Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

# Düsseldorf Local Division
## UPC_CFI_166/2024

# Order
**of the Court of First Instance of the Unified Patent Court**
**delivered on 6 September 2024**
**concerning EP 3 805 248 B1**

Headnotes:

1. Art. 25 UPCA constitutes uniform substantive law and Art. 62 (1) UPCA uniform procedural law, which takes precedence over national patent laws and whose content is to be interpreted independently by the Court.

2. A situation of imminent infringement may be characterised by certain circumstances which suggest that the infringement has not yet occurred, but that the potential infringer has already set the stage for it to occur. The infringement is only a matter of starting the action. The preparations for it have been fully completed. These circumstances must be assessed on a case by case basis.

3. Companies that are members of a group and play a key role in a distribution network for the infringing product – such as a sole manufacturer or a European sales and marketing hub – may also be considered as infringers if they are located outside the Contracting Member States but supply their products to other members of the group located in the Contracting Member States, while these companies distribute these products on the European market, including at least one Contracting Member State where the patent in suit is valid.

4. Rule R. 295 RoP (stay of proceedings) refers to actions and is therefore not applicable to applications for provisional measures.

5. The interpretation of the patent is not only mandatory for the Court, but also for the parties, who must submit their views on their proposed interpretation in their briefs.

6. It is the task of the parties to present technical arguments to the Court in a concentrated and comprehensible form. In particular, the technical argumentation must be focused and precise for the Court in order to be able to comply with the ambitious time limits set by the law. This is even more true in PI proceedings.

Keywords:

Lis pendens, claim interpretation, imminent infringement, provisional measures

APPLICANTS:

**1. Novartis AG,** Lichtstraße 35, 4056 Basel, Switzerland,

| | |
|---|---|
| Represented by: | Attorney-at-law Dr. Frank-Erich Hufnagel, Attorney-at-law Kilian Seidel, Freshfields Bruckhaus Deringer Rechtsanwälte Steuerberater PartG mbB, Maximiliansplatz 13, 80333 Munich, Germany, |
| Electronic address for service: | kilian.seidel@freshfields.com |
| Participating patent attorneys: | Cameron Marshall and Joanna Rowley, Carpmaels & Ransford LLP, One Southampton Row, London, WC1B 5 HA, United Kingdom |

**2. Genentech, Inc.,** 1 DNA Way, South San Francisco, CA 94080-4990, United States of America,

| | |
|---|---|
| Represented by: | Attorney-at-law Dr. Frank-Erich Hufnagel, Attorney-at-law Kilian Seidel, Freshfields Bruckhaus Deringer Rechtsanwälte Steuerberater PartG mbB, Maximiliansplatz 13, 80333 Munich, Germany, |
| Electronic address for service: | kilian.seidel@freshfields.com |
| Participating patent attorneys: | Cameron Marshall and Joanna Rowley, Carpmaels & Ransford LLP, One Southampton Row, London, WC1B 5 HA, United Kingdom |

DEFENDANTS:

**Celltrion Inc.,** 23 Academy-ro, Incheon 406-840, Republic of Korea,

| | |
|---|---|
| Represented by: | Attorney-at-law Emilia Zalewska, Attorney-at-law Laurens Buijtelaar, Bird & Bird (Netherlands) LLP, Office building SOM1, Gustav Mahlerlaan 42, 1082 MC Amsterdam, Netherlands, |
| Electronic address for service: | intellectualproperty@celltrion.com |

PATENT IN SUIT:

EUROPEAN PATENT NO. EP 3 805 248 B1

PANEL/DIVISION:

Panel of Local Division Düsseldorf

DECIDING JUDGES:

The order was issued by the presiding judge Ronny Thomas, by the legally qualified judge Dr Bérénice Thom acting as judge-rapporteur, the legally qualified judge Alima Zana and the technically qualified judge John Petersen.

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT: R. 209.1 RoP – Application for provisional measures

DATE OF ORAL HEARING: 31 July 2024

*Summary of the Facts:*

The Applicants are the proprietors of European Patent 3 805 248 B1 (Exhibit FBD 15, hereinafter: patent in suit) and allege (imminent) infringement against the Defendants.

The patent application of the patent in suit was filed on 8 September 2005, claiming priority from the applications US 60/609092 of 9 September 2004 (hereinafter Prio 1) and US 11/220362 of 6 September 2005 (hereinafter Prio 2). It is a divisional application of the European patent application EP 10009914.2 (published as EP 2 292 636; hereinafter EP 636) which is a divisional application of the European patent application EP 05806393.4 (published as EP 1 786 830; hereinafter EP 830). The application of the patent in suit was published on 14 April 2021 and the mention of the grant of the patent was published on 18 January 2023. Currently the patent in suit is in force in all Contracting Member States of the UPC except for Malta.

Claim 1 of the patent in suit reads as follows:

> *„A pharmaceutical formulation of anti-IGE antibody rhuMAb E 25, characterized in that the formulation is: about 150 g/L of the anti-IgE antibody in 0.02 M histidine, 0.2 M arginine-HCl, 0.04% polysorbate 20, pH 6.“*

The Defendant is the parent company of the Celltrion Group and specialised in the development of biopharmaceuticals, including antibody biosimilars. It researches, develops and manufacures its products and distributes them through a network of local subsidiaries in Europe.

Defendants 1) to 7) in the parallel proceedings before this Court (in the following referred to as Defandant 1) to 7) of UPC_CFI_165/2024) are subsidiaries of the Defendant. The Defendant holds a 100% nominal share in Defendant 1) of UPC_CFI_165/2024, which is also the holder of marketing authorization, and of Defendant 7) of UPC_CFI_165/2024. Defendant 1) of UPC_CFI_165/2024 in turn holds 100% nominal share ratio in Defendant 2) to 6) (UPC_CFI_165/2024).

The Defendant has developed a biosimilar product containing the antibody omalizumab (hereinafter: challenged embodiment) which Phase III clinical trial study was based on a comparison with the Applicant´s product XOLAIR®, which contains the patented formulation. The market name is OMLYCLO. The market authorization for the challenged embodiment was granted by the European Medicines Agency on 16 May 2024.

The Defendant´s group has the following manufacturing and distribution organisation: The Defendant carries out the research, development and production of its products. It distributes them

through a network of local subsidiaries in Europe. The Defendant distributes the products to Defendant 1) of UPC_CFI 165/2024, which serves as a sales and marketing hub in Europe. The Defendant 1) of UPC_CFI 165/2024 supplies its products to the other subsidiaries in Europe, such as the other Defendants of UPC_CFI 165/2024.

In August 2022, the Defendant publicly announced its intention to launch the challenged embodiment in the territory of Europe in 2024.

At the end of July 2023, the Defendant commenced proceedings in the UK seeking a declaration that the UK part of the patent in suit is invalid and a declaration of non-infringement (Exhibit FBD 10). In September 2023, the Applicants filed a counterclaim seeking, inter alia, an injunction restraining theDefendant from infringing the UK part of the patent in suit. Trial is expected to start in October 2024.

On 9 October 2023, Defendant and Celltrion Healthcare B.V. started accelerated proceedings on the merits before the District Court of The Hague, seeking revocation of the Dutch part of the patent in suit and a declaration of non-infringement (hereinafter: Dutch case or Dutch proceedings; exhibit FBD 12, 12a).

On 16 October 2023 Defendant filed an EPO opposition proceedings against the patent in suit.

In November 2023, an official of the Defendant stated in a Korean healthcare news portal that Celltrion’s goal is to be the first company to supply a XOLAIR® biosimilar to major countries.

On 23 November 2023, the Applicants sent a letter to the Defendant requesting that their rights be respected, and the Defendant's Council replied in respect of the patent in suit that the Defendant considered it invalid and not infringed.

On 25 March 2024, the Defendant issued a press release in which it emphasised its intention to launch the products on the European market as soon as possible after obtaining the European market authorisation.

At the end of March 2024, the Defendant participated in the Belgian Dermatology Days in Brugge with a booth displaying information about the challenged embodiment.

In the beginning of April 2024, the Applicants filed a counterclaim seeking a declaration that the Defendant´s formulation infringes at least claim 1 in the Dutch proceedings (Exhibit BB 27A).

On 10 April 2024, a […] of Defendant 2) of UPC_CFI_165/2024 sent an email to a potential customer informing him/her about the positive signal for a grant of a market authorization in the future and offering to stay in touch with relevant news (Exhibit FBD 36, 36a).

The European Medicines Agency market authorization for the challenged embodiment was granted on 16 May 2024 to Defendant 1) of UPC_CFI_165/2024.

On 24 May 2024, the Defendant issued another press release announcing the approval of the European marketing authorization and its plan to rapidly expand its market share.

