Incorporate With Care

BY KEVIN McCABE AND THOMAS STUART OF
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.

Kevin McCabe

Thomas Stuart

Mr. McCabe is a Director and Mr. Stuart a Technical Specialist with the firm.

Strike these words from your patent vocabulary: "hereby incorporated by reference in its entirety." Cook Biotech recently was taught that lesson by the Federal Circuit, and you should heed the Federal Circuit's advice.

Patent practitioners frequently use the phrase "herein incorporated by reference in its entirety" as a catchall or safeguard. When a reference is "incorporated by reference," it is as if that reference is repeated verbatim in the patent specification. 37 C.F.R. § 1.57. Patent practitioners use this phrase as a useful tool to bolster a patent specification's written description and/or enablement, and yet maintain a manageable length. Moreover, by incorporating a reference in the specification, the patent practitioner may be able to use material from the incorporated reference to overcome a rejection by the Patent Office, or in litigation to bolster the patent against a validity attack. *See* The Manual of Patent Examining Procedure §§ 2163.07(b) and 2181. The problem with this practice is that practitioners rarely, if ever, fully read and digest the cited reference.

The Federal Circuit's decision in *Cook Biotech, Inc., v. Acell, Inc.* clearly demonstrates why incorporation by reference should be used with caution. At issue in *Cook Biotech v. Acell* was the construction of the claim term "the luminal portion of the tunica mucosa." Previously, the U.S. District Court for the Northern District of Illinois (District Court) held that Acell infringed the U.S. Patent No. 5,554,389 ('389 patent) owned by Purdue Research Foundation and licensed to Cook Biotech Inc. In arriving at this finding, the District Court construed the term "urinary bladder submucosa" to be broad enough to include tissues other than the submucosa, including the "luminal portion of the tunica mucosa." Therefore, based on the broad claim construction by the District Court, a verdict of infringement was returned by the jury.

Upon appeal to the Federal Circuit, Acell argued that the patentee had defined the term "the luminal portion of the tunica mucosa" by way of subject matter it incorporated by reference into the patent. The pertinent section of the '389 "Detailed Description of the Invention" stated:

> The preparation of UBS [urinary bladder submucosa] from a segment of urinary bladder is similar to procedure for preparing intestinal submucosa detailed in U.S. Patent No. 4,902,508 ['508 patent], the disclosure of which is expressly incorporated herein by reference.

Acell contended that incorporation of the '508 patent by reference, defined the term "the luminal portion of the tunica mucosa" as ***only*** the epithelial layer of the tunica propria layer.

Cook accused Acell of "fishing" for a special definition by improperly importing a definition for the preparation of a matrix graft product from a different source into the claim. However, the Federal Circuit has previously held that the primary source of claim construction is the claim language, specification and prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Furthermore, claim terminology may be defined by the patentee in the specification. *Id.* "The specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Finally, the Federal Circuit has ruled that when construing a claim, the specification along with any incorporated references may be consulted. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F3d 1272, 1282 (Fed. Cir. 2000) "Incorporation by reference provides a method for integrating material from various documents into a host document … by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." Therefore, an incorporated reference may be consulted in order to construe claim terms as if the incorporated reference were a part of the specification.

In Cook Biotech, the incorporated '508 patent included a detailed drawing of the small intestine in which the layers of tissue included in the preparation were identified. In the '398 patent, the preparation of the urinary bladder submucosa was taught to be similar to the preparation from the small intestine as detailed in the '508 patent. Thus, the Federal Circuit construed "the luminal portion of the tunica mucosa," in light of the incorporated '508 reference, to contain only "the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria." The construction by the Federal Circuit substantially narrowed the claim construction of the District Court, and more importantly, led to the finding that tissues other than those defined by the '508 patent were ***specifically excluded*** from the preparation.

Thus, if you presently incorporate material by reference without first reading the incorporated reference and analyzing its ramifications, be forewarned that the material you incorporated could harm your patent as easily as it could help it. The better practice, which the present authors have used for years, is to limit what is incorporated. For example, rather than incorporating an entire patent, one should incorporate the examples or the few paragraphs of the patent that were originally intended to rely upon. If you feel that you must incorporate a patent in its entirety, we suggest that you take the time to read the reference. Don't repeat Cook Biotech's mistake.

This article reflects the present thoughts of the authors, and should not be attributed to Sterne, Kessler, Goldstein & Fox P.L.L.C. or any of its former, current, or future clients. The content is for purposes of discussion and should not be considered legal advice. IPT