Trials@uspto.gov
571-272-7822

Paper 27
Date: August 21, 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.
Petitioner

v.

CONVATEC TECHNOLOGIES, INC.
Patent Owner

Case IPR2013-00097 (LMG)
Patent 6,669,981

Before LORA M. GREEN, RAE LYNN P. GUEST, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION
Motion For Additional Discovery
37 C.F.R. § 42.51

I. INTRODUCTION

Patent Owner filed a motion for additional discovery (Paper 23),[1] which Petitioner opposes (Paper 21).

The motion is ***denied***.

II. BACKGROUND

ConvaTec seeks additional discovery of a full and complete copy of Smith & Nephew's 510(k) submission and subsequent approval of Durafiber ® AG to the U.S. Food and Drug Administration ("FDA) (Paper 23 at 1). ConveTec additionally requests non-public data and/or information used to support Smith & Nephew's 510(k) submission that relates to failure to produce the medical device by a method other than one encompassed by claims 1-8 and 10-20 of Patent 6,669,981 ("the '981 patent"); and/or any evidence of copying of those claims of the '981 patent (*id.* at 2).

ConvaTec also requests discovery of all data and/or information in the possession of Smith & Nephew relating to its submission for a declaration on non-infringement in the United Kingdom, such as documents relating to copying of the methods claimed in the '981 patent to make and commercially produce Durafiber® Ag (*id.* at 2-3).

ConvaTec argues that, in the UK proceeding, Smith & Nephew made confidential statements suggesting that after attempting work-up experiments to produce a Durafiber® Ag, it resorted to the methods of EP '510 to create the product in an earlier time frame (*id.* at 4 (citing Ex. 2004)). Thus, ConvaTec additionally requests discovery of all data and/or information related to Smith &

[1] Paper 23 refers to ConvaTec's Amended Motion for additional discovery.

Nephew's failure to produce Durafiber® Ag by a method other than a method encompassed by claims 1-8 and 10-20 of the '981 patent (*id.* at 3-4).

Finally, ConvaTec requests discovery of laboratory notebooks, protocols, or other documents that relate to ConvaTec's failure to produce Durafiber® Ag by a method other than a method encompassed by claims 1-8 and 10-20 of the '981 patent, as well as of copying of a method encompassed by claims 1-8 and 10-20 of the '981 patent (*id.* at 4).

III. ANALYSIS

An important Congressional objective in passing the Leahy-Smith America Invents Act was to provide a quick and cost effective alternative to federal district court patent litigation. *See* H. Rep. No. 112-98, at 45-48 (2011). With that goal in mind, the statute passed by Congress and the rules implementing the statute provide for limited discovery. *See* 35 U.S.C. § 316(a)(5)(A); 37 C.F.R. § 42.51(b). Additional discovery is available, but in *inter partes* review, only what is necessary in the interest of justice. *See* 35 U.S.C. § 316(a)(5)(B); 37 C.F.R. § 42.51(b)(2). The legislative history makes it clear that the interest of justice should be limited to minor discovery and special circumstances. 154 CONG. REC. S9988-89 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl). In light of this, and given the time deadlines imposed by Congress on these proceedings, the Board will be conservative in granting leave for additional discovery. *Id.*

The Board set forth factors to be considered in determining whether the additional discovery is in the interest of justice. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 20. These factors ("*Garmin* factors") are: (1) there is more than a possibility and a mere allegation that useful information will be discovered; (2) the proposed discovery does not seek litigation

positions or the underlying basis for those positions; (3) the requested information is not available through other means; (4) any instructions associated with the discovery are easily understandable; and (5) the discovery is not overly burdensome to answer. *See* Order – Authorizing Motion for Additional Discovery, IPR2012-00001, Paper 20 at 2-3.

ConvaTec contends that the discovery request is relevant to the secondary considerations of copying and failure of others, and the discovery requests are tailored those specific considerations of non-obviousness (Paper 23 at 5-6).

Under Federal Circuit jurisprudence, not every competing product that arguably falls within the scope of a patent is evidence of copying, because otherwise every infringement suit would automatically confirm the nonobviousness of a patent. *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). Copying as objective evidence of nonobviousness requires evidence of effort to replicate a specific product. *Wyers*, 616 F.3d at 1246; *Iron Grip Barbell Co.*, 392 F.3d at 1325.

While ConvaTec argues that Smith & Nephew copied a method encompassed by the challenged claims of the ’981 patent, ConvaTec does not assert that Smith & Nephew attempted to copy a specific product by that method (*see, e.g.*, Paper 21 at 7-11).

Moreover, when considering the *Garmin* factors, ConvaTec has not provided sufficient explanation and evidence that, in fact, something useful will be uncovered if discovery is authorized. ConvaTec cites the Summary of Safety and Effectiveness and substantial equivalence decision by the FDA for Smith & Nephew’s 501(k) submission for Durafiber® Ag dressing as evidence of copying (Paper 23 at 8-9 (citing Exhibit 2001)). Exhibit 2001 states that the “subject device

and the predicate device Aquacel Ag (K080383) have similar design, materials and manufacturing methods" (Ex. 2001 at 4). ConvaTec contends that statement provides "at the very least a strong inference that Smith & Nephew copied one or more of the methods claimed in the '981 method" (Paper 23 at 8-9).