*INDICATION OF THE PARTIES REQUESTS:*

The Applicant requests, that

I. Defendant is ordered to cease and desist, within the territory of all countries that are Contracting Member States of the Agreement on a Unified Patent Court (UPCA) at the time of the hearing on 31 July 2024, namely Germany, Portugal, France, Italy, Belgium, Sweden, Finland, Denmark, Latvia, Estonia, Slovenia, Lithuania, Bulgaria, Austria, Luxembourg, but excluding the territory of the Netherlands and the Republic of Malta,

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

a pharmaceutical formulation of anti-IgE antibody rhuMAb E25, characterized in that the formulation is: about 150 g/L of the anti-IgE antibody in 0.02M histidine, 0.2 M arginine-HCl, 0.04% polysorbate 20, pH 6.

(EP 3 805 248 B1, claim 1),

in particular in the form of the prefilled syringes as specified in the European marketing authorisation granted under reference number EU/1/24/1817.

II. Defendant shall pay to the Court a fine of up to EUR 250 000 for each individual (repeated) infringement of the orders under I. above.

III. Defendants is ordered to pay the interim costs of the proceedings.

IV. These orders shall be effective and enforceable immediately.

The Defendant/Defandants request(s),

1. to reject the applications for provisional measures dated 08.04.2024 in the form of the reply dated June 6 as inadmissible and/or in any case unfounded;

- in the alternative -

1.1. to stay the proceedings pursuant to ROP 295(l) pending a final decision in the Dutch proceedings;

- in the second alternative –

1.2. to stay the proceedings pursuant to ROP 295(a) pending a final decision in the EPO opposition and/or pending a final decision in the Dutch proceedings;

- in the third alternative -

1.3. to allow the defendant(s) to continue the alleged acts of infringement against the provision of a security deposit, the amount of which is at the discretion of the Court, but should not exceed €3,000,000;

- in the fourth alternative -

1.4. to make the imposition of interim measures dependent on the provision of a security deposit by the applicants, the amount of which is to be determined by the Court, but should not be less than €15,000,000;

- in the fifth alternative –

1.5 to order that an order on any provisional measure (notably an injunction) ceases to be enforceable in all relevant countries if the Patent is finally and/or at 1st instance revoked and/or amended in the EPO opposition proceedings

(ROP 213.2, ROP 354.2)

2. - also filed separately as a ROP 262.2 request-

order that the sections highlighted in grey in this submission and the exhibits are marked as confidential and the information contained therein shall be kept confidential from the public;

3. pursuant to ROP 9 No. 1 and Rule 158 (analogous) order the applicants to provide security within a period to be determined by the court for all expected legal costs of the defendants, including possible court costs, in an amount to be determined by the court;

3.1 in the event that the applicants do not comply with the order to provide security within the time limit set, we request, a default judgment against the applicants pursuant to ROP 355;

4. in accordance with ROP 9 No. 1 to set a time limit of 3 weeks for the applicants to file the action on the merits;

4.1 In the event that thw applicants do not comply withthe order to bring an action within the time limit set, we request a default judgment against the applicants pursuant to ROP 355;

5. order the applicants to pay interim costs of the proceedings analogous ROP 211(1)(d) in the amount of €138.562,80,- ;

6. in anticipation of further arguments in writing: dismiss *the* request for an interim award of Costs by the Applicants as late filed *and inadmissible*";

7. this order is immediately enforceable.

*Points At Issue:*

The parties dispute about different aspects.

Competence

The Defendant is of the opinion that the Local Division in Düsseldorf does not have competence to hear the case of the Defendant. The actions of the Defendant have no direct relevance to the territory of the UPCA.

There is no competence of the Local Division per Art. 7 (2), 71b (2) Brussel Ibis and per Art. 33 (1) a) UPCA for the Defendant. The fact that the Defendant is the ultimate parent company of the Celltrion group with various subsidiaries does not create competence for a local court/the UPC for a claim simply because there is a German affiliate in the corperate group.

The Applicants are of the opinion that the Local Division in Düsseldorf is competent to hear the proceedings against the Defendant pursuant to Art. 31, 32 (1) (c), 33 (1) (a), (b) UPCA and Art. 7 (2), 71b (2) Brussels Ibis.

The Defendant's 2) of UPC_CFI 165/2024 website states that the Defendant, together with its Celltrion Healthcare business division, offers research, development, production and distribution from a single source.

Art. 33 (1) b) UPCA does not contain a legal requirement that the cases must be so closely connected that there is a risk of inconcilable judgements. Art. 33 (1) (b) UPCA is to be interpreted and applied without reference to Art. 8 (1) Brussels Ibis and without recourse to the requirements set out in the Roche decision of the ECJ. Even if the Court were to apply the case law of the ECJ in the Roche decision, it would still have jurisdiction.

