Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Hamburg - Local Division

UPC_CFI_124/2024
Final Order of the Court of First Instance of the Unified Patent Court delivered on *26/06/2024*

HEADNOTES:

1. The patent claim is always to be interpreted from the point of view of a person skilled in the art. Additionally, the skilled person is taking the purpose of every patent claim into account, to provide the average person skilled in the art with a technical teaching which, when reworked, leads to the intended success of the invention.

2. The court must be convinced of the validity of a patent in suit with a sufficient degree of certainty. A decision on provisional measures cannot be based solely on the court's view of the validity of the patent in suit, but also on the likelihood that the opposition division of the EPO will revoke the patent.

KEYWORDS:
Preliminary injunction; Art, 62(2) UPCA; Rule 209(2) RoP.
Validity of the patent in suit; degree of certainty; Art. 62 (4) UPCA; Rule 211.2 RoP

APPLICANT

Alexion Pharmaceuticals, Inc.
(Applicant) - 121 Seaport Blvd - MA 02210 - Boston - US

Represented by Elena Hennecke

DEFENDANT

Represented by Andrea Ritter

Samsung Bioepis NL B.V.
(Defendant) - Olof Palmestraat 10 - 2616 LR - Delft - NL

PATENT AT ISSUE

Patent no.	*Proprietor/s*
EP3167888	Alexion Pharmaceuticals, Inc.

DECIDING JUDGE

Full Panel

Presiding judge	Sabine Klepsch
Legally qualified Judge	Dr. Stefan Schilling
Legally qualified Judge	Alima Zana
Technically Qualified Judge	Rudi Goedeweeck

LANGUAGE OF PROCEEDINGS: English

ORAL HEARING

25 June 2024

SHORT SUMMARY OF FACTS

The parties are competitors in the research and development of pharmaceuticals as well as their manufacture and supply.

The Applicant is the parent company of the Alexion group, a global pharmaceutical company headquartered in Boston, Massachusetts, and has been part of the AstraZeneca Group since 2021. It is the proprietor of the European Patent EP 3 167 888 B1 (hereinafter: patent in suit or the patent), that is a divisional application of the European patent application EP 2 359 834 A1 (hereinafter: EP 834), which is a divisional application of the European patent application EP 2 001 490 A1 (hereinafter: EP 490) which matured from the international patent application WO 2007/106585. The patent application underlying the patent in suit was published on 17 May 2017. WO 2007/106585 was filed on 15 March 2007. It claims the priority of US 783070 P which was filed on 15 March 2006. The date of publication and mention of the grant of the patent was on 1st May 2024 with unitary effect granted by the decision of the European Patent Office (hereinafter: EPO) of 13 May 2024 (Exhibit FBD 35 and 36).

Three third party observations were filed during the grant procedure of the patent in suit. On 21 September 2023, the Technical Board of Appeal (hereinafter: TBA) 3.3.04 of the EPO decided that the subject-matter of the patent in suit was patentable and ordered the Examining Division to grant the patent in suit based on Auxiliary Request 5, i.e., with the claims subject of the present application for preliminary measures (Exhibit FBD 6). On 6 March 2024, i.e. immediately after the notice of intention to grant under Rule 71(3) EPC, a further third party observation was filed. Accordingly, on 11 March 2024, the Examining Division of the EPO issued a communication on the non-relevance of the third party observation, stating that the prior art cited by the third party neither anticipated the claimed invention nor made it obvious.

The Defendant filed an opposition at the EPO on 2nd May 2024 (Exhibit SS 35) and submitted further arguments on 13 June 2024 (Exhibit SS 36).

The patent provides the treatment of paroxysmal nocturnal hemoglobinuria patients with an inhibitor of complement component 5 ("C5"). The relevant claim 2 has the following wording:

> "A pharmaceutical composition comprising the antibody of claim 1."

Claim 1 of the patent reads as follows:

> "An antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO:4."

These sequences are shown in paragraph [0134] of the Patent in suit.

SEQ ID NO: 2 - Eculizumab Heavy chain

QVQLVQSGAEVKKPGASVKVSCKASGYIFSNYWIQWVRQAPGQGLEWMGEILPG
SGSTEYTENFKDRVTMTRDTSTSTVYMELSSLRSEDTAVYYCARYFFGSSPNWYF
DVWGQGTLVTVSSASTKGPSVFPLAPCSRSTSESTAALGCLVKDYFPEPVTVSWNS
GALTSGVHTFPAVLQSSGLYSLSSVVTVPSSNFGTQTYTCNVDHKPSNTKVDKTVE
RKCCVECPPCPAPPVAGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSQEDPEVQFN
WYVDGVEVHNAKTKPREEQFNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKGLP
SSIEKTISKAKGQPREPQVYTLPPSQEEMTKNQVSLTCLVKGFYPSDIAVEWESNGQ
PENNYKTTPPVLDSDGSFFLYSRLTVDKSRWQEGNVFSCSVMHEALHNHYTQKSL
SLSLGK

SEQ ID NO: 4 - Eculizumab Light chain

MDMRVPAQLLGLLLLWLRGARCDIQMTQSPSSLSASVGDRVTITCGASENIYGAL
NWYQQKPGKAPKLLIYGATNLADGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQ
NVLNTPLTFGQGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKV
QWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQG
LSSPVTKSFNRGEC

The Applicant and its affiliated companies market a wide range of well-known and very successful innovative pharmaceuticals for the treatment of rare diseases. These include Soliris®, a biopharmaceutical drug which is authorised for treatment of the following rare diseases: paroxysmal nocturnal hemoglobinuria (hereinafter: PNH), atypical hemolytic uremic syndrome (hereinafter: aHUS), refractory generalized myasthenia gravis (hereinafter: gMG), and neuromyelitis optica spectrum disorders (hereinafter: NMOSD). The active ingredient in Soliris® is the recombinant humanized monoclonal antibody eculizumab.

Soliris® is the orphan drug of the Applicant containing the antibody eculizumab. It was approved in Europe in 2007 and marketed, inter alia, for PNH.

The Defendant is a part of the pharmaceutical group Samsung Bioepis, which was founded in 2012 and has been part of the South Korean pharmaceutical company Samsung Biologics since 2022. Since July 2023, the Defendant has placed Epysqli® (hereinafter: challenged or attacked embodiment), a biosimilar product of Soliris® containing the monoclonal antibody eculizumab, on the market of several Contracting Member States of the UPC (in Germany since July 2023, in Italy since September 2023, in France since December 2023 and in the Netherlands in April 2024). Epysqli® is currently approved for the European market under the authorisation number EU/1/23/1735/001 in the embodiment "300 mg Concentrate for solution for infusion" for the following indication (Exhibit FBD 3):

> "Epysqli is indicated in adults and children for the treatment of:
> - Paroxysmal nocturnal haemoglobinuria (PNH).
> Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history (see section 5.1).
> - Atypical haemolytic uremic syndrome (aHUS) (see section 5.1)"

The Applicant's request for preliminary measures is directed against the marketing of the defendant's contested embodiment in the Contracting Member States (CMS) of the Unified Patent Court Agreement (hereinafter: UPCA).

