

Keywords: 35 U.S.C. §112(a) (or ¶1); genus/species; predictable arts

General: A disclosure of a single species can satisfy the written description requirement of a genus if the other members of the genus are well-known in the art.

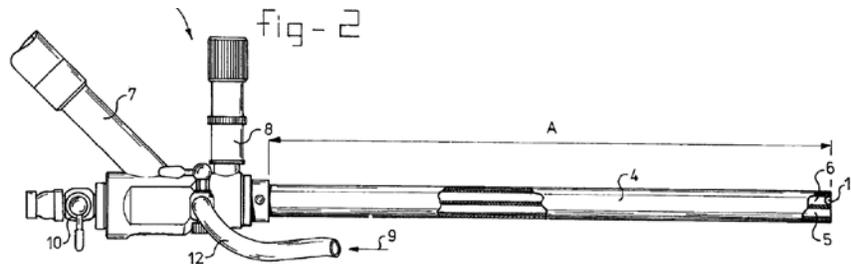
Hologic, Inc. v. Smith & Nephew, Inc., Covidien LP
 United States Court of Appeals for the Federal Circuit
 No. 2017-1389
 Decided: March 14, 2018

I. Facts

Smith & Nephew and Covidien own U.S. Patent No. 8,061,359 (“the ‘359 patent”), which issued from U.S. Patent Application No. 11/780,759 (“the ‘759 application”). The ‘359 patent is a continuation of a national stage entry of a PCT application. The national stage application and the PCT application have identical specifications, but the specification and claims of the ‘759 application were amended during prosecution to explicitly include an endoscope with a “light guide.” In other words, the claimed “light guide” is not explicitly present in the national stage or PCT application specifications or claims. Claim 1, for example, recites:

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...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....

Fig. 2 illustrates the endoscope with the two claimed channels 5 and 6, described as a “main channel” and a “viewing channel,” respectively. During prosecution, the specification of the ‘759 application was amended to disclose: “A connection 8 for a light source is also present, for connection to a light guide, such as a fibre optics bundle which provides for lighting at the end of lens 13.”



Hologic, Inc. initiated an *inter partes* reexamination of the ‘359 patent. The examiner rejected the claims of the ‘359 patent ultimately due to a determination that the PCT application specification lacks written description support for the “light guide,” thereby making the PCT application an invalidating obviousness reference. Specifically, the examiner concluded, among other things, that the “fibre optics bundle” species disclosed in the PCT application did not satisfy the broad genus of “light guides” added to the ‘759 application. The Patent Trial and Appeal Board (PTAB) reversed the examiner, finding that the earlier-filed PCT application has sufficient written description to provide support under 35 U.S.C. § 112(a) for the “light guide” to make it a priority document rather than an invalidating obviousness reference. Hologic appealed.

II. Issues

- 1) Did the PTAB err in determining that the PCT application specification provides sufficient written description support for the “light guide” recited in the claims of the ‘359 patent?

III. Discussion

1. No, the Federal Circuit found that the PTAB correctly determined that the claims of the ‘359 patent are fully supported by the PCT application specification¹. The Federal Circuit noted that under *Yeda Research*², the inquiry regarding whether the written description requirement is satisfied for the purposes of priority is a fact-finding they review for substantial evidence. The Federal Circuit also noted that under *Ariad*³, this fact-finding is based on an objective inquiry into whether the disclosure “reasonably conveys” to those skilled in the art that the inventor had possession of the claimed subject matter.

Regarding the present claims, the Federal Circuit first noted that, “the field of this invention is a predictable art, such that a lower level of detail is required to satisfy the written description requirement than for unpredictable arts.” Thus, the Federal Circuit determined whether the disclosed species of a “fibre optics bundle” reasonably conveys possession of the broader genus of “light guide,” given the predictable nature of the art.

The court noted that it was not disputed that a fibre optic bundle is a type of light guide, and the parties (including expert testimony) both agreed that various types of light guides are “well-known” in the art. In view of these facts, the court concluded that substantial evidence supports the finding of the PTAB that the disclosure of “fibre optic bundle” in the PCT application reasonably conveys to a PHOSITA that the inventor had possession of a “light guide.” Along with other findings related to other recitations in the claims, the Federal Circuit accordingly affirmed the PTAB’s decision that the claims of the ‘359 patent are supported by the PCT application specification, and affirmed the PTAB’s reversal of the examiner’s corresponding obviousness rejection of the claims based on the PCT application.

IV. Conclusion

The Federal Circuit held a disclosed single species of a genus can reasonably convey possession of the genus if: (1) the art is predictable, and (2) other species of the genus are well-known.

V. Appendix

Example of a “MyoSure®” surgical instrument available from Hologic:



¹ Other issues regarding the written description requirement were present in this case, but are beyond the scope of this brief

² *Yeda Research & Dev. Co. v. Abbott GmbH & Co. KG*, 837 F.3d 1341, 1344-45 (Fed. Cir. 2016).

³ *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).