Lis pendens objection

The Defendant argues that there is a case of lis pendens, in particular with regard to the Defendant and Defendant 7 of UPC_CFI_165/2024 (Dutch company). Both the alleged validity and the alleged infringement of the patent in suit are subject to the earlier Dutch proceedings initiated during the UPC transition period. Art. 29-32 of the Brussels Ia Regulation Recast (hereinafter referred to as Brussels Ibis) are applicable. The alleged infringement and the question of validity are already pending in the Netherlands, formally with respect to Defendant and Defendant 7 of UCP_CFI_165/2024 and also with respect to all other Defendants of UCP_CFI_165/2024. It is irrelevant that the Applicants carved out the Netherlands. The PI proceedings at hand will have to be followed by main proceedings. At least the possible UPC main action and the corresponding counterclaim for revocation are subject to Art. 31 Brussels Ibis. In the alternative, Art. 29 Brussels Ibis is directly applicable or at least Art. 30 Brussels Ibis applies.

The Applicants argue that the requirements of Art. 29, 30 and 31 Brussels Ibis are not met. According to Art. 24 (4) Brussels Ibis, the competence for the (final) assessement of the validity of the Dutch part of the patent in suit is limited to the Dutch court. Furthermore, the Dutch court does not have jurisdiction to rule (finally) on the validity of other parts of the patent in suit. Art. 31 Brussels Ibis is not applicable because only the Dutch court has exclusive jurisdiction over the Dutch part. In the light of Art. 29 Brussels Ibis, the present case and the Dutch case do not share a common cause of action. The Dutch case concerns the main proceedings, whereas the present case concerns provisional measures. For the same reason, Art. 30 Brussel Ibis is not applicable. In the present situation, there is no risk of irreconcible judgments. Moreover, the Dutch part of the patent in suit is excluded from this application, so that there is no risk of irreconcilable judgements.

Infringement

Applicants consider that the challenged embodiment infringes the patent in suit.

Defendant argues that XOLAIR® falls outside the scope of claim 1 as the formulation contains a significant amount of histidine hydrochloride monohydrate in addition to histidine. The challenged embodiment is only based on XOLAIR® but is not identical to it. Moreover, the patent in suit should be interpreted as limited to the process. The challenged embodiment is not made by using the

process shown in the description of the patent in suit.

Furthermore, the Applicants allege that the Defendant has on various occasions already engaged in conduct which could in any event be considered as an imminent infringement.

Applicants assert that at the end of March 2024 the challenged embodiment was advertised at the Belgian Dermatology Days in Bruges, Belgium. Furthermore, a […] of the Defendant 3) of UPC_CFI_166/2024 told an employee of […] that the Defendant´s Group will market the challenged embodiment in Belgium starting as of October 2024. Moreover, the […] held a staff meeting on 22 May 2024 and told that he had been approached by the Defendant´s group and had been informed about the challenged embodiment. The Defendants´s group announced that it would provide a number of samples of that biosimilar. The Applicants allege that the […]'s team of dermatologists also explained that they would not refrain from using these samples to form an opinion of the product and to use it on regular basis.

Applicants allege that Defendant´s group started active pre(marketing) of the alleged embodiment in the Netherlands as well.

Defendant´s Group informed a […] of the upcoming launch of an omalizumab biosimilar in the Netherlands, expected for October 2024. Also, a […] in [….] was informed by an associate of Defendant´s group that its omalizumab biosimilar was expected to be commercially available in the Netherlands by the end of summer 2024.

Applicants assert that employees of the French Novartis subsidiary were contacted by the French Economic Committee for Health Products (CEPS) in the context of a pricing request for a XOLAIR® biosimilar.

Finally, the Applicants allege, that at the EAACI congress in Valencia, Spain, from 31 May to 3 June 2024, one of the Defendant´s marketing personnel informed a visitor to the Defendant´s booth that the challenged embodiment was expected to be available in October/November 2024.

Defendant disputes any price discussions in France. Defendant 4) of UPC_CFI 165/2024 did not initiate any price negotiations in France, but only inquired about the patents relevant to the product Xolair®. The Defendant further asserts that there are no price negotiations in any UPC Contracting Member State. Defendant also alleges that it offered the challenged embodiment at the EAACI congress, but mentioned patent issues in many EU countries in the context of a launch following resolution of these issues.

Validity, Urgency, balance of interest

The validity of the patent in suit is also disputed. The Defendant argues that the patent is likely to be invalid on the grounds of added matter, lack of priority, lack of sufficient disclosure, lack of novelty and lack of inventive step. Issues of urgency and balance of interests are also disputed between the parties.

Defendants also argue that Applicants´ interim award of costs comes too late and is precluded as they failed to file a request with the application.

In order to avoid repetition, reference is also made to the parties' exchanged briefs and exhibits.

