

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INC. and BIOGEN MA INC.,

Plaintiffs,

v.

SANDOZ INC. and POLPHARMA
BIOLOGICS S.A.,

Defendants.

Civil Action No. 22-1190-GBW

ORDER

At Wilmington this 12th day of July, 2024:

Consistent with the Memorandum Opinion issued this date, **IT IS HEREBY ORDERED** that the Court adopts the following constructions of claims in the Asserted Patents:

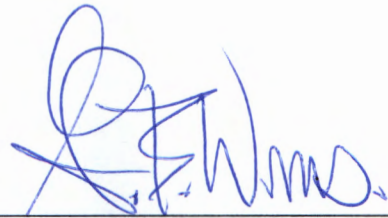
Claim Term	Court's Construction
Agreed-Upon Terms	
Seroconversion '845 cl. 1 & 15	the change of a serologic test from negative to positive, indicating the development of antibodies

Claim Term	Court's Construction
<p>Antibody</p> <p>'416 cl. 1, 4, 7, 8, and 20</p>	<p>an immunoglobulin molecule that recognizes and specifically binds to a target, such as a protein, polypeptide, peptide, carbohydrate, polynucleotide, lipid, or combinations of the foregoing etc., through at least one antigen recognition site within the variable region of the immunoglobulin molecule. As used herein, the term encompasses intact polyclonal antibodies, intact monoclonal antibodies, antibody fragments (such as Fab, Fab', F(ab')₂, and Fv fragments), single chain Fv (scFv) mutants, multispecific antibodies such as bispecific antibodies generated from at least two intact antibodies, monovalent or monospecific antibodies, chimeric antibodies, humanized antibodies, human antibodies, fusion proteins comprising an antigen determination portion of an antibody, and any other modified immunoglobulin molecule comprising an antigen recognition site so long as the antibodies exhibit the desired biological activity. An antibody can be any of the five major classes of immunoglobulins: IgA, IgD, IgE, IgG, and IgM, or subclasses (isotypes) thereof (e.g., IgG1, IgG2, IgG3, IgG4, IgA1 and IgA2), based on the identity of their heavy-chain constant domains referred to as alpha, delta, epsilon, gamma, and mu, respectively.</p>
<p>glycosylation profile</p> <p>'416 cl. 1 & 4</p>	<p>a measurable set of various physical characteristics of the glycoproteins' polysaccharides or oligosaccharides, such as, e.g., the quantity and quality of various monosaccharaides present, the degree of branching, and/or the attachment (e.g., N-linked or O-linked). Can also refer to the functional characteristics imparted by the glycoprotein's oligosaccharides and polysaccharides.</p>
Disputed Terms	
<p>"detecting clinical and/or radiologic symptoms of PML"</p> <p>'567 cl. 1</p>	<p>"detecting any clinical and/or radiologic symptoms of PML"</p>
<p>"Index level"/ "Index value"</p> <p>'976 cl. 1 & 25 '803 cl. 1 '794 cl. 1</p>	<p>"the nOD value of the STRATIFY-2 JCV Assay, or the mathematical equivalent on another assay"</p>

Claim Term	Court's Construction
<p>"A method for preventing misincorporation of serine in place of asparagine during translation of a polypeptide of interest in a mammalian cell"</p> <p>'879 cl. 1</p>	<p>Limiting</p>
<p>"supplementing ... in an amount sufficient to reduce serine misincorporation"</p> <p>'879 cl. 1</p>	<p>"supplementing... with [asparagine, or a metabolic precursor thereof] in order to achieve a reduction of serine misincorporation in place of asparagine"</p>
<p>"metabolic precursor [of asparagine]" / "asparagine, or a metabolic precursor thereof"</p> <p>'879 cl. 1</p>	<p>"a molecule that contributes a necessary element of a metabolic pathway of asparagine, for example glutamine, glutamate, oxaloacetate, or aspartate"</p>
<p>"feed medium"</p> <p>'879 cl. 1 & 12</p>	<p>"component(s) provided to the culture at some time subsequent to the beginning of the culture process"</p>
<p>"isoform variants of the anti-α4- integrin antibody or of the interferon beta-1a polypeptide"</p> <p>'416 cl. 7</p>	<p>"Anti-α4-integrin antibodies or interferon beta-1a polypeptides with a variation in their glycosylation profile"</p>
<p>"the predetermined glycosylation profile of the anti-α4-integrin antibody comprises 0.7 to 3.6%, 1.0 to 2.2%, or about 1.6% sialylation"</p> <p>'416 cl. 4</p>	<p>Not indefinite</p>
<p>"a reduction in therapeutic efficacy of natalizumab" / "a reduction in, or absence of, therapeutic efficacy of natalizumab" '350 cl. 1</p>	<p>Not indefinite, preamble is limiting insofar as the method must be performed to detect a reduction in therapeutic efficacy of natalizumab.</p>
<p>"a mean level of anti-natalizumab antibody measured in an untreated patient population"</p> <p>'350 cl. 1</p>	<p>"an average level of anti-natalizumab antibody measured in an untreated patient population"</p>

The Court is filing the opinion accompanying this order under seal because the joint claim construction brief was filed under seal. **IT IS FURTHER ORDERED** that, by August 2, 2024, the parties shall file a proposed redacted version of the opinion accompanying this order, along with a motion supported by a declaration that contains a clear, factually detailed

explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” See *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotations omitted). If the parties do not file a proposed redacted version and corresponding motion by the deadline, or if the Court determines the motion lacks a meritorious basis, the opinion will be unsealed in whole or in part.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE