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## Federal Circuit Patent Bulletin: *Soft Gel Techs, Inc. v. Jarrow Formulas, Inc.*

July 26, 2017

*“An incentive to conduct a confirmatory study frequently exists even when one has every reason to expect success.”*

On July 26, 2017, in *Soft Gel Techs, Inc. v. Jarrow Formulas, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Bryson,\* Hughes) affirmed the U.S. Patent and Trademark Office Patent Trial and Appeal Board inter partes reexamination decisions that certain claims of U.S. Patents No. 8,124,072, No. 8,105,583 and No. 8,147,826, which related to methods for dissolving a substance commonly referred to as CoQ10 in solvents known as monoterpenes, were invalid for obviousness under 35 U.S.C. §103. The Federal Circuit stated:

The question whether a patent claim is invalid for obviousness under 35 U.S.C. § 103(a) requires consideration of the scope and content of the prior art, differences between the prior art and the patent claim, the level of ordinary skill in the art, and any relevant secondary considerations. An obviousness determination also requires a person of skill in the art at the time of the invention to have had “an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” and a “reasonable expectation of success” in doing so.

Soft Gel contends that the Khan '786 patent teaches that it is difficult to dissolve CoQ10 in lemon oil. But what the Khan '786 patent states is that CoQ10 is difficult to dissolve in aqueous solvents, fixed (nonvolatile) oils, and triglycerides. Instead of suggesting the use of those types of solvents with CoQ10, the Khan '786 patent teaches the use of an essential (volatile) oil, such as lemon oil, peppermint oil, or spearmint oil, as a solvent for CoQ10. The Khan '786 patent merely

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Patent

notes the difficulty of dissolving CoQ10 in many solvents other than essential oils such as lemon oil.

Second, Soft Gel argues that the Khan '786 patent discloses only the melting of CoQ10 to convert it from a solid to a liquid in the presence of an essential oil. Soft Gel argues that Khan does not disclose dissolving CoQ10 in the oil. That point of contention is immaterial. Regardless of whether the Khan '786 patent is interpreted to disclose dissolving CoQ10 in an essential oil such as lemon oil, the Khan '786 patent does not teach away from the inventions. In fact, the Khan '786 patent teaches the use of essential oils to make CoQ10 more available to the body, which is precisely what is claimed in Soft Gel's patents. . . .

For those reasons, Soft Gel has failed to discredit the Board's finding that the Khan '786 patent does not teach away from the inventions of the Soft Gel patents. More importantly, Soft Gel's focused attack on the Khan '786 patent does not undermine the Board's decision, which is based on a combination of references. Read together, the Khan '786 patent and the Motoyama reference suggest using the monoterpenes in lemon oil, peppermint oil, and spearmint oil in conjunction with CoQ10.

Soft Gel further contends that a person of ordinary skill in the art would not have had a reasonable expectation of success in combining the references to use dlimonene in Motoyama's invention. Soft Gel points out that Motoyama, Nazzal, and the Khan '786 patent do not expressly mention d-limonene. Based on that omission, Soft Gel argues that a person of skill in the art would not have expected d-limonene to function like the carvone disclosed in Motoyama.

But Soft Gel ignores the finding that the main constituent of lemon oil, as used in Nazzal and the Khan '786 patent, is d-limonene, and the statement in Motoyama that the oil solvent that was the subject of Motoyama's invention includes "terpenes" such as d-limonene. Soft Gel also fails to account for the recommendations in the Nazzal reference. After describing the same formulation that is disclosed in the Khan '786 patent, Nazzal recommends further study of the "nature of the interaction that exists between CoQ[10] and essential oils" and, more specifically, the "[c]hemical components of essential oils, such as limonene, menthone, and carvone." As the Board noted, those recommendations for future research show that a person of skill in the art would have recognized—and at least one (Nazzal) did recognize—that the monoterpenes limonene and carvone are of interest in the essential oil-CoQ10 mixtures. Upon reading about carvone's role in dissolving CoQ10 in Motoyama, a skilled artisan would have been motivated to combine the two references. Because (1) Nazzal suggests testing the interaction of carvone and CoQ10 as well as the interaction of limonene and CoQ10, and (2) Motoyama teaches that carvone successfully dissolves CoQ10, a person of skill would reasonably expect that limonene, like carvone, would successfully dissolve CoQ10. A person of skill also would likely expect dlimonene to work, consistent with Nazzal's recommendation to study limonene based on his testing of lemon oil, of which d-limonene is the main constituent.

Soft Gel highlights a 2004 article co-authored by Dr. Khan, which evaluates the use of l-and d-limonene in SNEDDS. According to Soft Gel, the reason that Dr. Khan conducted that "follow[] up" research was because it must not have been obvious that the lemon oil results in his earlier experiments were attributable to d-limonene.

In making that argument, Soft Gel applies an incorrect legal standard for obviousness, requiring “absolute predictability” rather than “a reasonable expectation of success.” It is true that the Khan ’786 patent discloses lemon oil, not d-limonene. But that does not mean that a person of skill would not expect d-limonene, the main constituent of lemon oil, to work. Dr. Khan may have had just that expectation in conducting his subsequent research, in which he investigated whether d-limonene was responsible for the lemon oil-CoQ10 results. As the Board correctly noted, “[s]imply because [Dr.] Khan . . . [later] undertook a study to evaluate limonenes in [a self-nanoemulsifying drug delivery system] SNEDDS[] does not mean that it would not have been obvious [that limonenes] would have worked to some extent.” A supplemental study does not imply lack of awareness of the likely result; rather, studies are frequently conducted to confirm what is suspected to be true. An incentive to conduct a confirmatory study frequently exists even when one has every reason to expect success. As it happens, Dr. Khan was successful . . . .