*GROUNDS OF THE ORDER:*

The application for provisional measures is admissible, but unfounded. Although the objections based on competence and Lis pendens are not successful and there is no reason to stay the proceedings according to R. 295 RoP, the application must be rejected because the Court cannot find that the Defendant's conduct already constitutes an imminent infringement.

## I. Competence

The Local Division has competence to hear the case against the Defendant pursuant to Art. 31, 32 (1) (c), 33 (1) (a) UPCA and Art. 7 Nr. 2, 71 (b) Nr. 1, 2 Brussels Ibis.

It is undisputed that the Defendant is the ultimate parent company of its group entity including Defendant 2) of UPC_CFI_165/2024, which is allocated in Germany. The Defendant´s group has established the following manufacturing and distribution organisation for the European market: Defendant carries out research, development and production of its products. The Defendant distributes the products to Defendant 1) of UPC_CFI 165/2024, which serves as a hub for sales and marketing in Europe and is 100 % held by the Defendant. Defendant 1) of UPC_CFI 165/2024 supplies its products to the other subsidiaries, amongst others to Defendant 2). The Applicants allege that the Defendant will do the same when it offers the challenged embodiment on the European market.

Defendant's behaviour as a „spider in the web" supplying Defendant 2) through Defendant 1) as the sole manufacturer is sufficient to constitute an action which is part of the alleged threatened infringement which may occur in Germany as the hosting Contracting Member State of the Düsseldorf Local Division (see Art. 33 (1) (a) UPCA). The imminent infringement depends on whether the Defendant manufactures and supplies the challenged embodiment to Europe. This makes Defendant directly responsible for the distribution of the Defendant 2), as also shown on the German Website of the Defendant 2) (Exhibit FBD 45), where it reads as follows:

> "[…]*Celltrion Inc., together with its Celltrion Healthcare business division, offers research, development, production and distribution from a single source. As a result, Celltrion can now offer its cost-effective solutions for future-oriented therapies in 120 countries with more than 30 different local partners or own sales locations - including the German sales subsidiary Celltrion Healthcare Deutschland GmbH based in Bad Homburg*."

The question whether there is imminent infringement and therefore personal liability on the part of the Defendant is a question of fact and does not need to be decided for the purposes of determining the Court's jurisdiction.

## II. Lis pendens/Related actions

The Court decides to maintain its jurisdiction to rule on the application for provisional measures and not to stay the proceedings in favour of the Dutch proceedings.

Pursuant to Art. 71(a) Brussels Ibis, Art. 31 UPCA Art. 29 – 33 Brussels Ibis are directly applicable

(see UPC_CFI_230/230 (LD Paris), Decision of 4 July 2024, cif. 10.1).

1. Art. 29 Brussels Ibis

Art. 29 Brussels Ibis is not applicable in the present case. The Article requires that the parallel proceedings involve the same parties and the same cause of action.

In the earlier pending Dutch proceedings, the Defendant and Celltrion Healthcare B.V. seek for a declaration of non-infringement of the Dutch part of the patent in suit. In the application for provisional measures, the territory of the Netherlands as a Contracting Member State of the UPCA was carved out. The national Dutch part, which is the subject of the national non-infringement claim, is therefore not the subject of the present application. To that extent, the two cases do not have the same cause of action. As far as the Defendant is concerned, there is no risk of a duplicate decision, since the order in the present case would not affect the Dutch part of the patent in suit.

2. Art. 31 Brussels Ibis

Pursuant to Art. 31 (1) Brussels Ibis, any court other than the court first seised shall decline jurisdiction in favour of that court where actions come within exclusive jurisdiction of several courts.

This regulation accompanies Art. 29 Brussels Ibis and also requires the same cause of action (see Zöller/Geimer, 33rd edition, Art. 31 para 1). As already pointed out, this is not the case here, as the Dutch Court has exclusive jurisdiction only over the Dutch part of the patent in suit. As the Dutch part of the patent has been carved out, there are not several courts with exclusive jurisdiction in the present case.

3. Art. 30 Brussels Ibis

Art. 30 (1) Brussels Ibis does not require the same cause of action, but related actions. Even if it can be argued that the decisive issues in the two proceedings are in some way connected and that the proceedings for provisional measures need to be followed by the proceedings on the merits and are therefore only preliminary decisions on issues in the main proceedings, it is still within the discretion of the Court to decide whether to stay the proceedings. The Court considers that a stay of the proceedings is incompatible with the urgent nature of the provisional measures. The application is based on urgency and seeks an injunction against an imminent infringement in order to avoid irreparable harm. Urgency is a compelling argument against any delay caused by a stay of PI proceedings. The latter would be contrary to the purpose of PI proceedings. Art. 35 Brussels Ibis is not directly applicable, but its meaning must be considered in the context of the discretionary decision.

