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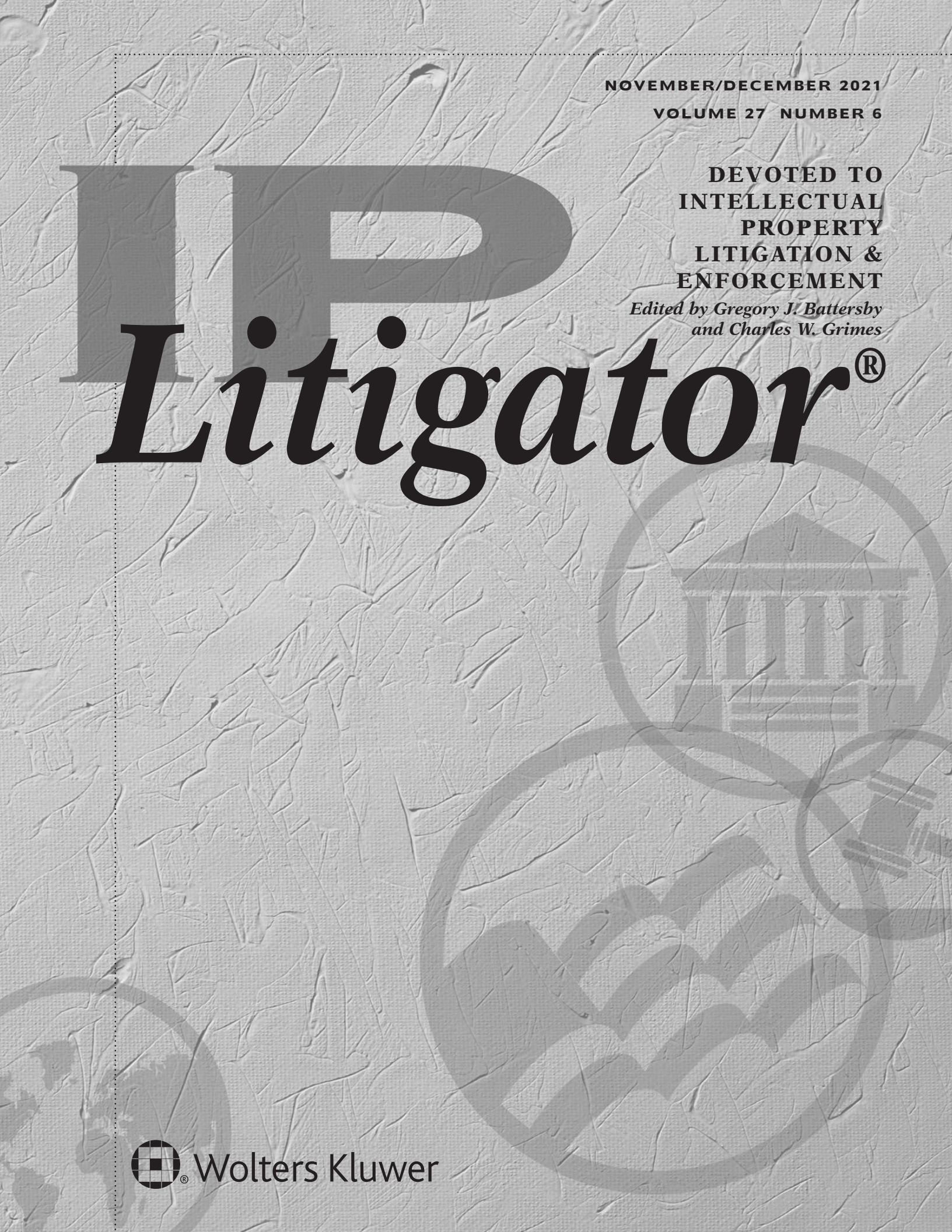

Wolters Kluwer

PTAB Provides Another Example of Invalid Claims for Lack of Written Description and Enablement

Marina I. Miller, Ph.D

Marina I. Miller, Ph.D., is an intellectual property partner in Oblon's Chemical Patent Prosecution group and has extensive experience in patent applications preparation and all aspects of U.S. and foreign patent prosecution in diversified technologies within the pharmaceutical, chemical, biotechnology, medical, physics and engineering disciplines Her legal experience covers all aspects of client counseling, patent portfolio development and management, prosecution, post grant proceedings, appeals, opinions of counsel, due diligence, pre-litigation, and litigation counseling.

In its recent decision, *Commonwealth Scientific and Industrial Research Organisation v. BASF Plant* Sciences *GmbH*, Case number PGR2020-00033, the PTAB (the Board) determined that all challenged claims of U.S. Patent No. 10,301,638 B2 were unpatentable for lack of written description and lack of enablement.

The Claim and Board Review

Commonwealth Scientific and Industrial Research Organization (Petitioner) filed a Petition to institute a post-grant review of claims 1–23 of the '638 patent owned by BASF Plant Science GMBH (Patent Owner). The patent, issued on May 28, 2019, relates to a process for the production of eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), and/or docosahexaenoic acid (DHA) in transgenic plants, and to "oils, lipids, and/or fatty acids which have been produced by the process." The patent describes that the yield of long-chain polyunsaturated fatty acids "can be increased by expressing an optimized Δ5-elongase sequence in transgenic plants" and that the fatty acids produced by the process are present with a content of, in each case, at least 5% by weight, based on the total fatty acids in the transgenic plant.

