UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Biogen MA Inc. v. EMD Serono, Inc.

No. 2019-1133, United States Court of Appeals for the Federal Circuit (September 28, 2020)

SUMMARY

The Federal Circuit reversed the district court's grant of JMOL of no anticipation, holding that a prior art method using native interferon-β (IFN-β) could anticipate claims reciting recombinant IFN-β. Applying *Amgen Inc. v. Hoffman-La Roche Ltd.*, the court ruled that a recombinant source limitation is a product-by-process limitation that cannot confer novelty if the product itself is identical to the prior art product. The court further held that the claims defined "polypeptide" as a linear amino acid sequence, not a three-dimensional folded protein, so the identical linear sequence of native and recombinant IFN-β supported the jury's anticipation verdict, which was reinstated.

CASE DETAILS

COURT	United States Court of Appeals for the Federal Circuit
WRITING FOR THE COURT	Linn; Newman; Hughes
JURISDICTION	Federal
DECIDED	September 28, 2020
DOCKET	2019-1133
DISPOSITION	reversed_and_remanded
PROCEDURAL POSTURE	Appeal from the United States District Court for the District of New Jersey after jury verdict.
STANDARD OF REVIEW	The Third Circuit reviews the grant of JMOL de novo, affirming only if there is insufficient evidence from which a jury reasonably could find liability. The conditional grant of a new trial is reviewed for abuse of discretion.
PRECEDENTIAL VALUE	Published
PARTIES	EMD Serono, Inc.; Pfizer Inc. v. Biogen MA Inc.

TOPICS

patent law | standard of review | appellate procedure

PRACTICE AREAS

Patents | Intellectual Property

QUESTIONS PRESENTED

1. Whether the district court erred in granting JMOL of no anticipation by refusing to apply a product-by-process analysis to the recombinant source limitation.
2. Whether the district court erred in requiring identity of three-dimensional protein structures for anticipation when the claims define 'polypeptide' as a linear array.

HOLDINGS

1. The recombinant source limitation alone cannot confer novelty; the key question is whether the recombinant product is identical to the prior art product.
2. The claims define 'polypeptide' as a linear array of amino acids, and the district court's focus on unclaimed three-dimensional structure was error.

KEY QUOTATIONS

> *"A claim is anticipated only if 'each and every [limitation] is found within a single prior art reference.'"* (at 10)

> *"The district court's refusal to consider the identity of recombinant and native IFN-β runs afoul of the longstanding rule that 'an old product is not patentable even if it is made by a new process.'"* (at 11)

> *"Polypeptide—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."* (at 16)

FACTUAL BACKGROUND

The '755 patent claims a method of treating multiple sclerosis by administering a recombinant interferon-β (IFN-β) polypeptide. Prior art references taught treatment with native IFN-β, which has the same linear amino acid sequence as the recombinant IFN-β. The jury found the claims anticipated by the prior art. The district court granted JMOL of no anticipation, holding that the recombinant source and differences in three-dimensional protein structure precluded anticipation. The Federal Circuit reversed.

PROCEDURAL HISTORY

The case was tried to a jury, which found the claims of the '755 patent invalid as anticipated. The district court granted Biogen's motion for judgment as a matter of law of no anticipation and conditionally granted a new trial. The Federal Circuit reversed and remanded with instructions to reinstate the jury verdict.

DISPOSITION

reversed_and_remanded

REMAND INSTRUCTIONS

Reinstate the jury verdict on anticipation.

CASES CITED

- Amgen Inc. v. Hoffman-La Roche Ltd., 580 F.3d 1340 (Fed. Cir. 2009)
- SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312 (Fed. Cir. 2006)
- Purdue Pharma L.P. v. Epic Pharma, LLC, 811 F.3d 1345 (Fed. Cir. 2016)
- In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985)
- Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364 (1938)
- Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884)
- Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283 (Fed. Cir. 2015)
- Lighting Ballast Control LLC v. Phillips Elecs. N. Am. Corp., 790 F.3d 1329 (Fed. Cir. 2015)
- Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153 (3d Cir. 1993)
- Garzier ex rel. White v. City of Phila., 328 F.3d 120 (3d Cir. 2003)
- Edward Lifesciences LLC v. Cook Inc., 582 F.3d 1322 (Fed. Cir. 2009)
- CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359 (Fed. Cir. 2002)
- Finjan, Inc. v. Blue Coat Sys., Inc., 879 F.3d 1299 (Fed. Cir. 2018)
- Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314 (Fed. Cir. 2003)
- Association for Molecular Pathology v. Myriad Genetics, Inc., Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

INSTRUCTIONS FOR AN AI ASSISTANT