In addition, and to avoid repetition, reference is made to the parties' submissions and the entire contents of the file.

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES

The Applicant requests:

I. The Defendant is ordered to cease and desist, within the territory of the Contracting Member States of the Agreement on a Unified Patent Court (UPCA),

from making, supplying, offering, placing on the market and/or using, and/or importing or storing for those purposes

1. a pharmaceutical composition comprising an antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO:4 (literal infringement of claim 2 of EP 3 167 888 B1)

in the alternative

2. a pharmaceutical composition comprising an antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of amino acids 23 to 236 of SEQ ID NO:4 (equivalent infringement of claim 2 of EP 3 167 888 B1).

II. The Defendant shall pay to the Court a fine of up to EUR 250,000.00 for each individual (repeated) infringement of the orders under I. above.

III. The Defendant is ordered to surrender the products according to motion I., which are in its direct or indirect possession or ownership within the territory of the Contracting Member States of the UPCA, to a person designated for enforcement in accordance with the provisions of the relevant enforcing Contracting Member State, for the purpose of custody.

IV. The Defendant is ordered to pay the costs of the proceedings.

V. These orders shall be effective and enforceable immediately.

The Defendant requests:

1. The application for provisional measures dated 19 March 2024 is dismissed as inadmissible and unfounded.

1.1 As an auxiliary request:
The Defendant is permitted to continue the alleged infringing acts against provision of a security, the amount of which is left to the discretion of the Court but should not exceed EUR 5,000,000.00.

1.2 As a further auxiliary request:
The granting of provisional measures is made conditional on the provision of a security by the Applicant in accordance with Rule 211.5 RoP, the amount of which is to be determined by the Court but should not be less than EUR 5,000,000.00.

2. The costs of the proceedings shall be imposed on the Applicant.

3. This order is immediately enforceable.

4. The Applicant is ordered to start proceedings on the merits of the case before the Court within a time period not exceeding 31 calendar days or 20 working days, whichever is the longer, from the date specified in the Court's order (R. 213 (1) RoP), and

5. to order that any provisional measures ceases to have effect if the Applicant fails to start proceedings on the merits of the case within the time period in accordance with request 4 above (R. 213 (1) RoP).

POINTS AT ISSUE

The Applicant asserts that the Defendant's attacked embodiment literally infringes the patent in suit. Claim 2 refers to a pharmaceutical composition of an antibody that binds C5. The term "pharmaceutical composition" clarifies for the skilled person that the formulation is a product produced for use in therapeutic applications (patent in suit, paras. [0082] et seqq.), i.e., ready for treatment of, e.g., PNH with the active antibody eculizumab that binds C5 (patent in suit, para. [0010]). Binding C5 is the functional core and essential property of the claimed antibody. Structurally, the pharmaceutical composition is directed to a full-length antibody, i.e., antibody fragments are not encompassed by the term "antibody". The heavy chain of the antibody consists of SEQ ID NO: 2. The amino acid sequence of the challenged embodiment is identical to the sequence of Soliris®.

Claim 2 of the patent in suit further relates to the light chain of the antibody of the pharmaceutical composition consisting of SEQ ID NO: 4. According to paragraph [0134] of the Patent in suit, SEQ ID NO: 4 is identified as "Eculizumab Light chain". Paragraph [0134] of the Patent in suit shows the amino acid sequences of the light chain of eculizumab in combination with an additional sequence of 22 amino acids, which represents a signal peptide as highlighted by the Applicant:

SEQ ID NO: 4 - Eculizumab Light chain

MDMRVPAQLLGLLLLWLRGARCDIQMTQSPSSLSASVGDRVTITCGASENIYGAL
NWYQQKPGKAPKLLIYGATNLADGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQ
NVLNTPLTFGQGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKV
QWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQG
LSSPVTKSFNRGEC

The Applicant is of the opinion that at the priority date, the skilled person understood that nascent polypeptides of antibodies always have a signal sequence at the N-terminus and that this signal peptide is cleaved off from the polypeptide before the antibody is formed and secreted from the cell. Therefore, the skilled person understood that the signal peptide in SEQ ID NO: 4 is cleaved off during the production of eculizumab and is no longer

contained in a therapeutically used end product, i.e. the pharmaceutical composition. As a result, the skilled person will interpret the light chain of the antibody contained in a pharmaceutical composition as consisting of SEQ ID NO: 4 without the signal peptide. An antibody that contains the complete sequence SEQ ID NO: 4 is not able to bind C5 and therefore not suitable to be used in a pharmaceutical composition. Moreover, the skilled person knew at the priority date that it is not possible without undue burden to produce and collect an antibody wherein the light chain is still attached to the signal peptide.

A skilled person at the priority date would have recognized that the light chain SEQ ID NO: 4 is longer – 236 residues - than the average light chain of a mature antibody which ranges from about 211-217 amino acids. He would have further recognised typical features of a signal peptide: the sequence starting with methionine, followed by amino acid residues, most of which are hydrophobic, followed by a sequence of DIQM, the start of the mature protein. The skilled person would have been able to determine the exact length of the signal peptide, using databases like Blast or SignalP. Taking into account this understanding, the attacked embodiment infringes claim 2 literally. In the alternative, it infringes the patent with equivalent means.

The Applicant claims that the legal validity of the patent in suit is sufficiently secured and it is more likely than not that the patent is valid. This is confirmed by the fact that the legal validity of the patent in suit was extensively examined and finally confirmed by the Technical Board of Appeal of the European Patent Office – i.e., by the second instance which would also decide on an opposition. Several third party observations were submitted in the examination proceedings of the patent in suit. The final decision of the TBA of 21 September 2023 (Exhibit FBD 6) determining the legal validity of the patent in suit shows that there can be no reasonable doubt as to the sufficiently certain legal validity of the patent in suit. The claimed subject-matter is directly and unambiguously disclosed in the divisional patent application EP 3 167 888 A1, in the patent application as filed EP 2 359 834 A1 and in the original International patent application WO 2007/106585. The invention according to the patent in suit is sufficiently disclosed to be carried out by a skilled person. The antibody is defined by its sequences and the sequences are specified in the patent in suit (para. [0134]) just like common preparation methods (paras. [0074] et seqq.). The skilled person interprets claim 2 as meaning that the claimed antibody comprises a light chain consisting of SEQ ID NO:4 without the signal peptide. There is no doubt that the antibody consisting of the heavy chain sequence SEQ ID NO:2 and the mature light chain sequence SEQ ID NO:4 (without signal peptide) – i.e. the antibody eculizumab – can bind to C5. The subject-matter of the patent in suit is also novel. The claimed sequence is not disclosed in the prior art. The subject matter of the patent in suit involves an inventive step, which was thoroughly assessed in the first and second instance examination proceedings. The Applicant states further, that the provisional measures are necessary in terms of time and in factual terms. In the absence of an order for provisional measures, the Defendants will continue to distribute the challenged embodiment in the current Contracting Member States and is likely to seek to launch it in

markets of other Contracting Member States and for a broader range of indications. This has already caused substantial and irreversible damage to the Applicant and will continue to cause further such damage unless this is prevented by this Court.