Smith & Nephew responds that the "FDA Website states '[a] claim of substantial equivalence does not mean that the new and predicate devices must be identical'" (Paper 21 at 10 (citing Ex. 1027)). Specifically, Smith & Nephew asserts that in ConvaTec's own 510(k) application for Aquacel® Ag identifies Aquacel® as the predicate device, even though it does not contain any silver (*id.* (citing Ex. 1028)).

Thus, in view of ConvaTec's own 510(k), a statement of substantial equivalence by the FDA is not sufficient evidence that in fact something useful will be uncovered if discovery is authorized. That is, Aquacel Ag®, which contains silver ions and which ConvaTec asserts had a manufacturing method that is similar to Smith & Nephew's Durafiber® Ag, would also have a manufacturing method that is similar to Aquacel®, which does not contain silver ions and thus would fall outside the methods of the challenged claim of '981 patent. Thus, a statement of substantial equivalence by the FDA is not sufficient evidence of copying to meet the *Garmin* factor (1) that there is more than a possibility and a mere allegation that useful information will be discovered.

ConvaTec also contends that, in Smith & Nephew's declaration of non-infringement in the UK courts, Smith & Nephew only relied on the precise concentration of the binding agent to distinguish its claims the method claimed in the EP patent (Paper 23 at 10 (citing Ex. 2003 at 3, ¶ 7)). According to ConvaTec, Smith & Nephew's declarations and admissions during the UK proceeding suggest

that Smith & Nephew's process for producing Durafiber® Ag fall with the scope of the challenged method claims (*id.*).

Smith & Nephew responds that ConvaTec is mischaracterizing what occurred in the UK proceeding (Paper 21 at 11). According to Smith & Nephew, in order to simplify the proceeding, it elected to only go forward on the noninfringement ground related to the concentration level of the agent (*id.* (citing Ex. 1029 at 5, ll. 6-13)).

Exhibit 2003 is the Third Witness statement of Morag Macdonald, who was authorized to make the statement on behalf of ConvaTec (Ex. 2003 at 1, ¶ 1). Mr. Macdonald testified:

> [A]t the hearing for directions in this summary judgment application Smith & Nephew admitted that it has no other non-infringement argument in relation to the process it uses to produce its silverised Durafiber wound dressing. As a result Smith & Nephew amended its Claim Form and Particulars of Claim to limit the relief it seeks in this action to whether the use of 0.77% concentration of binding agent falls within the scope of protection of the Patent.

(*Id.* at 3, ¶ 7.)

Exhibit 1029 is a transcript of the proceedings in the UK infringement suit before Mr. Justice Floyd. Counsel for Smith & Nephew stated:

> To simplify it, we would accept for the purposes of this patent in this jurisdiction that, as it were, the only non-infringement point that would arise after our process description is the level of binding agent. In other words, it is the construction point or nothing.

(Ex. 1029 at 5, ll. 6-10).

Upon review of the exhibits, we agree with Smith & Nephew that it did not admit that it copied one of ConvaTec's processes, but for the concentration range, but that the issue regarding the concentration range arose as a way to simplify the

UK proceedings. Thus, we conclude that Smith & Nephew's reliance on the concentration range of the binding agent in the UK proceeding is not sufficient evidence of copying to meet *Garmin* factor (1) that there is more than a possibility and a mere allegation that useful information will be discovered.

As to failure by others, ConvaTec asserts that it possesses confidential information from the same UK proceeding that suggests that Smith & Nephew tried to utilize methods that were not encompassed by the challenged claims of the '981 patent (Paper 23 at 11 (citing Ex. 2004)).

An allegation of failure of others, however, is not evidence of nonobviousness unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem. *In re Allen*, 324 F.2d 993, 997 (CCPA 1963). Absent in ConvaTec's motion is a threshold amount of evidence tending to show widespread failure to solve the problem addressed by the challenged claims. Evidence of failure by Smith & Nephew's efforts is not sufficient to demonstrate widespread efforts and failure.

Finally, ConvaTec's requests are overly burdensome and would require a significant expenditure of time, along with human and financial resources. For example, request 5 asks for discovery of "[l]aboratory notebook and other documents containing data and/or information that indicates Smith and Nephew's: a) failure to produce Durafiber® Ag by a method other than a method encompassed by any one of claims 1-8 and 10-20 of ConvaTec's '981 patent; and/or b) copying a method encompassed by of any one of claims 1-8 and 10-20 of ConvaTec's '981 patent" (Ex. 2005 at 3). We agree with Smith & Nephew that the requests are broad in scope, and are not limited to certain custodians or types of documents or data (Paper 21 at 15).

IV. CONCLUSION

For the reasons set forth above, we conclude that ConvaTec has not met its burden to show that the additional discovery is necessary in the interest of justice.

V. ORDER

It is:

ORDERED that motion for additional discovery is *denied*.

Petitioner:

Jeff B. Vockrodt
Rodger L. Tate
Christopher H. Yaen
Hunton & Williams, LLP
jvockrodt@hunton.com
rtate@hunton.com
cyaen@hunton.com

Patent Owner:

Jeffrey Guise
Peter R. Munson
Lorelei P. Westin
Wilson Sonsini Goodrich & Rosati, PC
jguise@wsgr.com
pmunson@wsgr.com
lwestin@wsgr.com