

Smith & Nephew, Inc. v. ConvaTec Technologies, Inc., Final Written Decision Finding All Claims Unpatentable and Denying Motion to Amend

Article By:

Intellectual Property Litigation Drinker Biddle

Takeaway: In providing evidence on the secondary considerations of commercial success and industry praise, the patent owner must show a nexus between the evidence and the claimed invention, including some evidence that the product relied upon for commercial success actually practices the claims of the patent.

In its [Final Written Decision](#), the Board determined that claims 1-5 and 7-14 of the '828 Patent are **unpatentable**. The Board also denied Patent Owner's **Motion to Amend**. Further, the Board denied Petitioner's Motion to Exclude and dismissed as moot Patent Owner's Motion to Exclude. The '828 Patent describes methods of enhancing the photostability of silver in antimicrobial materials for use in wound dressing and medical devices.

The Board began with claim construction, stating that claims are given the broadest reasonable meaning as understood by one of ordinary skill in the art taking into account the specification of the patent. The Board first construed the term "to incorporate the desired silver concentration into said polymer." The Board agreed with Patent Owner that the claims encompass an ionic interaction between free silver ions and a polymer, but did not agree that the claims are limited to that single type of interaction based upon the claim language and the specification. The Board then turned to the meaning of the term "a solution comprising an organic solvent." Patent Owner relied on a declaration from its expert to establish that the presence of an organic solvent creates an environment for ion exchange and the specification to show a certain water to alcohol ratio. However, the Board found that the express language of the claims does not recite any ratio and may be broadly construed to encompass any solution comprising an organic solvent in an amount sufficient to prepare a silver solution. The Board then pointed to the definition in the specification to construe the term "binding of said silver into said polymer." Lastly, the Board construed the term "substantially photostable" noting that the '828 Patent defines "photostable" as "[c]ontrolled colour change to a desired colour with minimal change thereafter," but does not define "desired color." Patent Owner contended that "desired color" should exclude any color other than white or purple based upon testimony of its expert. Petitioner contended that "photostable" should be interpreted broadly due to lack of evidence to support what a skilled artisan would have considered to be a "desired color" as required by the claims. The Board was not persuaded by Patent Owner's expert's testimony because it was limited to the "desired color" of a specific product that she was familiar with in

practice, and not generally to all wound dressings. The Board specifically found no reason to exclude purple as a desired color. The Board then looked to a Federal Court decision and a dictionary definition to construe “substantially” to mean that the claim is open to at least some degree of additional color change beyond that described in the definition of the term “photostable.”

The Board then turned to the unpatentability arguments, setting out the legal standards established by the Federal Circuit for proving anticipation and obviousness. The Board then examined the first ground of unpatentability – claims 1-5, 7, 10, and 11 as anticipated and/or obvious over Kreidl. Patent Owner’s main argument as to anticipation of claim 1 (and 2-5 and 7) was that the bandage in Kreidl is made from cotton fibers that are incapable of carrying out ion exchange reactions and, thus Kreidl does not disclose a chemical association of silver ions with the polymer. Patent Owner’s argument was substantially directed to its interpretation of the phrase “incorporate . . . into” and “binding.” Because the Board rejected Patent Owner’s interpretation of that claim language, it was not persuaded by Patent Owner’s arguments. Patent Owner also argued that Kreidl does not disclose the required concentration of organic solvent, but because the Board found that the claims do not require such, that argument was also rejected. Therefore, the Board found that claims 1-5 and 7 are anticipated by or obvious over Kreidl. As to claims 10 and 11, Petitioner’s expert declared that a standard gauze should not retain more than 4% of silver nitrate on the fiber, and Patent Owner did not challenge this statement or show why it was incorrect. Therefore the Board found that claims 10 and 11 are also anticipated by or obvious over Kreidl.