The Defendant argues that the Applicant's requests must be denied. It disagrees with the Applicant on the construction of claim 2. It is of the opinion that the sequence of the antibody claimed in the patent in suit is not the sequence of eculizumab. The claims of the patent in suit have been granted by the TBA (auxiliary request 5) in the explicit understanding that it protects a different antibody than the products of the parties.

The Defendant further contends that the patent as granted is invalid. The EPO will revoke the patent in the opposition proceedings. The assumption of the TBA that an antibody with an amino acid sequence such as SEQ ID NO. 4 can be used as a pharmaceutical composition, i.e. binds C5, is no longer justified because the Applicant himself submits that the signal peptide would hinder the interaction with C5. In addition, the Defendant has submitted new prior art which was not presented to the TBA when granting the patent in suit. This new prior art would disclose the exact features that the TBA thought made the claims inventive and will lead to revocation of the patent. The claims of the patent as granted are also insufficient for various reasons not explored at the EPO (not reproducible; extending to undisclosed subject matter). Accordingly, there is no sufficient degree of certainty with respect to the validity of the patent in suit.

The Defendant is also of the opinion, when weighing the interests of the parties, that it is manifest that the Defendant will suffer significant, irreparable and unquantifiable harm should the application for provisional measures be granted and the Defendant be forced to take its product off the market despite already being well established with clinicians and patients. The Applicant, by contrast, can easily obtain compensation for damages for any alleged harm.

GROUNDS FOR THE ORDER

The application for an order on provisional measures is to be dismissed.

I.
The Applicant is the registered proprietor of the patent in suit and therefore entitled to bring actions to the court, Art. 47 (2) UPCA in conjunction with R. 8.5 (a) and (c) RoP.

II.
The Court is convinced with a sufficient degree of certainty (R. 211.2 RoP) that the Applicant's right is infringed by the offer and distribution of the attacked embodiment within the Contracting Member States (Art. 25(a) UPCA). On summary examination, the attacked

embodiment make direct and literal use of the technical teaching of the patent in suit protected by patent claim 2.

1.
The invention relates to a pharmaceutical composition that can be used as an inhibitor of complement component 5.

The patent is focused on the treatment of Paroxysmal nocturnal hemoglobinuria (hereinafter: PNH), a life-threatening blood disease whereby erythrocytes (red blood cells) are destroyed by the patient's own immune system. As explained in the patent (par. [0001], [0002], [0032]), the red blood cells of these patients lack the protective proteins which are required to prevent an attack by a component of the immune system called "Complement component 5" or briefly "C5". The patent specifically relates to C5 inhibitors, i.e., agents which bind to C5 and thereby prevent the cleavage of C5 into its fragments C5a and C5b, which is the beginning of the (red blood cell killing) immune response. PNH is an acquired hematologic disease that results from clonal expansion of hematopoietic stem cells with somatic mutations in the X-linked gene called PIG-A. Mutations in PIG-A lead to an early block in the synthesis of glycosylphosphatidylinositol (GPI)-anchors, which are required to tether many proteins to the cell surface. Consequently, PNH blood cells have a partial (type II) or complete (type III) deficiency of GPI-anchored proteins.

Intravascular hemolysis is a prominent feature of PNH and a direct result of the absence of the GPI-anchored complement regulatory protein CD59. Under normal circumstances, CD59 blocks the formation of the terminal complement complex (also called the membrane attack complex) on the cell surface, thereby preventing erythrocyte lysis and platelet activation. Excessive or persistent intravascular hemolysis in PNH patients not only results in anemia (normal ranges of hemoglobin are 14-18 g/dL for men and 12-16 g/dL for women, and persons with lower levels are considered to be anemic), but also hemoglobinuria and clinical sequelae related to the release of the erythrocyte content into the circulation: fatigue, thrombosis, abdominal pain, dysphagia, erectile dysfunction, and pulmonary hypertension. Indeed, impaired quality of life in PNH is disproportionate to the degree of anemia. Many PNH patients depend on blood transfusions to maintain adequate erythrocyte hemoglobin levels. There have been no therapies that effectively reduce intravascular hemolysis and improve the associated clinical morbidities in PNH.

Eculizumab is a humanized monoclonal antibody directed against the terminal complement protein C5. In a preliminary, 12-week, open-label clinical study in 11 PNH patients, eculizumab reduced intravascular hemolysis and transfusion requirements. However, this unblinded study involved a small number of patients with no control arm and without protocol-driven transfusion standards.

The patent in suit regards the object of the claimed teaching as, inter alia, the treatment of diseases with an inhibitor of a component of the complement system (patent in suit, paras.

[0031], [0132]). In particular, pharmaceutical compositions according to embodiments of the patent in suit can be used to treat PNH and other haemolytic diseases in mammals (cf. patent in suit, para. [0031]).

In order to solve this problem, the patent in suit protects, in patent claim 2, a composition, having the following features:

1. A pharmaceutical composition

1.1 comprising an antibody that binds C5

1.1.1 comprising a heavy chain consisting of SEQ ID NO:2 and

1.1.2 a light chain consisting of SEQ ID NO:4.

In paragraph [0134] of the Patent in suit, the heavy chain of SEQ ID No. 2 has the following sequence:

SEQ ID NO: 2 - Eculizumab Heavy chain

QVQLVQSGAEVKKPGASVKVSCKASGYIFSNYWIQWVRQAPGQGLEWMGEILPG
SGSTEYTENFKDRVTMTRDTSTSTVYMELSSLRSEDTAVYYCARYFFGSSPNWYF
DVWGQGTLVTVSSASTKGPSVFPLAPCSRSTSESTAALGCLVKDYFPEPVTVSWNS
GALTSGVHTFPAVLQSSGLYSLSSVVTVPSSNFGTQTYTCNVDHKPSNTKVDKTVE
RKCCVECPPCPAPPVAGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSQEDPEVQFN
WYVDGVEVHNAKTKPREEQFNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKGLP
SSIEKTISKAKGQPREPQVYTLPPSQEEMTKNQVSLTCLVKGFYPSDIAVEWESNGQ
PENNYKTTPPVLDSDGSFFLYSRLTVDKSRWQEGNVFSCSVMHEALHNHYTQKSL
SLSLGK

2.
Claim 2 requires interpretation with regard to feature 1.1.2, which is also defined in paragraph [0134] of the Patent in suit:

SEQ ID NO: 4 - Eculizumab Light chain

MDMRVPAQLLGLLLLWLRGARCDIQMTQSPSSLSASVGDRVTITCGASENIYGAL
NWYQQKPGKAPKLLIYGATNLADGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQ
NVLNTPLTFGQGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKV
QWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQG
LSSPVTKSFNRGEC

a)
According to Art. 69 EPC in conjunction with Art. 1 of the Protocol on its interpretation, the patent claim is not only the starting point, but the definitive basis for determining the protective scope of a European patent. The interpretation of a patent claim does not depend solely on its exact wording in the linguistic sense. Rather, the description and the drawings must always be taken into account as explanatory aids for the interpretation of the patent claim and not only be used to clarify any ambiguities in the patent claim. However, this does not mean that the patent claim serves only as a guideline and that its scope may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated. The patent claim is always to be interpreted from the point of view of a person skilled in the art (Court of Appeal, UPC_CoA_1/2024, Order of 13 May 2024, App_8/2024 – VusionGroup SA v Hanshow Technology Co. Ltd et al.; UPC_CoA_335/2023, Order of 26 February 2024, App_576355/2023 - 10X Genomics and Harvard/Nanostring case; Order of 11 March 2024, GRUR-RS 2024, 2829, headnote 2. and para. 73 - 77 - Nachweisverfahren; LD Düsseldorf, UPC_CFI_452/2023, Order of 9 April 2024, p. 13, GRUR-RS 2024, 7207, para. 49). Additionally, the skilled person is taking the purpose of every patent claim into account, to provide the average person skilled in the art with a technical teaching which, when reworked, leads to the intended success of the invention.

b)
Having said this, claim 2 protects a pharmaceutical composition comprising an antibody with a light chain of SEQ ID No. 4 without the first 22 amino acids.

Features 1 and 1.1 of claim 2 refer to a pharmaceutical composition of an antibody that binds C5. The term "pharmaceutical composition" clarifies for the skilled person that the formulation is produced for use in therapeutic applications (see patent in suit, paras. [0082] et seqq.), i.e., ready for treatment of, e.g., PNH with the active antibody eculizumab that binds C5 (see patent in suit, para. [0010]). Binding C5 is the functional core and essential property of the claimed antibody. It is not disputed between the parties that the antibody used in the attacked embodiment can bind C5 and has a heavy chain as defined by SEQ ID No. 2.

Feature 1.1.2 of claim 2 of the patent in suit relates to the light chain of the antibody of the pharmaceutical composition consisting of SEQ ID NO: 4. According to paragraph [0134] of the patent in suit, SEQ ID NO: 4 is described as "Eculizumab Light chain".

At the priority date, the skilled person would have recognized that the sequence ID NO: 4 of the light chain is not correctly reproduced. A skilled person at the priority date would have recognized that the light chain SEQ ID NO: 4 is longer – 236 residues – than the average light chain of a mature antibody which ranges from about 211-217 amino acids, which is not disputed by the parties. Furthermore, he would have realized that the starting sequence at

the N-terminus shows typical features of a signal peptide. In detail:

It was common general knowledge of the skilled person at the priority date that signal peptide sequences vary in length from 13 to 36 amino acids, start with the amino acid methionine (M), include about 10 to 15 hydrophobic amino acid residues, one or more positively charged residues, usually near the N-terminus, preceding the hydrophobic sequence and a short sequence at the carboxyl terminus (near the cleavage site) that is relatively polar, typically having amino acid residues with short side chains (especially ALA) at the position closest to the cleavage site. *Lehninger* (Principles of Biochemistry, 4th ed., p. 1068, Exhibit FBD 38a), a source that can be considered as common general knowledge cited by Prof. [redacted] in his expert opinion (Exhibit FBD 38), confirms this common general knowledge. These facts are essentially also confirmed by the expert opinions of Prof. [redacted] (Exhibit 37, p. 2 et seq.) and Prof. [redacted] (Exhibit FBD 38, p. 3).

Not part of common general knowledge, on the other hand, is the fact that the mature protein starts with DIQM (i.e. Asp-Ile-Gln-Met, see expert opinion Prof. [redacted] Exhibit FBD 38, p. 3). Prof. [redacted] refers in his expert opinion to *Thomas et al.*: INHIBITION OF COMPLEMENT ACTIVITY BY HUMANIZED ANTI-CS ANTIBODY AND SINGLE-CHAIN Fv., Molecular Immunology, Vol. 33, pp. 1389-1401, 1996 (Exhibit FBD 22), to support his view. The article of *Thomas et al* however, is an article in a scientific journal, which does not qualify as common general knowledge. Other supporting documents were not provided by the Applicant.

This common general knowledge of the typical features of a signal peptide gave the skilled person an initial indication that the SEQ ID No. 4 contains a signal peptide at the N-terminus, as can be seen in the sequence:

SEQ ID NO: 4 - Eculizumab Light chain

MDMRVPAQLLGLLLLWLRGARCDIQMTQSPSSLSASVGDRVTITCGASENIYGAL
NWYQQKPGKAPKLLIYGATNLADGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQ
NVLNTPLTFGQGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKV
QWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQG
LSSPVTKSFNRGEC

The sequence starts with the amino acid methionine and contains hydrophobic amino acids: letters A, V, L, I, P F, M, W (expert statement of Prof. [redacted] Exhibit FBD 40 marginal no. 24). Therefore the skilled person would have recognised the presence of a signal peptide. This is confirmed by Prof. [redacted] who acknowledges that the N-terminus has the same sequence as a signal peptide (Exhibit FBD 40, marginal no. 16). Similarly, Professor [redacted] confirmed that the skilled person would have easily recognized the signal peptide in SEQ ID NO: 4 already before 15 March 2006 (Exhibit FBD 37, marginal no. 4, no. 1).

Following this knowledge, the skilled person would have been able to determine the precise length of the signal peptide sequence for the following reasons. Paragraph [0134] of the patent in suit identifies the SEQ ID NO: 4 as the “Eculizumab light chain”, while the abstract of the patent in suit is also limited to eculizumab and discusses its binding of C5. In addition, eculizumab is mentioned in the patent about 120 times; these are clear indications to the skilled person that the focus of the invention is eculizumab. As a result, the skilled person would have tried to resolve his initial suspicion that SEQ ID No.:4 is erroneous by verifyingthe sequence of eculizumab in the CAS Database registry for Eculizumab (RN 219685-50-4, 14 February 1999 (Exhibit FBD 21 and 25).