## III. No stay of proceedings pursuant R. 295 RoP

Rule R. 295 RoP refers unambigously to actions and is therefore not applicable to applications for provisional measures. Hence, there is no room to stay the proceedings either pending a final decision in the Dutch proceedings or pending a final decision in the EPO opposition and/or pending a final decision in the Dutch proceedings.

## IV. Interpretation of claim 1

The interpretation of the claim is the common basis on which both the validity issue and the infringement issues are to be decided (see UPC_CoA_335/2023, NanoString/10x Genomics, see p. 27; UPC_CFI_7/2023 (LD Düsseldorf), Decision of 3 July 2024). The interpretation of the patent is therefore not only mandatory for the Court, but also for the parties, who must submit their views on their proposed interpretation. The parties were right to do so.

Due to lack of infringement, the Court does not have to decide on the likelihood of validity, so the claim interpretation focuses on those parts of the claim that are relevant for the infringement issue.

1.
The patent in suit relates to a process for concentration of antibodies and therapeutic products thereof.

As regards to the background to the invention the patent in suit initially refers to known methods for isolation, purifying, and concentrating biological materials which include e.g. chromatogrophy, ultrafiltration and lyophilization. In this context, the patent in suit cites the article by R. Hatti-Kaul, et al., "Downstream Processing in Biotechnology" in Basic Biotechnology, Chap. 9, pages 187-211, 2nd ed., Cambridge University Press (2001). The patent in suit further states that processes for making concentrated monoclonal antibody preparations for administration to humans are also known and refers as an example to U.S. Patent no. 6,252,055, which uses ultrafiltration and which re-circulates the resulting filtrate (para. [0001] of the patent in suit; following paragraphs without citation are those of the patent in suit). The patent in suit then addresses some challenges associated with available antibody concentration methods. These are namely low fluxes, long process times, large membrane areas, mechanical recovery yield and losses, and others (see para. [0002]). According to the patent in suit these and other challenges can contribute to a high total cost of manufacture and ultimately higher costs to therapeutic drug consumers (para [0002]).

The formulated problem of the patent in suit is a need for improved processes for preparing highly concentrated protein formulations, such as liquid antibody preparations and therapeutic products thereof (para [0003]).

As a solution the patent in suit provides the pharmaceutical formulation of claim 1. The claim can be structured by following features:

1. A pharmaceutical formulation of anti-lgE antibody rhuMAb E25, characterized in that the formulation is:

2. about 150g/L of the anti-IgE antibody,

3. in 0.02 M histidine,

4. 0.2 M arginine-HCl,

5. 0.04% polysorbate 20,

6. pH 6.

2.
In view of the dispute there is a need for further explanation of feature 3 and the nature of a product claim.

a) Skilled person

The skilled person is a person with an academic education at master level in pharmacy, biochemistry or chemical engineering, with the latter two including a specialisation in pharmaceutics. Furthermore, such person has at least 3 to 5 years of experience in the industry or a research institution in formulating and developing of proteins formulations including antibody formulations (see Exhibit BB 49, cif. 11).

b) "0.02 M histidine"

The skilled person will understand that the amount of 0.02 M histidine in feature 3 includes the presence of its protonated form with a counterion.

The wording of the claim is limited to the specific components as there is no indication that "is" has a different meaning than "consists of". Nor is there any indication in the description that other components are contained. However, the skilled person will not stop its interpretation at the philological meaning but will always have in mind the technical function of the feature as such and the features in the context of each other. Therefore, it will not read every feature exclusively, but will understand that the feature 0.02 M histidine has to be seen in the context with the claimed pH of 6 (feature 6). Histidine has the function of a buffer to protect a solution from change. It has an optimal buffering capacity at around the claimed ph 6. The skilled person commonly knows what chemical structure the components need to have in order to reach a certain pH. This means that for the claimed ph 6, histidine has to be present in a more or less 1:1 mixture of its neutral form and its protonated (1+) form with a counterion.

The mere reference in the Defendant´s rejoinder to the expert opinion of Prof. Frijlink II (Exhibit BB 44), according to which the skilled person understands the term histidine as meaning histidine base (cf. page 108 of the Rejoinder), is not sufficient to assert a different interpretation. If a party necessarily considers that a technical argument must be substantiated by a party´s expert opinion, it is for the parties to present the technical argument to the Court in a concentrated and comprehensible form. This is not the case where mere reference is made to a party´s expert report, nor is it the case where a party´s expert report is copied verbatim into the brief. In particular, the technical arguments must be focused and precise for the Court in order to comply with the ambitious time limits set by the law. This applies to the main proceedings and, of course, even more so to PI proceedings.

