Summary; 1/5/2011 Office Action).

(App. Br. 14).

The Examiner disagrees and finds that "the use of the term 'fiber optics bundle' in the priority documents does not demonstrate that the inventor had possession of an endoscope with any type of light guide." (RAN 28). The Requester agrees with the Examiner's assessment (Resp. Br. 13–14). We are persuaded that the Examiner erred.

The Federal Circuit has explained that its case law recognizes that: determining whether a patent complies with the written description requirement will necessarily vary depending on the context. *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005). Specifically, the level of detail required to satisfy the

Case: 17-1389 Document: 1-2 Page: 30 Filed: 12/21/2016

(31 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Id.* For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* at 1359.

Ariad Pharm., 598 F.3d at 1351.

As pointed out by the Patent Owner, there is no dispute that "fibre optic bundles" is a type of a light guide, or that various types of light guides were also well-known in the art (App. Br. 15; Decl. Dominicis ¶ 12; see also Decl. Walbrink ¶¶ 10(c) and 30). Moreover, the field of optical guides is not an unpredictable field. Correspondingly, given the knowledge of those in the art, and the predictability of the technology involved, the preponderance of the evidence indicates that Emanuel PCT disclosure of a "fibre optics bundle" reasonably conveys to those of ordinary skill in the art that the inventor was in possession of the broader genus of a "light guide."

While the Requester cites to various cases of the Federal Circuit in support of the Examiner's position (Resp. Br. 13–14), we again note that compliance with the written description requirement is a question of fact, which must be resolved on a case-by-case basis as indicated by the numerous Federal Circuit cases cited by the Patent Owner in support of its appeal (App. Br. 15–16). *Vas-Cath* 935 F.2d at 1563; *see also Ariad Pharm.*, 598 F.3d at 1352 ("whatever inconsistencies may appear to some to exist in the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.").

Case: 17-1389 Document: 1-2 Page: 31 Filed: 12/21/2016

(32 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

Therefore, in view of the above, we reverse the Examiner's finding that Emanuel PCT fails to provide written description for the claims of the '359 patent, and find that the '359 patent is entitled to claim priority to Emanuel PCT. Accordingly, we also find that Emanuel PCT is not prior art against the '359 patent and reverse the Examiner's rejection based thereon.

Finally, the Patent Owner's further arguments asserting that rejection exceeds the Patent Office's statutory authority because it contradicts the original Examiner's finding (App. Br. 38–40), and that the rejection is unconstitutional in view of the related litigation's jury verdict (App. Br. 40–41), are not only beyond the jurisdiction of the Board to decide, but are also moot in view of the above reversal of the Examiner's rejection.

### **ORDER**

The Examiner's rejection is REVERSED.

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. § 1.956. In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

### **REVERSED**

Case: 17-1389 Document: 1-2 Page: 32 Filed: 12/21/2016 (33 of 35)

Appeal 2016-006894 Reexamination Control 95/002,058 Patent US 8,061,359 B2

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