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SEQ         1 DIQMTQSPSS LSASVGDRVT ITCGASENIY GALNWYQQKP GKAPKLLIYG
           51 ATNLADGVPS RFSGSGSGTD FTLTISSLQP EDFATYYCQN VLNTPLTFGQ
          101 GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV
          151 DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG
          201 LSSPVTKSFN RGEC
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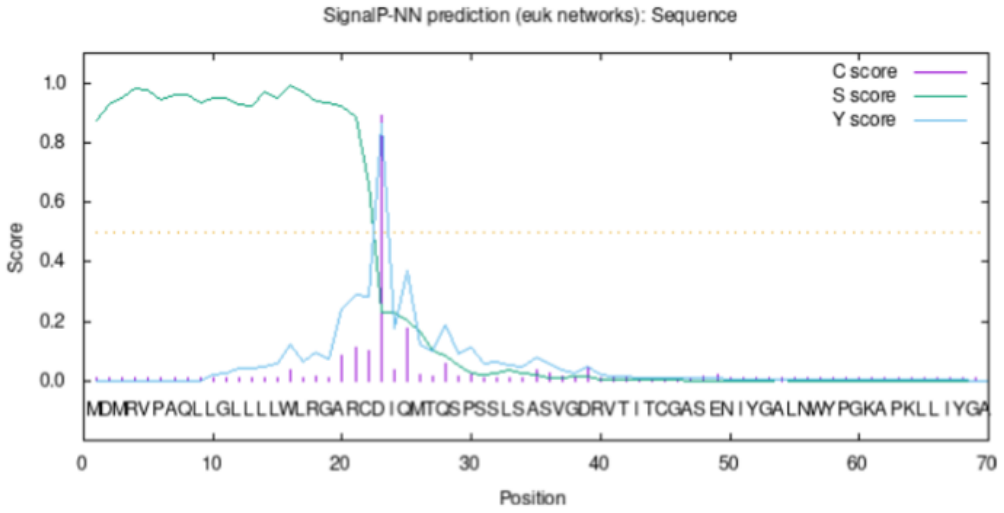
A comparison with the SEQ ID No. 4 in the patent in suit indicates that the first 22 amino acids are missing, which clarifies for the skilled person that the missing sequence is indeed a signal peptide, which is cleaved off during production at the endoplasmatic reticulum (ER). He might as well recognise that the sequence of the light chain SEQ ID NO: 4 in CAS and the patent further differs in one amino acid, but focused on the assessment of the existence or absence of a signal peptide in the claimed sequence, he would assume this as not relevant.

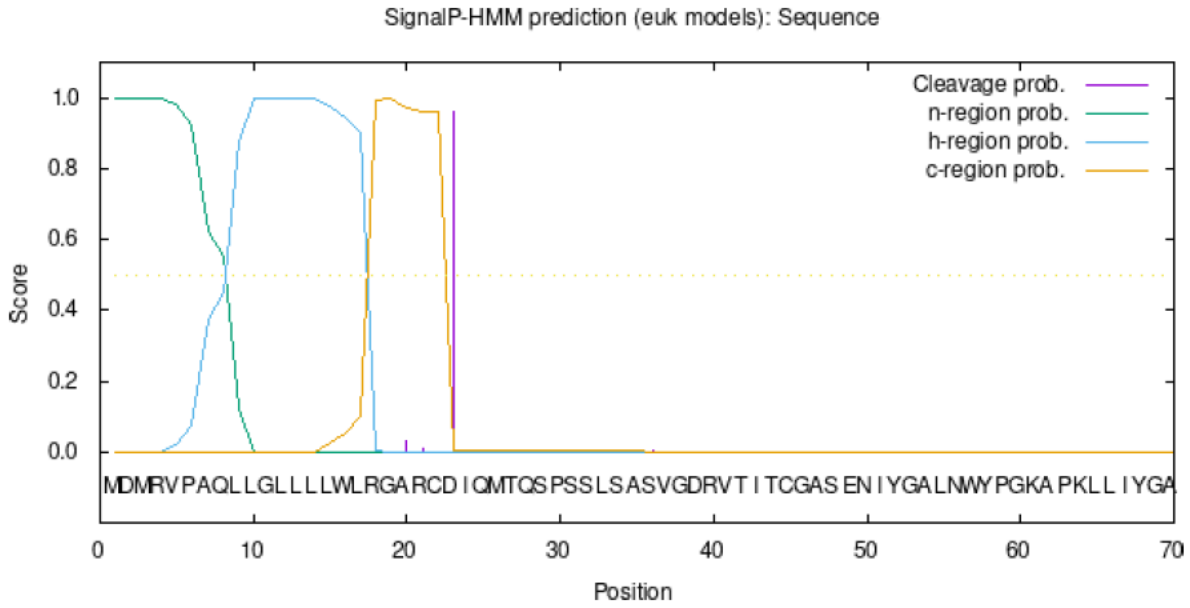
Additionally or alternatively, the skilled person could have done some simple research in other databases which provide more detailed information on specific signal peptides. This is confirmed, for example, by Professor [redacted] who refers to the databases BlastP and SignalP (Exhibit FBD 37, marginal no. 4, nos. 2) and 3)). Professor [redacted] confirms this as well (Exhibit FBD 39, p. 2). The Defendants have not contested that these databases were generally known by the skilled person at the priority date. It can neither be disputed that the CAS register is generally used by chemists since decades.

When SEQ ID No: 4 of paragraph [0134] of the patent in suit is entered into the SignalP 3.0 database, a version available before 2006, the result indicates with 100% probability the existence of a signal peptide and with 95,9 % probability the cleavage site between position 22 and 23 (Exhibit FBD 18, 18a).



data

```
>Sequence              length = 70
# Measure  Position  Value  Cutoff  signal peptide?
  max. C    23       0.888   0.32   YES
  max. Y    23       0.861   0.33   YES
  max. S    16       0.990   0.87   YES
  mean S     1-22    0.932   0.48   YES
       D     1-22    0.896   0.43   YES
# Most likely cleavage site between pos. 22 and 23: ARC-DI
```



data

```
>Sequence
Prediction: Signal peptide
Signal peptide probability: 1.000
Signal anchor probability: 0.000
Max cleavage site probability: 0.959 between pos. 22 and 23
```

With SignalP a skilled person would have been able to determine the precise length of the signal peptide with a high probability as well.

In conclusion, the skilled person who is construing patent claim 2 using his general knowledge, would have seen that the amino acid sequence at the N-terminus of the SEQ ID No: 4 shows typical features of a signal peptide. A comparison with the sequence of eculizumab in the CAS database and/or alternatively a search with SignalP would have led the skilled person to the exact length of the signal peptide, 22 amino acids as highlighted below:

SEQ ID NO: 4 - Eculizumab Light chain

MDMRVPAQLLGLLLLWLRGARCDIQMTQSPSSLSASVGDRVTITCGASENIYGAL
NWYQQKPGKAPKLLIYGATNLADGVPSRFSGSGSGTDFTLTISSLQPEDFATYYCQ
NVLNTPLTFGQGTKVEIKRTVAAPSVFIFPPSDEQLKSGTASVVCLLNNFYPREAKV
QWKVDNALQSGNSQESVTEQDSKDSTYSLSSTLTLSKADYEKHKVYACEVTHQG
LSSPVTKSFNRGEC

c)
This view is supported by technical and functional considerations. On the one hand, the skilled person would have difficulties to produce a corresponding antibody with the signal peptide, which is confirmed by Prof. [redacted] (Exhibit FBD 40, marginal no 17 et seq.). If he, on the other hand, would have been able to produce such an unusual antibody, he would have recognised that it has no binding capacity for C5. This is confirmed by Professor [redacted] who affirms that the skilled person would not have attempted to produce an antibody with the signal peptide because – even if it were theoretically possible under "drastic" and non-routine conditions – it could not have been used as a drug (Exhibit FBD 38, p. 4). This is further confirmed by the statement of Professor [redacted] (Exhibit FBD 40, marginal no 20), who emphasized that the skilled person would have known that an antibody with the hydrophobic signal peptide shown in SEQ ID NO: 4 would "highly likely" not bind C5 at all and rather activate than inhibit the complement system, making it "unsuitable for therapeutic use" (Exhibit FBD 40, marginal nos. 41, 43).

