BIOGEN MA INC. v. EMD SERONO, INC., Appeal No. 2019-1133 (Fed. Cir. September 28, 2020). Before Newman, Linn and Hughes. Appealed from D.N.J. (Judge Cecchi).

Background:

Plaintiff owns a patent directed to a method of treating a viral condition, a viral disease, cancers or tumors, by administration of a pharmaceutically effective amount of a recombinant polypeptide related to human interferon-β ("IFN-β"). Defendant sold and marketed Rebif, a recombinant interferon-β product used for the treatment of Multiple Sclerosis, and Plaintiff sued Defendant for infringement (alleging contributory and induced infringement).

After a five-week trial, a jury found that the asserted claims were anticipated by two references teaching the use of native IFN-β to treat viral diseases—i.e., the human immune system naturally produces IFN-β (which, given the definition of "polypeptide" in the patent, meets the claim limitations) in small amounts, and it was undisputed that IFN-β harvested from human cells ("native IFN-β") was used in the prior art to treat viral conditions.

On cross-motions, the district court granted judgment as a matter of law (JMOL) of no anticipation in favor of Plaintiff and conditionally granted a new trial on anticipation. The district court concluded that just because recombinant and native IFN-β share the same linear amino acid sequence is not enough for purposes of anticipation in this case because the claims expressly required administration of a "therapeutically effective amount" of a recombinant polypeptide that "displays antiviral activity" and thus the product resulting from the claimed recombinant process is further defined by the folded three-dimensional structure of the protein. Defendant appealed.

Issue/Holding:

Did the district court err in granting JMOL of no anticipation? Yes, reversed and remanded (with instructions to reinstate the jury verdict on anticipation).

Discussion:

The Federal Circuit explained that the key question for anticipation in this case is whether the native "polypeptide" is identical to the "polypeptide" "produced by" the recited recombinant process. Plaintiff argued that only three-dimensional proteins can be therapeutically effective and have antiviral activity, and therefore the "product" to be analyzed for novelty is the folded three-dimensional protein, not just the mere amino acid sequence. However, the Federal Circuit stated that this is incorrect because the argument fails to give effect to Plaintiff's explicit definition of "polypeptide" in the patent at issue.

Here, Plaintiff explicitly defined "polypeptide" in the patent at issue as a "linear array of amino acids connected one to the other by peptide bonds between the α-amino and carboxy groups of adjacent amino acids". The Federal Circuit found that the polypeptide structure at issue is thus defined by reference to its "linear" array, without regard to its folded protein structure. The Federal Circuit indicated that this lexicographic choice must be respected, and found that the native IFN-β polypeptide and the claimed recombinant IFN-β polypeptide are identical for purposes of the asserted claims (Plaintiff did not dispute that the sequential order of the amino acid residues for native IFN-β is the same as the sequential order of the amino acid residues for recombinant IFN-β). Accordingly, the Federal Circuit reversed the district court's grant of JMOL of no anticipation and the conditional grant of a new trial on anticipation.