

**Keywords:** priority; inherent disclosure; adequate written description.

**General:** The U.S. Court of Appeals for the Federal Circuit determines that the patent in question is adequately supported by inherent disclosure of the priority document.

*Yeda Research and Development Co. Ltd. v Abbott GmbH & Co. KG*

Decided September 20, 2016

**I. Facts**

Proteins are linear chains of amino acids that form complex, three-dimensional shapes that enable proteins to perform biological functions. The two ends of the chain of amino acids that form a protein are the N-terminus (designated as the beginning of the protein) and the C-terminus (designated as the end of the protein). There are twenty amino acids that occur in natural proteins, each identified by a three letter abbreviation (*e.g.*, Arginine => Arg, Histidine => His, *etc.*). A protein can be described in many different ways, including an using a partial or complete amino acid sequence, molecular weight, biological activity, and based on how the protein is degraded by digestive enzymes.

Tumor Necrosis Factor a (“TNFa”) is a naturally occurring protein that is associated with various immunological diseases. In May and July of 1989, Abbott GmbH & Co. KG (“Abbott”) filed two German provisional applications, P3915072 (“the ‘072 application”) and P3922089 (“the ‘089 application”), that describe a “novel protein” that binds to and neutralizes TNFa. The provisional applications disclosed only a partial N-terminus sequence of the novel protein, as well as the molecular weight, some biological activity, and degradation characteristics when exposed to trypsin. In May 1990, Abbott filed a PCT application claiming priority to the ‘072 and ‘089 applications. In September of 1991, the PCT application became a U.S. national stage application, and eventually issued as 5,344,915 (“the ‘915 patent”) in September of 1994, with claims that cover TBP-II (without explicitly naming it), as set forth below.

1. A purified and isolated TNFa-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence

Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys  
Arg Leu Arg Glu

where Xaa is hydrogen, a phenylalanine residue (Phe), or the amino acid sequences Ala Phe, Val Ala Phe, Gln Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe or Leu Pro Ala Gln Val Ala Phe.

In January 1990, between the filing of '072/'089 and the filing of the PCT application, Dr. Hartmut Engelmann independently published an article that identified two proteins (TBP-I and TBP-II) that bind to and neutralize TNFa.

In August 1992, Yeda Research and Development Co. Ltd. (hereinafter "Yeda") filed a continuation application 07/930,443 ("the '443 application") involving substantially similar claims as the '915 patent, resulting in the Board declaring an interference. During the interference the Board assigned the '915 patent the filing date of the PCT application and further determined that the '915 patent was invalid as being anticipated by Engelmann. Abbott filed suit in district court seeking review of the Board's final decision.

In 2008, the district court granted summary judgment for Abbott, determining that the '072 application inherently discloses the TBP-II protein and provides adequate written description of the invention claimed in the '915 application. As such, the district court vacated the Board's decision and remanded for further proceedings. On remand, in 2010, the Board held that the '072 application sufficiently disclosed TBP-II and that the '915 patent deserved the benefit of the earlier filing date of the '072 application. Yeda responded by filing a district court action seeking review of the Board's decision. In 2015, the district court affirmed the Board's decision and granted Abbott summary judgment. Yeda subsequently appealed the district court's 2008 and 2015 decisions to the U.S. Court of Appeals for the Federal Circuit.

## **II. Issues**

- 1) Did the district court err in determining that there was adequate written description support for the '915 patent in the '072 application?
- 2) Should prosecution history should have precluded Abbott from being able to rely on inherent disclosure?
- 3) Was the Board's finding of adequate written description supported by substantial evidence?

## **III. Discussion**

- 1) No. In order for the claims of the '915 patent to receive the filing date of the '072 application, the claimed invention must be disclosed by the priority document in a way that clearly allows a person of ordinary skill to recognize that the inventor possessed the claimed subject matter at the date of filing. Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed properties that are inherent to the invention, then the specification serves as adequate written description to support subsequent patent applications that explicitly recite these inherent properties. *See Kennecott*, 835 F.2d at 1423. Here,

both parties agreed that TBP-II is the *only* protein with the N-terminus sequence and properties disclosed by the '072 application. Accordingly, the '072 application sufficiently enables and describes TBP-II and, therefore, inherently discloses the remaining amino acids in the N-terminus sequence of TBP-II, providing adequate written description support to claim the N-terminus sequence of TBP-II in the '915 patent. As such, the district court correctly determined that a complete N-terminus sequence of a protein need not be disclosed by the priority document for there to be adequate written description support for explicitly claiming this N-terminus sequence.

2) No. During prosecution of the '915 patent, the examiner rejected claims based on prior art that disclosed a protein with the same source, weight, and function as the protein claimed in the '915 patent. Based on Engelmann, Abbott argued that the cited art concerned only TBP-I, and that TBP-II includes an N-terminus sequence of five amino acids that are not present in TBP-I and that match the chain recited in the claims of the '915 patent. Accordingly, Abbott's response did not solely rely on amino acids missing from the priority applications. Rather, Abbott argued that the portion of the N-terminus sequence disclosed by '072 is sufficient to conclusively determine that '072 and '915 are directed to TBP-II, while the cited art is directed to TBP-I.

3) Yes. As the district court noted, the Board determined that the '072 application identified nine of the fifteen amino acids of the N-terminus sequences recited in the claims of '915. Additionally, the Board also noted several biological characteristics of the protein disclosed in the '072 application. Furthermore, since it was undisputed that no known protein other than TBP-II has these characteristics, the Court determined that the Board's decision was properly supported by substantial evidence.

#### **IV. Conclusion**

Whenever possible, priority documents should be drafted to include all relevant details regarding the invention. However, in situations in which an applicant has sufficient data in hand to demonstrate possession and is waiting for additional characterization data that would delay filing of the priority document, one could consider proceeding by timely filing the priority document and relying on the doctrine of inherent disclosure to support the position that inherent properties of the invention, whether or not explicitly disclosed in the priority document, are fully supported.