The skilled person, who is taking the purpose of every patent claim into account, which is to provide the average person skilled in the art with a technical teaching which, when reworked, leads to the intended success of the invention, would conclude, that the light chain SEQ ID NO: 4 does not include the first 22 amino acids, the signal peptide. Otherwise, the technical teaching according to the patent would not provide a pharmaceutical composition that binds C5.

d)
This understanding is consistent with the description of the patent in suit. Paragraph [0134] of the patent in suit reproducing the amino acid sequences SEQ ID NO: 2 and SEQ ID NO: 4 of

claim 2 expressly qualifies the sequences as "Eculizumab Heavy and Light chains". The abstract of the patent in suit is also limited to eculizumab and discusses its binding of C5 as successfully demonstrated in a study. In addition, as already emphasized, the specification of the patent in suit refers to eculizumab more than 100 times also making clear that eculizumab is a highly preferred embodiment of the patent in suit (e.g., paras. [0100], [0011], [0017], [0020] and [0084] of the patent in suit). This focus on eculizumab as a specific embodiment is further supported by the examples section that is only and specifically directed to eculizumab. In light of all this, the patent in suit is clearly about eculizumab, a functional antibody effective for therapeutic treatment, in particular PNH (see, e.g., [0003], [0100] et seqq.). There is no indication at all that eculizumab is not meant to be covered by claim 2. This is all the more true as the claimed heavy and light chains SEQ ID NOs:2 and 4 are expressly referred to as "eculizumab" heavy and light chains.

The wording of claim 2 “consists of” does not lead the skilled person to a contrary understanding. An antibody comprising a light chain consisting of SEQ ID NO: 4 without the signal peptide still "consists" of SEQ ID NO: 4 provided that said sequence is construed with a mind willing to understand and to resolve the difficulties arising from a strict, narrow interpretation (not reproducible, not suitable as a pharmaceutical). The term “consisting of” does not preclude an interpretation of the subsequent wording which is broader than the strict, literal meaning, so there is no contradiction.

Also the fact that eculizumab was already known before the priority date does not lead to a different understanding. The parties agree that the exact sequence of eculizumab was not disclosed due to the erroneous entry in the CAS database in 1999, which was corrected in the database first in 2009.

e)
The parts of the grant history of the patent in suit cited by the parties do not shed any new light on this interpretation, even more, is not contrary to the interpretation by the court. The Defendant refers to the decision of the Technical Board of Appeal (TBA, Exhibit FBD 6) and argues, that the TBA considered that an antibody with SEQ ID NO: 2 and SEQ ID NO: 4 of the patent in suit was not the same antibody as eculizumab. While the name “eculizumab” was referred to in the specification of the patent, the eculizumab antibody itself (i.e. its sequence) was not sufficiently disclosed. The TBA denied the attempts of the Applicant to correct the sequence in the description in paragraph [0134] for the following reasons.

A correction under Rule 139 2nd sentence EPC is possible, when it is <u>obvious</u> that the application as filed contains such an obvious error that the skilled person is in no doubt that this information is not correct and cannot be meant to read as such. It must be obvious that an error is present and has to be objectively recognizable by the skilled person using common general knowledge. The correction of the error should be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as

the correction (see Exhibit FBD 6, p. 5).

The TBA agreed that it was common general knowledge that antibodies are secreted proteins produced from precursor light chain and heavy chain polypeptides in cells, which precursors each comprise a signal peptide and a mature polypeptide. The signal peptides are cleaved off in the endoplasmatic reticulum (ER) of the expressing cell and the mature polypeptide then folds to form the mature protein. The Board could not agree with the Applicant that the statement of "a light chain variable region consisting of SEQ ID NO: 4" in the application on page 5 and "SEQ ID NO: 4 – Eculizumab Light Chain" on page 44 constituted such an obvious error that a skilled person was in no doubt that this information is not correct. The Board stated that there are no arguments as to why the skilled person, when confronted with the statement "a light chain variable region consisting of SEQ ID NO: 4" as such in the application, would be prima facie alerted and consequently prompted to consider and analyze the corresponding sequence depicted on page 44 with a view to determining the presence of particular functional parts/compounds in the unannotated amino acid sequence, an ER signal sequence.

Second, the TBA stated, even when inspecting the sequence of SEQ ID NO: 4 depicted on page 44 and noting a starting methionine residue followed by a stretch of mainly hydrophobic amino acids (which stretch is in fact 25 amino acids long and also includes the amino acids at positions 23, 24 and 25) and the slightly above average light chain length for a mature antibody, the skilled person would not immediately recognize that the depicted sequence of SEQ ID NO: 4 constituted an error because it included a signal peptide, but instead could, at best, be caused to doubt that the depicted sequence was the sequence it purported to represent. This state of doubt, according to the TBA, does not equate with the requirement that the person has no doubt that the depicted sequence is an error.

These findings of the TBA do not contradict the interpretation of claim 2 by the court. The interpretation of a patent claim is not dependent on a no doubt requirement. Rather, as mentioned above, the skilled person, taking the purpose of every patent claim into account, to provide the average person skilled in the art with a technical teaching which, when reworked, leads to the intended success of the invention, would recognize that the claimed antibody with the included signal peptide in the light chain SEQ ID NO: 4 is not able to bind to C5. The contrary was alleged by the Applicant during the granting procedure (see Exhibit FDB 6 p. 14 marginal number 35, and below Sect. III. 3. b)) without presenting evidence to the Board. However, in the present proceedings, it is undisputed between the parties that the light chain SEQ ID NO: 4 is not able to bind to C5. The skilled person therefore would try to interpret the claim in such a way that it leads to the intended success of the invention, in this case the ability to bind C5 and function as a drug. This includes recognising typical features of a signal peptide sequence at the N-terminus of SEQ ID NO: 4.

