

VI. CONSTRUCTIVE REDUCTION TO PRACTICE

A. Close is No Cigar

Goeddel v. Sugano

Goeddel v. Sugano, ___ F.3d ___, ___ USPQ2d ___ (Fed. Cir. 2010)(opinion by Circuit Judge Newman for a panel that also consisted of Circuit Judges Lourie and Bryson), is further evidence of how exacting the written description requirement of the first paragraph of 35 USC 112 can be—particularly when the count defines the subject matter of an interference with great precision.

Goeddel was a consolidated appeal from decisions of the BPAI in two different interferences. However, the operative fact was that the counts of both interferences recited a molecule containing a specific sequence of 166 amino acids derived by cleaving the first 21 amino acids from a naturally occurring compound containing 187 amino acids.¹ The only issue on appeal was the propriety of the BPAI’s decision granting Sugano the benefit of the filing date of a Japanese patent application.² Goeddel argued that it wasn’t entitled to benefit because the Japanese patent application lacked both a written description of the subject matter defined by the two counts and an enabling disclosure for that subject matter. The BPAI had granted Sugano’s motions for benefit over both of those arguments. The Federal Circuit reversed and remanded, but it expressly decided only the written description issue.³

¹ The count in one interference recited “[a] DNA encoding a mature human fibroblast interferon having a total of 166 amino acids of the sequence... and unaccompanied by a human fibroblast interferon presequence.” The count in the other interference recited “[a] composition comprising water and a nonglycosylated mature human fibroblast interferon polypeptide having a total of 166 amino acids and the following amino acid sequence...[,] said composition being free of any glycosylated human fibroblast interferon.”

² As noted in § X.J.3., numerous other issues had been presented below. The board decided some of those issues and deferred other issues to post-interference ex parte prosecution.

³ The court stated that “The question is not whether one skilled in this field of science might have been able to produce...[the molecule in question] 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’.” That statement can be read to suggest that the court was at least sympathetic to Sugano’s

The BPAI had found, and Sugano did not deny, that “[t]he sequences...[in question] are not explicitly disclosed [in the Japanese application].”⁴ However, the naturally occurring predecessor was disclosed, and the specification of the Japanese application referenced a publication which Sugano argued “demarcated the line between the DNA encoding the...[amino acids to be cleaved off] and the DNA encoding...[the molecule recited in the counts].”⁵ The BPAI held that the molecule recited in the counts would have been “‘readily apparent’ to a person skilled in this field, in view of the Japanese Application’s description of the precursor...and [the publication referenced by Sugano]...”⁶; that “the Japanese Application satisfies the requirements of constructive reduction to practice because...[the referenced publication]’s partial sequence of the first 13 amino acids of...[the molecule recited in the counts] would allow [sic; would have allowed] a person skilled in the field of the invention to determine where in the 187 amino acid precursor the presequence ends and the mature sequence begins”⁷; and that “one skilled in this field ‘should have been able to envision’ the DNA molecule that would encode...[the molecule recited in the counts] unaccompanied by its presequence....”⁸

Unfortunately for Sugano, “readily apparent” and “should have been able to envision” weren’t good enough for the court. According to it:

The Japanese Application does not describe...[the molecule in question] and does not describe the DNA coding for...[the molecule in question] unaccompanied by the presequence. Sugano described its invention, in the initial Japanese Application, as the recombinant production of the 187 amino acid precursor, using a gene that encompasses

arguments on enablement.

⁴ ___ F.3d at ___, ___ USPQ2d at ___.

⁵ ___ F.3d at ___, ___ USPQ2d at ___.

⁶ ___ F.3d at ___, ___ USPQ2d at ___.

⁷ ___ F.3d at ___, ___ USPQ2d at ___.

⁸ ___ F.3d at ___, ___ USPQ2d at ___.

“at least the entire coding regions.” Section 112, in the context of interference priority,⁹ requires that the subject matter of the counts be described sufficiently to show that the applicant was in possession of the invention. That a modified gene encoding the 166 amino acid protein could have been “envisioned” does not establish constructive reduction to practice of the modified gene. * * * The Japanese application does not describe a bacterial expression vector that directly produces...[the molecule in question], nor does it suggest producing a modified gene to directly encode the 166 amino acid...[molecule in question].¹⁰

⁹ By “in the context of interference priority,” I think that the court was referring to the fact that, in an interference, only a single embodiment need be “described sufficiently,” not the entire scope of the claim.

¹⁰ ___ F.3d at ___, ___ USPQ2d at ___.