



ARE Patent Alert: The Federal Circuit Invalidates Pharmaceutical Claims Based on Indefiniteness

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A recent decision by the Federal Circuit highlights the importance of word selection and consistency in drafting patent applications.

In *IBSA Institut BioChimique, S.A., Altergon, S.A., IBSA Pharma Inc., v. Teva Pharmaceuticals USA, Inc.*, Slip Op. 2019-2400 (Fed. Cir. July 31, 2020), the Federal Circuit affirmed a lower court's holding that the asserted claims of a pharmaceutical patent were indefinite under 35 U.S.C. 112(b).

Of interest, in its analysis, the Federal Circuit agreed with the lower court that discrepancies between the U.S. patent and a certified translation of the Italian priority application suggested that the applicant intentional changed the language of the priority document in the U.S. patent. As a result, one skilled in the art would understand that the modified language has a different meaning than that used in the priority application such that the priority application was afforded no weight in determining the meaning of the disputed term which was ultimately determined to be indefinite.

IBSA is the assignee of U.S. Patent No. 7,723,390 ("the '390 Patent") entitled, "Pharmaceutical Formulation for Thyroid Hormones." Following the filing of an ANDA by Teva, IBSA filed suit asserting patent infringe of claims 1, 2, 4 and 7-9 of the '390 Patent. Independent claim 1 requires, among other things, "a soft elastic capsule consisting of a shell of gelatin material containing a liquid or half-liquid inner phase... said liquid or half-liquid inner phase being in direct contact with said shell without any interposed layers."

The parties disagreed with respect to the meaning of the term "half-liquid," but agreed that the "intrinsic record does not define 'half-liquid.'" Slip Op., p. 4. IBSA argued that the term means "semiliquid, i.e. having a thick consistency between solid and liquid." Slip Op., p. 3. Teva argued that the term was indefinite. *Id.*



IBSA explained that the Italian word “semiliquido” was used in the priority application in the same places as the term “half-liquid” in the ‘390 Patent. Since the certified translation of the priority application translated the term “semiliquido” as “semi-liquid,” IBSA contended that one skilled in the art would have understood the term “half-liquid” in the ‘390 Patent to be synonymous with the term semi-liquid.

The lower court disagreed and cited a number of discrepancies between the priority application (as set forth in the certified translation) and the ‘390 Patent other than the use of “half-liquid.” The lower court concluded that these differences, including the use of “half-liquid” in place of “semi-liquid,” were intended by the applicant to convey a different meaning than that set forth in the priority application such that no weight was accorded to the priority application with respect to claim construction.

The Federal Circuit acknowledged these differences and identified additional differences with respect to the claims and the specification and agreed with the lower court’s conclusion that the differences between the ‘390 Patent and the priority application suggest that the applicant intended to use different language to convey a different meaning. Accordingly, one of skill in the art would have understood that the term “half-liquid” used in the ‘390 Patent was intended to have a different meaning than the term “semi-liquid” (semiliquido) used in the priority application, contrary to IBSA’s proposed construction.

The Federal Circuit further noted that during prosecution, a dependent claim including the term “semi-liquid” was presented as dependent on an independent claim that used the term “half-liquid.” This claim did not issue in the ‘390 Patent, but the Federal Circuit considered its presentation further evidence that applicant understood the two terms to have different meanings.

The court concluded that the intrinsic evidence did not support IBSA’s proposed construction and also failed to “establish the boundaries” of the term “half-liquid.” Slip Op., p. 12. The Federal Circuit accorded little weight to IBSA’s extrinsic evidence noting that the dictionary definition relied on by IBSA was not from a scientific dictionary and related to the term “semi-liquid” rather than “half-liquid.” The Federal Circuit further discounted the use of the term “half liquid” in other patents since it was used in a different and specific context.

The deposition testimony of IBSA’s expert Dr. Chyall was also deemed unpersuasive as the



Federal Circuit indicated that it demonstrated the difficulty that one of skill in the art would have in attempting to identify the boundaries set by the term “half-liquid” since Dr. Chyall admitted that he was unsure whether IBSA’s construction would include certain types of gel and slurries that were disclosed in the prior art and distinguished during prosecution. See Slip Op., p. 13.

Since neither the intrinsic nor the extrinsic evidence would allow one of skill in the art to determine the scope of the invention with reasonable certainty, the Federal Circuit agreed with the lower court that the claims were invalid as indefinite under 35 U.S.C. 102(b).

In light of this decision, one should consider consistency of terms when drafting patent applications.

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