

*Goeddel v. Sugano*

Court of Appeal for the Federal Circuit

Decided September 7, 2010

Summary by Ryan Chirnomas



Last week, the CAFC issued a decision in *Goeddel v. Sugano*. This is an interesting application of the §112, first paragraph, written description requirement to the context of interferences. This case turns on whether Sugano’s Japanese priority document provides constructive reduction to practice, and thus complies with 35 U.S.C. §112.

The technology of this case relates to recombinant production of human fibroblast interferon (“hFIF”). hFIF is a naturally occurring protein in humans which is 166 amino acids, and is formed by the cleavage of the first 21 amino acids of a 187 amino acid precursor protein. Both Sugano and Goeddel sought to patent a recombinant DNA process for producing the mature hFIF protein directly, without the 21 amino acid presequence. The DNA encoding the 187 amino acid precursor of hFIF is not useful for expressing the mature 166 amino acid hFIF in *e. coli*.

Sugano relies on a Japanese priority document to predate Goeddel’s earliest priority. In Sugano’s priority document, the amino acid sequence of the full 187 amino acid precursor of hFIF is disclosed. However, the priority document does not explicitly identify the nucleic acid or amino acid sequences of the 166 mature hFIF protein. The Japanese document also does not explicitly identify the demarcation between the 21 amino acid presequence and the 166 amino acid mature hFIF. Instead, the Japanese priority document referred to a journal article which disclosed the first 13 amino acids of the mature hFIF protein. Based on this journal article, the Japanese priority document concluded that a plasmid used in the examples thereof “encompasses the entire coding region of the protein of the above mRNA and probably the coding region of the signal peptide.”

Based on the above, the Board of Patent Appeals and Interferences held that one skilled in the art “should have been able to envision” the DNA molecule which encodes the 166 amino acid mature hFIF protein and held that the mature hFIF protein was “readily apparent.” However, upon appeal, the CAFC disagreed. Although all parties agreed that one skilled in the art *could have* identified the boundary between the precursor and the mature hFIF sequence, the Japanese priority document did not describe this explicitly.

In order to comply with the written description requirement, it must be shown that the inventor was in possession of the invention, via actual or constructive reduction to practice. The CAFC stated that the question of whether the mature hFIF protein could be “envisioned” is not relevant: “The question is not whether one skilled in this field of science might have been able to produce mature hFIF by building upon the teachings of the Japanese Application, but rather whether that application “convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.”” This quote demonstrates a key difference between the written description requirement and the enablement requirement. Since the Japanese application did not disclose the mature hFIF protein, the CAFC held that Sugano was not in possession of the invention at the time of the Japanese application, and thus could not properly claim priority.

Although this may seem like a particularly harsh decision, this case serves as a good reminder to explicitly disclose each possible permutation and variation of one’s invention in the originally filed application. Additionally, for biotechnology cases, one should deposit samples when a written description is not practical. As always, it is better to include too much information than too little. Although it is not necessary to explain every detail of the invention, it is important to err on the side of over-inclusiveness to avoid a situation such as Sugano’s.

*Ryan Chirnomas is an Associate in the Biotechnology group at Westerman, Hattori, Daniels and Adrian LLP. Any questions or comments may be directed to [rchirnomas@whda.com](mailto:rchirnomas@whda.com). This article is for informational purposes only. The comments herein are the views of the author only and do not necessarily represent the views of Westerman, Hattori, Daniels and Adrian LLP or its clients.*