Independent Claims 1 and 9 read:

> 1. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids, and/or fatty acids comprise 60 to 85% by weight of polyunsaturated fatty acids based on the total fatty acids in the transgenic plant, wherein said polyunsaturated fatty acids comprise at least 20% by weight of eicosapentaenoic acid (EPA), at least 2% by weight of docosapentaenoic acid (DPA), and at least 4% by weight of docosahexaenoic acid (DHA) based on the total fatty acids in the transgenic plant in the form of triacylglycerides.
>
> 9. Oils, lipids and/or fatty acids produced by a transgenic *Brassica* plant, wherein said oils, lipids and/or fatty acids comprise a total amount of at least 54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant.

The Board reviewed Claim 8 (dependent upon claim 1) and independent claim 9, which require that the oils, lipids, and /or fatty acids produced by a transgenic *Brassica* plant and "comprise a total amount of at least 54% by weight of polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant." Petitioner contended that the patent did not include any embodiments that have at least 54% by weight of polyunsaturated ω3-fatty acids, and that, in the only one example that is present, "the seed-oil of a transgenic *Brassica juncea* plant comprised between 17.2% and 19.6% polyunsaturated ω3-fatty acids, far below the 'at least 54%' recited in" claims 8 and 9. Petitioner pointed to the examples in the patent of other transgenic plants, *O. violaceous* and *A. thaliana*, that do contain at least 54 wt.% of polyunsaturated ω3-fatty acids, and argued that the '638 patent did not assert or show that "the amount of the polyunsaturated ω3-fatty acids in *O. violaceous* or *A. thaliana* leaf is representative of the amount of polyunsaturated ω3-fatty acids in the total fatty acids of transgenic *Brassica*."

The Patent Owner's Defense

Patent Owner responded that the example directed to the embodiments recited in claim 9 used a constitutive promoter "that causes the genes included in the construct

to be express[ed] in every tissue in the transgenic plant." Patent Owner argued that a POSITA would have known that the leaf data presented in Tables 2 and 3 for *O. violaceus* and *A. thaliana* plants were collected from transgenic plants produced using this constitutive promoter, and that "the genes encoding for the desaturases and elongases contained therein would have been expressed throughout the entire plant." Accordingly, a POSITA "would have known that, given the use of a constitutive promoter, the inventors' decision to sample the leaves of their exemplary transgenic plants (as shown in the data presented in Tables 2 and 3) was likely and understandably made for the sake of convenience."

Patent Owner further argues that the *Brassica juncea* seeds analyzed in Table 6 were from a plant that "is not an embodiment of the inventions recited in claims 9 and 10 of the '638 patent" and that "the data in Table 6 were obtained from a plant created using a different construct (pSUN-9G) directed to a different embodiment of the invention, not pertinent to an assessment of whether claims 9 and 10 recite patentable subject matter." A POSITA "would have understood that the results shown in Table 2 and Table 3 with regard to *O. violaceous* would have been present in the *B. napus* and *B. juncea* plants produced using the [pGPTV] construct" because "*O. violaceous* is a close relative of *B. napus* and *B. juncea*," and the plants "share a close evolutionary relationship" and have "a similar fatty acid substrate profile."

The Board disagreed with Patent Owner that a POSITA would have disregarded the *Brassica* seed data in Table 6 because it was obtained from a plant created using the pSUN-9G construct instead of the pGPTV construct used to produce the *O. violaceous* and *A. thaliana* plants analyzed in Tables 2 and 3. The Board noted that claim 9 was directed to oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant, and did *not* include any limitation regarding the use of constitutive promoters or recite any specific construct that must be used to produce the claimed transgenic plant. "The claim, therefore, is broad enough to encompass transgenic *Brassica* plants produced using the pSUN-9G construct, and we are not inclined, on this record, to import into claim 9 a requirement that the transgenic *Brassica* plant be produced using the pGPTV construct. We do not discern, nor are we directed to, any disclosure in the '638 patent that indicates that a person having ordinary skill in the art would have disregarded the only data in the patent that demonstrates the quantitative amounts of polyunsaturated ω3-fatty acids in the oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant because the pSUN-9G construct was used to produce the transgenic *Brassica* plant."

Patent Owner similarly argued that the ω3-fatty acid results shown in *A. thaliana* "would have demonstrated to a [POSITA] that the construct is robust in that it works in *B. napus*." Accordingly, because the pGPTV construct produced "at least 54% ω3-fatty acids in *A. thaliana* and *O. violaceous*, a [POSITA] would have readily understood the same result would have been produced in the *B. napus* and *B. juncea* plants produced using the same construct."

The Board agreed with the Petitioner that the '638 patent does not reasonably convey to a POSITA that the inventors were in possession of the claimed oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that "comprise a total amount of at least 54% by weight of the polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant" as required by claims 8 and 9.