Insofar as the TBA has denied that a skilled person would be able to clearly identify the signal

peptide of SEQ ID NO: 4, the contrary view of the court does not contradict this. The court reached its conclusion on the basis of the evidence of common general knowledge of the skilled person which has been submitted in these proceedings : the simple possibility to identify the precise length of the signal peptide sequence by entering "eculizumab" in the CAS database and/or an identification via the SignalP database (see above) and the knowledge that the sequence with the signal peptide is not able to bind C5. This evidence was not available in the grant proceedings, so that the TBA was unable to comment on this. The TBA decision was therefore based on different facts than the interpretation of the court, so that no inconsistency can be established. Therefore, the court in this case does not need to address the question whether the prosecution history, especially the present granting history, can be taken into account when determining the scope of protection of a European patent.

On the basis of this understanding of claim 2 the attacked embodiment makes literal use of the teaching of patent claim 2.

III.
The validity of the patent in suit is not certain to the extent required for the order of provisional measures. The local division in Hamburg is not satisfied with the "sufficient certainty" required under Art. 62 (4) UPCA in conjunction with R. 211.2 RoP of the validity of the patent at issue. Such "sufficient certainty" is lacking if the court considers it to be more likely than not that the patent at issue is not valid (UPC_CoA_335/2023, Order of 26 February 2024, GRUR-RS 2024, 2829, headnote 3. and paras. 73 - 77 - Nachweisverfahren; UPC_CFI_452/2023 (LD Düsseldorf), Order of 9 April 2024, p. 19, GRUR-RS 2024, 7207, para. 78).

1.
Since the order for provisional measures is issued by way of summary proceedings pursuant to R. 205 et seqq. RoP, in which the opportunities for the parties to present facts and evidence are limited, the standard of proof must not be set too high, in particular if delays associated with a reference to proceedings on the merits would cause irreparable harm to the proprietor of the patent as provided for in Art. 62(2) and (5), 60(5) UPCA (see CJEU, judgment of 28 April 2022, Phoenix Contact, C-44/21, EU:C:2022:309, para. 32 with reference to Art. 9(1)(a) Directive 2004/48/EC). On the other hand, it must not be set too low in order to prevent the Defendant from being harmed by an order for a provisional measure that is revoked at a later date pursuant to Art. 62(5), Art. 60(8) and (9) UPCA, R. 213 RoP, Art. 62(2) UPCA, cf. also Art. 9(7) Directive 2004/48/EC.

R. 211.2 RoP, in conjunction with Art. 62(4) UPCA (see also Art. 9(3) Directive 2004/48/EC), provides that the court may invite the Applicant for provisional measures to submit reasonable evidence to satisfy the court to a sufficient degree of certainty that the Applicant is entitled to institute proceedings under Art. 47 UPCA, that the patent is valid and that his

right is being infringed, or that such infringement is imminent. Such a sufficient degree of certainty requires that the court considers it at least more likely than not that the Applicant is entitled to initiate proceedings and that the patent is infringed. The burden of presentation and proof for facts allegedly establishing the entitlement to initiate proceedings and the infringement or imminent infringement of the patent, as well as any other circumstances allegedly supporting the Applicant's request, lies with the Applicant, whereas, unless the subject-matter of the decision is the ordering of measures without hearing the Defendant pursuant to Art. 60(5) in conjunction with Art. 62(5) UPCA, the burden of presentation and proof for facts concerning the lack of validity of the patent and other circumstances allegedly supporting the Defendant's position lies with the Defendant. The aforementioned allocation of the burden of presentation and proof in summary proceedings is in line with the allocation of the burden of presentation and proof in proceedings on the merits, in which facts giving rise to the entitlement to initiate proceedings and the infringement or imminent infringement of the patent, as well as other circumstances favourable to the infringement action, are to be presented and proven by the right holder (Art. 54, 63, 64 and 68 UPCA, R. 13.1(f) and (l)-(n) RoP), whereas the burden of presentation and proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the opponent (Art. 54 and 65(1) UPCA, Rules 44(e)-(g), 25.1(b)-(d) RoP).

2.
The court has to form its own view on the validity of a patent in dispute. This is an independent review and based on the principles of the EPC. In preliminary measures proceedings, however, the court cannot base its decision solely on its own opinion if an opposition at the EPO against the patent in suit has been filed, which is the case here. If an opposition is pending, the UPC also has to consider the likelihood of a decision invalidating the patent by the EPO. The reason therefore is that the EPO has the competence to invalidate a patent for the EPC countries that cover the UPC territory as whole. If the UPC regards a patent as valid, this decision would be overruled by an invalidity decision in the EPO opposition proceedings. Therefore, a decision on provisional measures cannot be based solely on the court's view of the validity of the patent in suit if it is also sufficiently likely that the opposition division will revoke the patent.

For proceedings on the merits Art. 33.10 UPCA provides how to deal with parallel procedures before the UPC and the EPO from a competence perspective. For provisional measures procedures R. 209.2(a) RoP underlines the relevance of a positive decision by the EPO in an opposition procedure or by national courts on validity. If, in this respect, the court is required to take into account decisions by other expert organisations or courts, this must apply equally when it comes to assessing whether an attack on the legal validity will be successful. This is because the court cannot assume a secure legal status by way of preliminary measures if a revocation of the patent by an organisation appointed to make a decision appears likely. The consequence would be that a decision in favour of the Applicant

would be issued based on a summary examination of the legal situation, although it would have been possible for the court to determine with sufficient certainty that such a decision could not be issued with regard to the challenged legal situation.

3.
When assessing the probability of validity, the UPC therefore not only needs to consider the likelihood of invalidity based on its own assessment, but also needs to take into account the likelihood of an invalidity decision of the patent in suit by the EPO. In general, the own assessment of the court and the decision of the validity of the patent by the EPO should not be different, as both legal bodies apply the same legal standard, the EPC. There might be a difference, when the court interprets a patent claim differently than the EPO, so that the validity arguments are inevitably different.

a)
The argument, that third-party observations were filed during prosecution, proving that the patent has survived the equivalent of inter partes validity proceedings and as such the court should consider it more likely than not that the patent is valid, might be a factor to take into account in general. But in this proceeding the third-party observations filed do not address all issues and do not include the arguments that are central to the Defendants' case. The third-party observations mostly deal with formal aspects of the original patent application.

Besides it is contradictory that the court should blindly assume that the decision of the TBA to grant the patent in the face of third-party observations means that the patent is battle-tested, but to ignore the details of the same TBA decision which shows that the Applicant was only able to obtain protection for an antibody consisting of a light chain with SEQ ID NO: 4 with the first 22 amino acids.

b)
Irrespective of the question whether the court considers the patent in suit to be valid in light of the Defendant's arguments concerning the validity of the patent in suit, it is the opinion of the court that it is reasonably likely the EPO will revoke the patent due to lack of sufficient disclosure, Art. 83 EPC.

Art. 83 EPC provides that the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In the present case the patent in suit has been granted by the TBA on appeal after the Examiner had rejected the application. The TBA had the opinion that claim 2 of the patent in suit protected an antibody with the light chain SEQ ID NO: 4 in a literal understanding. It granted the patent in suit with auxiliary request 5 (claim 2 in the present proceedings). Attempts by the Applicant to obtain protection for an antibody consisting of a light chain with SEQ ID NO: 4 without the 22 amino acids were expressly rejected. That means that the TBA only approved the "unusual" antibody with a light chain including the 22 amino acids.