The Board next discussed the argument that claim 9 is obvious over Kreidl in view of Bahia. Petitioner argued that Kreidl describes the requisite diluted alcohol and Bahia discloses the requisite industrial methylated spirits and industrial alcohol used in processing wound dressings. Patent Owner argued that the teachings of Kreidl and Bahia cannot be combined because of the vast differences between the processes disclosed in both. The Board found that Patent Owner provided no persuasive evidence that Petitioner’s reasoning is in error and agreed that it would have been obvious to one of skill in the art to combine the references.

The Board then discussed whether claims 12-14 are obvious over Kreidl, Walder, Ronan, and Romans. Turning first to claims 12 and 13, Petitioner acknowledged that Kreidl did not disclose the duration in which the gauze is exposed to the silver nitrate solution, but that Walder, Ronan, and Romans teach exposing a polymer to silver nitrate for a duration of time encompassed by the ranges set forth in claims 12 and 13. The Board found that Patent Owner’s arguments were not persuasive because Patent Owner did not show why the processes described in Walder, Romans, and Ronan could not be combined with Kreidl. Regarding claim 14, Petitioner asserted that Kreidl teaches that the amount of time the material is soaked in a sodium chloride solution is a result-effective variable, therefore, it would have been obvious to vary the time the gauze of Kreidl is soaked in the sodium chloride solution. The Board found that Patent Owner did not respond to Petitioner’s evidence and arguments, therefore claim 14 is also obvious over Kreidl, Walder, Ronan, and Romans.

The Board then discussed claim 8 as being obvious over Kreidl, Bahia, and Ronan. The Board noted that Patent Owner did not demonstrate any error in Petitioner’s argument that it would have been obvious to replace the cotton gauze of Kreidl with the gel fiber dressing of Bahia, or to apply the Kreidl process to provide the silver chloride as an antiseptic in the gel fiber dressing of Bahia.

The Board then examined Petitioner’s argument that claims 1-5, 7, 8, and 10-13 are anticipated or obvious over Ronan, as evidenced by Kreidl and Romans. Patent Owner argued that Ronan does not disclose or suggest “incorporation” of silver onto anionic polymers substrates. Because this argument is based upon Patent Owner’s interpretation of the phrase “incorporate . . . into,” the

Board rejected this argument. The Board also found that Patent Owner did not demonstrate any error in Petitioner's further challenges to claims 1-5, 7, 8, and 10-13 as anticipated by or obvious over Ronan.

The Board then turned to the argument that claim 9 is obvious over Ronan and Bahia. Just as with Petitioner's other argument as to claim 9, it stated that although Ronan does not disclose the recited alcohols, Bahia does. For the same reasons as above, the Board found that claim 9 is obvious over Ronan and Bahia.

The Board then discussed Petitioner's argument that claims 1-5 and 7-9 are anticipated under 35 U.S.C. § 102(e) by Gibbins. Gibbins provides many examples that the Board interpreted to be consistent with Petitioner's arguments and the interpretations provided by Petitioner's expert. Therefore, the Board found that claims 1-5 and 7-9 are anticipated by Gibbins under 35 U.S.C. § 102(e).

The Board then examined the argument that claims 10-13 are obvious over Gibbins, Walder, Ronan, Romans, and Kreidl. Patent Owner's main argument is that Walder, Ronan, and Romans cannot be properly combined with Gibbins, but the Board disagreed. Therefore, the Board found that claims 10-13 are obvious over Gibbins, Walder, Ronan, Romans, and Kreidl.

Finally, the Board discussed whether claim 14 is obvious over Gibbins and Kreidl. Petitioner noted that while Gibbins does not disclose the duration of exposure to sodium chloride in its process, Kreidl teaches that the amount of time is a result-effective variable. Just as above, the Board agreed with Petitioner and found that claim 14 is obvious over Gibbins and Kreidl.

