

ABBVIE DEUTSCHLAND GMBH & CO., KG v. JANSSEN BIOTECH, INC., Appeal No. 2013-1338, -1346 (Fed. Cir. July 1, 2014). Before Lourie, O'Malley, and Chen. Appealed from D. Mass. (Judge Saylor).

Background:

Plaintiff sued Defendant for infringement of its patents relating to a family of structurally similar antibodies derived from a lead composition.

Defendant challenged Plaintiff's patents as not complying with the written description requirement because Plaintiff's functional claiming would cover an entire genus of which the lead composition was not representative.

The District Court agreed with Defendant and ruled that the asserted claims were invalid for lack of written description. Plaintiff appealed.

Issue/Holding:

Did the District Court err in ruling that Plaintiff's patents were invalid for lack of written description? No, affirmed.

Discussion:

The Federal Circuit agreed with the District Court's ruling, relying heavily on *Ariad Pharm. Inc. v. Eli Lilly & Co.* After quoting several passages from *Ariad* and noting Plaintiff's concession that structural features of the genus were not disclosed, the Federal Circuit said that the question reduced to "whether the patents sufficiently otherwise describe representative species to support the entire genus."

The Plaintiff defined the claims in terms of functional language and as such, the Federal Circuit stated that "when a patent claims a genus using functional language to define a desired result, the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." The Federal Circuit stated that the Plaintiff's specification failed to so demonstrate.

Moreover, the Federal Circuit distinguished between species "representing the genus throughout its scope" and those that "only abide in a corner of the genus," analogizing the genus to a plot of land. Here, the court said, the latter was true, and "that Plaintiff's patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus." The Federal Circuit accordingly found that Plaintiff's patents did not meet the written description requirement.

Notably, the Federal Circuit summed up its holding with a paraphrase of another holding in *Ariad*:

Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus.

The Federal Circuit thus affirmed the District Court's judgment of invalidity on written description grounds.