Moreover, the party´s expert only says that he would not draw this conclusion because there are two possible ways to reach pH 6, one of which is to use a mixture of histidine base and salt. Since there are a large number of possible counterions, the patent does not teach in particular which counterion can or should be selected (see Exhibit BB 44, cif. 34-40). The expert therefore agrees that said mixture is a way of reaching pH 6. As the skilled person is aware of the claimed concentration of histidine and the claimed pH, it seems rather natural to use the mixture of histidine base and salt, since the latter is part of its common knowledge. In addition, Cl- is present anyway due to arginine-HCl, so Histidine HCl is present as well. On the contrary, there is no need for a further teaching of the patent, but a clear indication not to use a histidine salt when reading the claim as

a whole.

c) Product claim

Claim 1 is undoubtedly a product claim and cannot be read as limited to the process. The wording is clear and final. Claim 1 protects the individual components of the pharmaceutical formulation, not the process steps for its manufacture.

## V. Infringement

Although the challenged embodiment makes use of the technical teaching of the patent in suit (cf 1.) and the Defendant and the Defendants 1) - 7) of UPC_CFI 165/24 are cumulatively liable for their actions (cf. 2.), the Court cannot find relevant activities of the Defendants which already are actions of infringement or cross the line to imminent infringement (cf. 3).

### 1. Challenged embodiment infringes claim 1

The Applicants stated that, as a biosimilar, the formulation of the challenged embodiment must be identical to their XOLAIR® formulation, which, according to the Court's interpretation, falls within the scope of claim 1 despite the presence of histidine (0.009 M) and histidine-Cl (0.011). The Defendant 1) of UPC_CFI 165/2024 has already obtained a marketing authorisation confirming that the alleged formulation is a biosimilar to XOLAIR®. The Defendant has not substantially disputed that the challenged embodiment falls within the scope of claim 1 and realises each feature. In the context of a product claim it is irrelevant that the Defendant does not use the process.

### 2. Cumulative Liability

The Defendant and Defendants 1) to 7) of UPC_CFI_165/24 are cumulatively liable because they acted in a close and interdependent commercial relationship based on their structure as a large group of companies.

The production and distribution structure as such is not disputed by the parties. The Defendant is responsible for the reseach, development and production of the products. Defendant 1) of UPC_CFI_165/2024 serves as the hub for sales and marketing in Europe. Defendant supplies the products to Defendant 1) of UPC_165/2024. Defendant 1) distributes the products to other local subsidiaries where they will be commercialized in the single national territories of the UPCA Contracting Member States.

Defendant states that each of the Defendants 1) to 7) of UPC_CFI_165/2024 is responsible for regulatory management and organisation. These facts do not contradict but rather confirm the role of each of the Defendants of UPC_CFI_165/2024 in Germany, Belgium, France, Finland, Italy and the Netherlands as part of the group's network to organise local formalities and create the conditions for local distribution. Even if they are no proxies and each subsidiary independently manages the market entry of its products in its national territory, the Applicants substantially stated that Defendant and Defendant 1) of UCP_CFI 165/2024 are the ”spiders in the web“ in providing biosimilar products for the European market. They supply their products to the European

market and the other Defendants distribute them accordingly. The chain goes from the Defendant to Defendant 1) of UPC_CFI_165/2024 as the “gatekeeper“ for Europe and from there to the other Defendants of UPC_CFI_165/2024. The actions of the Defendants of UPC_CFI_165/2024 are attributed to the Defendant and vice a versa.

The Applicant alleges that the Defendant is going to offer the challenged embodiment by using its established network structure, including the Defendants of UPC_CFI_165/24.

3. No imminent infringement

Pursuant to Art. 62(1) and Art. 25(a) UPCA, the Defendants' conduct does not yet constitute an imminent infringement.

a)
Contrary to the Defendant's view, the Court is not required to apply different national laws to European bundle patents, such as the patent in suit, during the transitional period.

