

## Goeddel v. Sugano

Nos. 09-1156, -1157, Fed. Cir. (Newman,\* Lourie, Bryson)

***The Board erred in ruling that priority is established if a person of skill in the art could “envision” the invention of the counts.***

On September 7, 2010, the Federal Circuit reversed and remanded the USPTO Board of Patent Appeals and Interferences decision awarding priority of invention to Sugano in an interference between U.S. patent application Serial No. 07/374,311 (Goeddel) and U.S. Patents No. 5,326,859 and No. 5,514,567 (Sugano). The interference counts related to DNA encoding the 166 amino acid mature human fibroblast interferon factor (hFIF) without a presequence. The Federal Circuit stated:

Interference priority is awarded to the first applicant to conceive the invention, provided that the invention is duly reduced to practice, actually or constructively. Reduction to practice of the subject of the interference count may be established by evidence of its actual performance, or constructively by filing a patent application that describes and enables its practice in accordance with 35 U.S.C. §112. An invention for which the priority of a foreign patent application is available in accordance with treaty and statute may rely on the content of the foreign application for constructive reduction to practice, provided that the requirements of §112 are met.

The Sugano Japanese Application describes the invention therein as: “a novel recombinant plasmid, having a gene which encompasses at least the entire coding region of the human fibroblast interferon messenger RNA . . . .” The application states: “The ‘entire coding region’ means the part specifying the whole amino acid sequence of the protein of the human fibroblast interferon in the human fibroblast interferon messenger RNA sequence. [I]n awarding priority to Sugano the Board found that mature hFIF would be “readily apparent” to a person skilled in this field, in view of the Japanese Application’s description of the precursor hFIF and a scientific article by Knight that is referenced in the Japanese Application . . . .

The Board held that the Japanese Application satisfies the requirements of constructive reduction to practice because Knight’s partial sequence of the first 13 amino acids of mature hFIF would allow 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. . . . Referring to the high level of skill in

this field, the Board held that although not explicitly described in the Japanese Application, “the amino acid of, and DNA sequence encoding, mature hFIF would be readily apparent.” Accordingly, the Board held that a person of skill in the field of the invention, reading the Japanese Application, would conclude that Sugano was in possession of the invention of the interference counts.

Goeddel argues that the Board erred in finding constructive reduction to practice, for the Japanese Application describes only the expression of precursor hFIF. Sugano conceded before the Board that the Japanese Application does not describe plasmids that express mature hFIF directly. . . . Although Dr. Roberts’s opinion was that “in view of the Knight disclosures, one of ordinary skill would have immediately understood that the presequence consists of the first 21 amino acids because the Knight disclosures teach that the mature sequence begins with the amino acid sequence Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser,” constructive reduction to practice “is ‘not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device.’” . . . Sugano argues that it is unnecessary for the Japanese Application to describe explicitly the amino acid sequence of mature hFIF or suggest obtaining mature hFIF. Sugano argues that patent applications are “written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before,” and thus “it is unnecessary to spell out every detail of the invention in the specification.” Thus Sugano argues that it sufficed that the Japanese Application referred to the Knight article, for with that article the Japanese Application “conveyed” mature hFIF with “reasonable clarity” to a person of skill in the art . . . .

Although the experts for both sides agreed that a skilled person “could” identify the boundary between the presequence and the mature hFIF based on the Knight article, the Japanese Application does not describe the subject matter of the interference counts. The Japanese Application does not describe mature hFIF and does not describe the DNA coding for mature hFIF 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 “at least the entire coding region.” Section 112, in the context of interference priority, 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 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.” The Japanese application does not describe a bacterial expression vector that directly produces the mature hFIF, nor does it suggest producing a modified gene to directly encode the 166 amino acid mature hFIF.

The Board erred in ruling that priority is established if a person of skill in the art could “envision” the invention of the counts. . . . The Board’s decision that the Japanese Application constitutes constructive reduction to practice of the subject matter of these interferences is not in accordance with law, for the Japanese Application does not meet the criteria of §112, first paragraph, as to this subject matter. The award of priority to Sugano is reversed. The cases are remanded for appropriate further proceedings.

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