The Board next discussed the evidence of secondary considerations of nonobviousness presented by Patent Owner, specifically commercial success, industry acclaim, long-felt but unsolved need, and copying. Patent Owner argued that its AQUACEL® Ag product line has been commercially successful. The Board noted that it is the patent owner's burden to show a nexus between the commercial success and the feature recited in the claims. Patent Owner provided testimony to support its argument that there is a nexus between the claimed features of claim 1 and the commercial success, but the Board found that Patent Owner had not shown that the sales were the result of the claimed invention. Specifically, Patent Owner provided no details of the manufacturing process of its product line to show that the products are manufactured using the steps recited in the claims and during cross-examination, Patent Owner's declarant could not confirm whether specific products in the product line were covered by the claims of the '828 Patent. Regarding industrial acclaim, the Board also found that Patent Owner presented no evidence that the praise it received was directed to any particular feature of the method recited in the claims. The Board also found that Patent Owner's evidence of long-felt but unmet need was not persuasive because it did not show that the advantages of the claimed invention was not met by prior art or that the long-felt and unmet need was solved by the particular steps recited in the claims. Finally, the Board found that Patent Owner's evidence of copying was not persuasive because the statement that two products have "similar manufacturing methods" is not sufficient to demonstrate that either product is made using the steps of the claimed invention, and Patent Owner did not provide any evidence of the actual manufacturing product for the allegedly copied product.

The Board then focused on Patent Owner's Motion to Amend. The Board noted that Patent Owner bears the burden of proof to establish that it is entitled to the relief requested. Patent Owner requested that amended claim 15 replace claim 1. The Board first noted that Patent Owner's citation to claim 1 as well as sections of the issued '828 patent is not sufficient to show support in the written

disclosure as originally filed, and Patent Owner did not state that the specification of the issued patent is identical to the specification originally filed in the application. Further, the Board found that the citations provided by Patent Owner did not fully explain how the '828 Patent supports the newly added limitations. Because the Board found that the Motion did not establish that the disclosure provided written description support for the amended claim, the Board did not address the patentability of the amended claim over the prior art, but noted in a footnote that it believes that the amended claim is unpatentable in view of Gibbins.

Finally, the Board addressed both parties' Motions to Exclude Evidence. Petitioner's Motion sought to exclude the commercial success testimony provided by Patent Owner on the basis that it does not establish that the products are covered by the claims of the '828 Patent. The Board stated that this is not a proper basis for exclusion; therefore, the Motion was denied. Patent Owner's Motion sought to exclude the declaration of Petitioner's expert on the basis that he is not qualified as an expert to testify with respect to the claimed subject matter of the '828 Patent. The Board found that Patent Owner's arguments go to the weight of the testimony, not the admissibility and that the Board did not rely upon this evidence in its determination, therefore, the Motion was moot. Patent Owner's Motion also sought to exclude two exhibits in Petitioner's opposition to the Motion to Amend regarding the examples in Gibbins. The Board stated that it did not rely upon these exhibits, therefore, this portion of the Motion was also moot.

APJ Snedden wrote a concurrence that concurred with the majority's conclusion that claims 1-5 and 7-14 are anticipated or obvious, but dissented from the interpretation of the term "photostable." APJ Snedden stated that purple is not a "desired colour" under the evidence on record. APJ Snedden also disagreed with the majority's determination that "minimal change" may refer to a change of color from a desirable to an undesirable color. However, because the claims only require the silver to be "substantially photostable," APJ Snedden stated that the silver may undergo some minimal discoloration to an undesirable color and still fall within the claims. Based upon these interpretations, APJ Snedden disagreed with the reliance on Example 25 of Gibbins, but agreed with the outcome based upon Example 24 of Gibbins. APJ Snedden also agreed that the Motion to Amend was deficient.

***Smith & Nephew, Inc. v. ConvaTec Technologies, Inc.*, IPR2013-00102**

Paper 87: Final Written Decision

Dated: May 29, 2014

Patent 7,267,828 B2

Before: Lora M. Green, Rae Lynn P. Guest, and Sheridan K. Snedden

Written by: Guest

Concurrence by: Snedden

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