

The Federal Circuit Declares Upon Further Review - it's Very Obvious: Soft Gel Technologies, Inc., v. Jarrow Formulas, Inc.

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Introduction

On July 26, 2017, in *Soft Gel Technologies, Inc., v. Jarrow Formulas, Inc.* (Appeal No. 17-1051, Fed. Cir. July 26, 2017), the Court of Appeals for the Federal Circuit (“the CAFC”) affirmed the Patent and Trial Appeal Board’s (PTAB) rulings from three *inter partes* reexaminations invalidating numerous claims of three patents assigned to Soft Gel Technologies, Inc. (“Soft Gel”) on obviousness grounds. The CAFC, in affirming the PTAB, applied various canons of obviousness law to refute Soft Gel’s position, specifically emphasizing that an obviousness rejection cannot be overcome by attacking references individually, and that only a reasonable expectation of success, rather than absolute predictability of success, is required as a basis of motivation to combine references.

Soft Gel Patents

Each specification of the Soft Gel patents (“U.S. Patent Nos. 8,124,072 (“’072 patent”), 8,105,583 (“’583 patent”), and 8,147,826 (“’826 patent”)”) describes a method for dissolving a substance commonly referred to as CoQ10 in solvents known as monoterpenes. The patented inventions include a composition (“’583 patent”), a soft gelatin capsule (“’072 patent”) and a method of making such a soft gelatin capsule (“’826 patent”), each claiming a solution of CoQ10 is dissolved in monoterpene. *Soft Gel Technologies*, Appeal No. 17-1051 at 3. CoQ10 is a coenzyme (i.e., a chemical compound that is required for the biological activity of certain proteins) which is necessary for certain metabolic processes. *Id.* Studies have shown CoQ10 to be effective in regulating blood pressure and cholesterol levels, as well as preventing various diseases such as certain types of cancers. *Id.* at 4. However, the Soft Gel patents indicate that CoQ10 is sparingly soluble in aqueous based solvents such as water, which limits the bioavailability of the coenzyme to the body. *Id.* As a solution for increasing the bioavailability of CoQ10 within the body, the Soft Gel patents describe the discovery of monoterpenes such as limonene, carvone, and derivatives thereof as solvents for CoQ10, with the amended claims of the Soft Gel patents specifically reciting a derivative of limonene identified as d-limonene. *Id.* at 4-6.

Inter Partes Reexamination

On September 15, 2012, Jarrow Formulas, Inc. requested an *inter partes* reexamination of the Soft Gel patents, which was granted by the PTAB and resulted in the PTAB’s rejection of almost all of the claims of the patents. During the *inter partes* reexamination, the PTAB identified and considered five key references for review against the claims of the Soft Gel patents. The first reference considered by the PTAB was a Patent Application Laid-Open Disclosure No. S57-42616 (“Motoyama”). The PTAB found the Motoyama reference disclosed that CoQ10 is “highly soluble” in a particular monoterpene known as carvone. Specifically, Motoyama disclosed several examples in

which CoQ10 was dissolved in l-carvone and placed in capsules which were administered to dogs with high indications of bioavailability within the animals. *Id.* at 7.

The second and third references considered by the PTAB contained overlapping disclosures: U.S. Patent No. 7,588,786 issued to Khan and Nazzal (“Khan ‘786 patent”), and a dissertation authored by Nazzal (“Nazzal”). The PTAB found that both references, similar to the disclosures of the Soft Gel patents, noted the poor solubility of CoQ10 in aqueous solvents such as water. Furthermore, each reference posited that solvents such as lipids or oils could be used instead. *Id.* To prove this premise, Nazzal and the Khan ‘786 patent both disclosed an experiment that demonstrated the melting temperature of CoQ10 could be lowered to the average human body temperature by mixing the coenzyme with a sufficient amount of solvents such as essential (volatile) oils including peppermint oil, spearmint oil, and lemon oil. *Id.* at 8. The Nazzal dissertation concludes with a list of six recommendations for future studies, one of which was to study the chemical components of essential oils such as limonene, menthone, and carvone for their potency in lowering the melting point of CoQ10. *Id.* at 8-9.

The fourth reference relied on by the PTAB was *Fenaroli’s Handbook of Flavor Ingredients* (“Fenaroli”), which the PTAB found disclosed that lemon essential oils have many different components but contain approximately 90 percent limonene by weight. The fifth reference cited by the PTAB was a monograph published by the World Health Organization’s International Agency for Research on Cancer (“IARC”). The PTAB found that monograph stated that limonene is “the most frequently occurring monoterpene.” Furthermore, the PTAB found the monograph disclosed that limonene occurs naturally in the d- and l- forms, and that “the d- form comprises 98-100 percent of the limonene in most citrus oils.” *Id.* at 10.

Based on these five references, the PTAB found grounds for invalidating various claims of each of Soft Gel patents on the basis of obviousness. In its ruling, the PTAB held that the combination of the five references suggests the invention claimed in each Soft Gel patent –i.e. using d-limonene (as Motoyama had used carvone) to dissolve CoQ10 for oral formulations. Further, the PTAB found a person of skill in the art (“POSITA”) would have been motivated to combine those references and would have had a reasonable expectation of success in doing so. *Id.* at 11.