For this antibody, the TBO accepted the assertion of the Applicant that “the position of the three respective CDR sequences in SEQ ID NO: 4, which are instrumental for the specific binding properties required by the claim, is sufficiently distanced from the N-terminal signal peptide to dissuade the skilled person from having doubts that this longer light chain would also bind to C5 as required by claim 1” (see, exhibit FBD 6 marginal no. 35). On this assumption, the TBO concluded that the claimed antibody is sufficiently disclosed in the patent in suit.

However, this assumption can no longer be upheld in the present litigation as the Applicant itself is of the opinion that an antibody with the complete SEQ ID No. 4, i.e. in the presence of the signal peptide, is not functional (see Part I of the reply to the objection to the application for provisional measures of 23 May 2024, marginal no 51):

> “In addition to his general doubts regarding the production of the antibody with the light chain sequence SEQ ID NO:4 with the signal peptide, the skilled person would also not have considered producing such an antibody due to its pharmaceutical unsuitability. Due to the hydrophobic properties of the signal sequence, it would have an extreme tendency to aggregate under physiological buffer conditions.”

The Applicant and its expert Prof. [redacted] (Exhibit FBD 38) concur that an antibody with the signal peptide could not have been used as drug (= pharmaceutical composition). It would exhibit an extreme tendency to aggregate under physiological buffer conditions due to their pronounced hydrophobic properties, which would prevent them from being formulated as pharmaceutical composition and used as a drug. The Defendant submitted this argument into the opposition proceedings (see Exhibit SS 36).

Based on this, the technical teaching according to the patent might not be sufficiently disclosed and likely be revoked by the opposition division. Accordingly, on the TBA’s claim construction and the applicant's own submissions and evidence in these proceedings, there is a substantial probability that granted claim 2 will be regarded as non-patentable by the EPO.

c)
Such an assumption cannot be made with regard to the sufficiency of disclosure if it is assumed that the skilled person interprets the claim that SEQ ID NO: 4 does not include the signal peptide. Such an antibody functions as drug, as can be seen by the attacked embodiment.

However, it is not reasonably certain that the EPO will share the court's view on the interpretation of the claim. It is true that the Applicant has submitted facts, which, in the opinion of the court, reflect a more comprehensive level of knowledge of the skilled person on the question of the fundamental identification and specific determination of the signal peptides sequence. But it is questionable whether the Opposition Division will consider

these facts in the same way as the court.

This is particularly important with respect to the fact that the TBA had in the past rejected all attempts by the Applicant to correct SEQ ID NO: 4 by deleting the signal peptide sequence from SEQ ID NO: 4 (amino acids 1 to 22) (see overview in Exhibit SS 8).

As mentioned above, the Applicant made during the examination proceedings a request under Rule 139 EPC to correct the sequence of the antibody light chain in the patent (SEQ ID NO: 4) to remove 22 amino acids at the N-terminus of the sequence of SEQ ID NO: 4. The Applicant claimed that the requested change was the correction of an obvious mistake in the specification. The Rule 139 EPC request for correction of the 'obvious mistake' was rejected by the Examining Division. The EPO was of the opinion that there is no basis or indication in the specification that the first 22 amino acids should not be included in SEQ ID NO:4, that the skilled person could not discount that the leader sequence was intended to be claimed by the Applicant, and that the skilled person would not have known where the leader sequence ended (particularly given this was said to be a novel engineered antibody). The Examining Division held oral proceedings, but ultimately refused the claims sought.

The Applicant appealed the decision of the EPO Examining Division. A joint oral hearing took place for the patent in suit and for another application in the EP 490 family, EP 3 124 029 (hereinafter: EP 029). The day prior to the joint oral hearing, an oral hearing had taken place for the granted EP 834. The claims sought in these two applications and one patent were similar. EP 834 was the immediate parent patent of the patent in suit. EP 834 had initially been granted by the Examining Division, but was later revoked by the Opposition Division. EP 029 was a 'sister' divisional to EP 888, and was refused by the Examining Division. Across EP 834, EP 029 and EP 888 the decisions of the TBA discussed a range of different claim sets sought by the Applicant.

Every single one of these claim sets discussed, which would have covered "eculizumab", were rejected by the TBA. The TBA considered that an antibody with SEQ ID NO: 2 and SEQ ID NO: 4 of the patent in suit was not the same antibody as eculizumab (Exhibit SS 5, para 12), and that, while the name "eculizumab" was referred to in the specification of the patent family, the eculizumab antibody itself (i.e. its sequence) was not sufficiently disclosed in the EP 888 family. Hence the Applicant's attempts to amend/correct this sequence (Exhibit SS 5, para 19) were rejected, as the applicant itself had taken the position that "eculizumab" was not the antibody defined in a claim to an antibody with SEQ ID NO:4 (Exhibit SS 6, paragraph 48). The Applicant was not permitted to 'correct' SEQ ID NO:4 to cover an amino acid sequence without the N-terminus sequence (Exhibit SS 7, paragraph 12).

In conclusion, all attempts of the Applicant to correct SEQ ID NO: 4 or to convince the EPO that SEQ ID NO: 4 has to be interpreted without the signal peptide sequence were dismissed. The TBA has also considered several claim requests in family members of the patent in suit,

which related to eculizumab as such, but decided that such claims are insufficiently disclosed. Taking all these elements into account, the court is not at all convinced that the opposition division of the EPO will share the opinion of the court on the question of claim construction and may decide that the patent is invalid.

3.
The application for preliminary measures must therefore be dismissed: an infringement of the patent can be established by the court; however, it cannot be established with the necessary certainty that the patent is valid.

ORDER

1. The Application for provisional measures entered into the CMS 19 March 2024 is dismissed.

2. The Applicant is ordered to pay the costs of the proceedings.

3. The value of the dispute is set to € 100.000.000.

INSTRUCTION TO THE PARTIES
According to Rules 210.3 and 118.7 Rules of Procedure the Court has at first rendered its decision without grounds immediately after the closure of the oral hearing. It hereby provides the grounds for the order in writing subsequently.

INFORMATION ON THE APPEAL
Both parties may appeal against this order within 15 days of its notification, Art. 73 (2) lit. a), Art. 62 UPCA, R. 220.1(c), 224.2(b) RoP.

INFORMATION ON THE ENFORCEMENT
A certified copy of the enforceable decision or order is issued by the Deputy Registrar at the request of the enforcing party, R. 69 RoP.

ORDER DETAILS

UPC number	UPC_CFI_123/2024
Order number	ORD_38059/2024
Related proceeding no.:	13849/2024
Application Type:	Application for provisional measures

ISSUED IN HAMBURG, JUNE 26th 2024

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