The Board noted that there was no dispute that "plant" as recited in the claims encompasses whole plants, and, alternatively, parts of plants. Example 12 in the '638 patent describes the analysis of seeds extracted from transgenic *Brassica juncea* plants transformed with the pSUN-9G construct. The results of that analysis are presented in Table 6 which presents the determination of the fatty acids in seeds from transgenic *Brassica juncea* and shows that the lipids in the seeds comprise 17.2–19.6% polyunsaturated ω3-fatty acids which is well below the "at least 54% by weight of the polyunsaturated ω3-fatty acids based on the total fatty acids in the transgenic plant" required by claims 8 and 9. The Board disagreed that the data in Table 6 is not relevant to the written description issue because the plant was produced using "a 'seed specific' promoter that would *only* express the construct *in the seeds* of the plant" and "is not an embodiment" of the invention recited in claim 9. The Board explained that seeds of the transgenic *Brassica juncea* plant are "a transgenic *Brassica* plant" within the scope of the challenged claims, however, and the fatty acids produced by those seeds are "fatty acids produced by a transgenic *Brassica* plant" as recited in the challenged claims, regardless of whether the construct is expressed in other parts of the transgenic *Brassica juncea* plant. Example 10(a), the only other example in the patent that is directed to the amount of fatty acids produced by transgenic *Brassica* plants, describes the generation of transgenic *Brassica napus* and *Brassica juncea* plants using the pGPTV construct. Patent Owner argued that the pGPTV construct was "the construct relevant" to claim 9. In Example 10(a), "mature seeds were harvested and analyzed for elongase expression such as Δ6-elongase activity or for Δ5- or Δ6-desaturase activity by means of lipid analyses," and "lines with elevated contents of polyunsaturated C20- and C22-fatty acids were identified." According to Patent Owner, because Example 10 reports "the inventors' identification of 'lines with elevated contents of polyunsaturated C20- and C22-fatty acids,'" "the inventors expressly described the construct would result in greater than 54% ω3-fatty acids in two species of *Brassica*." The Board

noted that the patent did not report quantitative data regarding the amount of polyunsaturated ω3-fatty acids in the oils, lipids, and/or fatty acids produced by the seeds of the transgenic *Brassica* plants described in Example 10(a). The Board was not persuaded that a POSITA would have understood the inventors' qualitative statement about the "elevated contents of polyunsaturated C20-and C22-fatty acids" to mean that the inventors were in possession of oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise any specific amount of polyunsaturated ω3-fatty acids, let alone at least 54% by weight as required by claims 8 and 9.

Patent Owner also pointed to Tables 2 and 3 of the patent, which reported that the leaves of transgenic *O. violaceous* and *A. thaliana* plants generated using the pGPTV construct produce fatty acids that comprise at least 54% by weight of polyunsaturated ω3-fatty acids as support for its contention that the transgenic *Brassica* plants made using the same construct would achieve the same results. The Board, however, pointed out that Patent Owner did not point to any disclosure in the patent indicating that the amount of polyunsaturated ω3-fatty acids in transgenic *O. violaceous* or *A. thaliana* plants is representative of the amounts in transgenic *Brassica* plants.

The Board further noted that Table 2 showed that the total amount of ω3-fatty acids in the transgenic *O. violaceous* leaves (57%) is practically unchanged as compared to the control (wild-type) *O. violaceous* leaves (55.9%), and the total amount of ω3-fatty acids in the transgenic *A. thaliana* plant (58%) was lower than that of the control (wild-type) *A. thaliana* leaves (64.6%). The Board concluded that a POSITA would have understood that transgenic *Brassica* plants produced using the pGPTV construct would produce the same fatty acids as those reported for *A. thaliana* and *O. violaceous* in Tables 2 and 3 but would ***not*** have understood that the same amounts would be produced.

The Board used a similar analysis to conclude that the '638 patent does not teach a person of ordinary skill in the art how to make or use the claimed oils, lipids, and/or fatty acids produced by a transgenic *Brassica* plant that comprise at least 54% by weight of polyunsaturated ω3-fatty acids. The Board stated that although Example 10(a) of the patent taught how to produce transgenic *Brassica* plants using the pGPTV construct, it did not provide any quantitative information about the amount of polyunsaturated ω3-fatty acids produced by the oils, lipids, and/or fatty acids produced by those plants. "At best, the '638 patent teaches how to make transgenic *Brassica* plants with 'elevated contents of polyunsaturated C20-and C22-fatty acids' as compared to the wild-type *Brassica* plants." The Board concluded that the claims were not enabled by the disclosures in the '638 patent and were unpatentable under 35 U.S.C. § 112.

Takeaways

This case is another example demonstrating the importance of providing sufficient description of the claimed embodiment. The reliance on different embodiments and examples and mixing data from various examples to provide support for what is claimed, but not specifically described and/or exemplified in the specification, may lead to lack of written description and lack of enablement rejections of the claimed embodiment, especially when the interchangeability of the different species or embodiments is not known or would not have been understood by a POSITA.