

**CAPON V. ESHHAR: WRITTEN DESCRIPTION UNDER 35 U.S.C. §112,
FIRST PARAGRAPH**

In a recent case of relevance to the pharmaceutical and biotechnology industries that centered on the written description requirement of the patent statute, 35 U.S.C. §112, first paragraph, the U.S. Court of Appeals for the Federal Circuit (“CAFC”) in *Capon v. Eshhar*, 03-1480, -1481 (Interf. No. 103,887) held that “§112 does not impose a *per se* rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field.”

At issue were a patent (“the Capon patent”) and patent application (“the Eshhar application”) that were directed towards chimeric DNA encoding single-chain chimeric proteins for expression on the surface of immune cells, the expression vectors encoding the genes, and cells transformed by the chimeric DNA. The chimeric proteins enhance the immune system by providing cells with specific, cell-surface antibodies in a form that can penetrate diseased sites, e.g., solid tumors.

Pursuant to 35 U.S.C. §§102(g) and 135(a), a patent interference proceeding was conducted by the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (“the Board”) to determine which applicant is the first inventor. Under 35 U.S.C. §6(b), during an interference proceeding, the Board may, in addition to determining priority of invention, redetermine patentability. The question of patentability was raised, and an *inter partes* proceeding ensued focusing on this point. As a result, the Board invalidated all of the claims considered in the interference proceeding without analysis of their scope or relation of the claim scope to the breadth of the specifications.

In describing its decision, the Board said “we are held by controlling precedent to understand that the full scope of novel chimeric DNA the parties claim is not described in their specifications under 35 U.S.C. §112, first paragraph, by reference to contemporary and/or prior knowledge in the art of the structure, formula, chemical name, or physical properties of many protein domains, and/or DNA sequences which encode constructs made in accordance with the plans, schemes, and examples thereof the parties disclose.” The Board further explained that the Capon patent and Eshhar application “do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.”

Both parties appealed the Board’s decision to the CAFC arguing that their specifications provide sufficient instructions and examples for identifying, obtaining, and assembling the desired DNA segments into chimeric genes with the appropriate citations to the scientific literature for each step of the preparation to satisfy §112, first paragraph.

The CAFC held that: 1) the Board erred in refusing to consider the state of the scientific knowledge, as presented, and in declining to consider the separate scope of each claim; 2) the Board’s requirement for the chimeric DNA sequences to be analyzed

and reported in the specification does not add descriptive substance; and 3) the Board erred in holding that the specifications do not meet the written description requirement by not reiterating the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.

A second focus of the CAFC's ruling considers whether the specifications adequately supported the scope of the relevant claims. The Director argued that certain permutations possible within the claims could be ineffective for the intended purpose rendering the claims too broad. The inventors argue that they have provided adequate breadth in their specifications, as required under 35 U.S.C. §112, first paragraph, and that the specifications provide for testing the effectiveness of various combinations.

The CAFC indicates the need to recognize the variability in "unpredictable" fields of science" for determining appropriate claim scope. The CAFC states "It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize the generic invention." The CAFC also states in regard to the support necessary for a generic invention "...the sufficiency of the support must be determined in the particular case." Thus, claim scope must be determined claim by claim in light of the specification in each case, taking into account the variability and unpredictability of the scientific field(s) in question.

In light of this ruling, the pharmaceutical and biotechnology industries may stand to benefit from this interpretation of the "written requirement" stipulation of 35 U.S.C. §112, first paragraph.

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