CAFC Analysis

On appeal to the CAFC, Soft Gel challenged three of the PTAB’s findings during the *inter partes* reexaminations” 1) that d-limonene is the main constituent of lemon oil, 2) that the Khan ‘786 patent does not teach away from the claimed invention, and 3) that a POSITA would have had a reasonable expectation of success regarding the combination.

The CAFC began its analysis by setting forth two canons of obviousness law: “the question of 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 patent claim, the level of ordinary skill in the art, and any relevant secondary considerations,” and “[A]n obviousness determination also requires a person of skill in the art at the time of the invention to have had an ‘an apparent reason to combine the known elements in the fashion claimed by the patent at issue,’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 418 (2007), and a “reasonable expectation of success” in doing so, *Alza Corp. v. Mylan Labs., Inc.* 464 F. 3d 1286, 1289 (Fed. Cir. 2006).

The CAFC refuted Soft Gel’s first position and found that d-limonene is the main constituent of lemon oil. In support of its position, the CAFC agreed with the PTAB’s finding that IARC and Fenaroli references disclosed that lemon oil consists of approximately 88 to 90 percent d-limonene

by weight. *Soft Gel Technologies* Appeal No. 17-1051 at 12. Soft Gel provided an additional reference, which tested essential oil from a number of different lemon species and disclosed one sample in which the limonene content was only 38.1 percent. However, the CAFC found this additional reference actually bolstered the PTAB's conclusions, as upon reviewing the testing of the other samples in the additional reference, the CAFC found that the amount limonene found in all of the samples discussed therein ranged from a minimum 38.1 percent to a maximum of 95.8 percent, and in each of the samples the amount of limonene was still much greater than that of any other constituent in the sample. *Id.*

Soft Gel advanced its second position that the Khan '786 patent teaches away from dissolving CoQ10 in lemon oil by arguing, *inter alia*, that the Khan '786 patent states that it is difficult to dissolve CoQ10 in lemon oil. However, upon a closer inspection of the Khan '786 patent, the CAFC found the reference actually discloses that CoQ10 is difficult to dissolve in aqueous solvents and fixed (*nonvolatile*) oils, and in lieu of using these types of oils to dissolve CoQ10, essential (*volatile*) oils such as lemon, peppermint, or spearmint oils should be used as a solvent for CoQ10. *Id.* at 13. The CAFC further indicated that Soft Gel's approach of attacking an individual reference in the context of making a teaching away argument was improper as "non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." See *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The CAFC found that, when read together, the Khan '786 patent and the Motoyama reference suggest using the monoterpenes in lemon, peppermint, and spearmint oil in conjunction with CoQ10. *Id.* at 14-15.

In advancing its final position that a POSITA would not have had a reasonable expectation of success in combining the references to use d-limonene in Motoyama's invention, Soft Gel argued, *inter alia*, that neither the Motoyama, Nazzal, nor the Khan '786 patent expressly mentioned d-limonene, and therefore a POSITA would not have expected d-limonene to function like the carvone disclosed in Motoyama. The CAFC countered that position by indicating that Soft Gel had ignored the fact that the main constituent of lemon oil as used in Nazzal and the Khan '786 patent is d-limonene, as well as the recommendation in the Nazzal reference to further study the interaction that exists between CoQ10 and essential oils, specifically the chemical components of essential oils such as limonene, menthone, and carvone. *Id.* at 15.

Based upon these teachings, the CAFC held that a POSITA having the benefit of these references would be motivated to combine them as (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. Thus, a POSITA would reasonably expect that limonene, like carvone, would successfully dissolve CoQ10, and further would reasonably expect d-limonene 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. *Id.* at 15-16.

In further support of the position that there was no reasonable expectation of success in combining the references, Soft Gel additionally presented an article, co-authored by Khan after the issuance of the Khan '786 patent and the publication of the Nazzal dissertation, which evaluates methods of delivering d-limonene to the body. Soft Gel posits that the reason Khan conducted the 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. *Id.* at 16. In response to this position, the CAFC conceded that while the Khan '786 patent explicitly discloses lemon oil in lieu of d-limonene, this did not give rise to the inference that a POSITA would not expect d-limonene, the main constituent of lemon oil, to operate in the same manner, and suggested Khan may have had just that expectation when conducting his subsequent research.

The CAFC further indicated that by making this argument, Soft Gel advanced an incorrect legal standard for obviousness which requires “absolute predictability” rather than a reasonable “expectation of success”. *Noelle v. Lederman*, 355 F. 3d, 1343, 1352 (Fed. Cir. 2004) Furthermore, the CAFC stated that 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. *Soft Gel Technologies* Appeal No. 17-1051 at 16.

Conclusion

This case demonstrates that patent practitioners must be (1) conscientious when choosing evidence to support their positions, and (2) aware of the proper legal standards that either support or refute their positions. In this case, there were many instances where Soft Gel cited passages in a reference that on their face seemed to support their position. However, upon a closer inspection of the entire reference, it became clear that the reference did not actually teach what Soft Gel proposed it did. Further, Soft Gel erred in failing to properly consider canons of obviousness law in making the arguments to support their position, as evidenced by the CAFC underscoring that an obviousness rejection cannot be overcome by attacking references individually, and only a reasonable expectation, rather than an absolute predictability, of success is required as a basis of motivation to combine references.