In the absence of an opt-out (Art. 83 (3) UPCA) the patent will be under the jurisdiction of the UPC. With the creation of the UPC, Art. 64 (3) EPC, which stipulates that national law applies to patent infringement proceedings (cf. Benkard/Henke, EPC, 4th ed., Art. 64 para. 29), was amended on the basis of Art. 149a (1) (a) EPC. The amendment changes the jurisdiction (Art. 31, 32 UPCA), the procedural law (UPCA and RoP), the effect of the decision (Art. 34 UPCA) and the enforcement (Art. 82 UPCA) in favour of the UPC as European infringement court (cf. Tilmann/Plassmann/v. Falck/Dorn (german version), Unitary Patent, Unified Patent Court, Art. 34 EPGÜ para. 14). The UPCA also creates a uniform substantive law of infringement (see Art. 25, 26 UPCA), which interferes with Art. 64 (1) EPC in a permissible manner via Art. 142 (1) UPCA (see Tilmann/Plassmann/v. Falck/Dorn (german version), Unitary Patent, Unified Patent Court, Art. 34 EPGÜ para. 4, 21, 35). This substantive law in the UPCA will become part of the national law of the Contracting Member States after the UPCA has been ratified by the respective member state and incorporated or implemented into its law. In this respect, Art. 25 et seq. of the UPCA take precedence over the patent infringement provisions in the single national patent laws of the UPCA Contracting Member States as special provisions with regard to patent infringement (cf. in the result also Luginbühl/Hüttermann/Boos, Einheitspatentsystem, Art. 24 EPGÜ para 40).

It is therefore for the Court to determine independently, on the basis of the UPCA, what requirements must be met in order for an infringement to exist. In the case at hand, the additional question is whether it is necessary to order provisional measures to prevent imminent infringement pursuant to Art. 62(1) UPCA. As the latter is a procedural provision, it is clear from the above that the Court must also interpret it itself, certainly in the light of Union law, but without recourse to national patent law.

b)
Since claim 1 of the patent in suit is a product claim, the requirements for direct infringement are – in addition to the product being the subject matter of the patent in suit – acts of use namely making, offering, placing on the market, or using a product which is the subject matter of the patent, or importing or storing the product for those purposes. Only offering is seriously alleged in the present case and the Court cannot find any conduct of the Defendant which already constitutes offering.

c)
The parties are therefore right to argue about the question of whether the Defendant's conduct gives rise to imminent infringement.

aa)
In order for a patent infringement to be considered imminent, there must be concrete indications in the overall circumstances that an infringement is imminent (cf Tilmann/Plassmann/v. Falck/Dorn (german version), Unitary Patent, Art. 62 Rn. 16). A situation of imminent infringement must be characterised by certain circumstances which indicate that the infringement has not yet occurred but that the potential infringer has already set the stage for it to occur. The infringement is only a matter of starting the action. The preparations for it have been fully completed. These circumstances must be assessed on a case-by-case basis. The burden of presentation and proof in this regard lies with the Applicants.

bb)
It should be noted that the "Bolar exception" is not relevant in this case, nor is it related to an SPC or a generic drug case.

The question to be answered is whether the conduct of the Defendant´s and Defendants´ of UPC_CFI_165/2024 leads to the conclusion that they more likely than not intend to enter the market during the patent term without any further ado. Applicants are not required to accept a situation that would lead to the renegotiation of their contracts with their customers for their own product in 2024, or that would affect their ability to negotiate of new contracts in 2025. This would certainly be the case if a concrete offer of the challenged embodiment were made to the market, which would constitute direct infringement. It is sufficient for an offer if the act in question actually creates a demand for the product which the offer is likely to satisfy (cf. UPC_CFI_177/2023 (LD Düsseldorf), Order of 18 October 2023). In the present case, this would be an advertisement in which the Defendant and Defendants of UPC_CFI_165/2024 would be able to supply, in compliance with all the regulatory measures applicable to the medical market in the Contracting Member States, in particular by mentioning a specific price, if a potential customer wished to place an order. It should be noted that potential customers are familiar with the practices of the pharmaceutical industry. They are more likely to regard statements about future market entry as vague announcements when regulatory measures and pricing and reimbursement conditions have not yet been finalised. In order for an infringement to be imminent, in the present case means that all pre-launch preparations must have been completed in such a way that an offer can be made at any time. Rather than looking at individual events in isolation, it is necessary to make an overall assessment of the activities.

cc)
The Court cannot find that that the Defendant and the Defendants of UPC_CFI 165/2024 have already completed all the pre-launch preparations as such.

It is true that the Defendant obtained a marketing authorisation for the challenged embodiment. And the Defendant cleary promoted the challenged embodiment at the EAACI Congress at the end of May/beginning of June by displaying on its booth the message „Omlyclo´ is omalizumab – Now approved“. However, this advertising message did not show any specific timeline and there is no specific information that any price negotiations or reimbursement applications by the Defendants of UPC_165/2024 have already started or are ongoing. Nor is there any specific situation in which samples were actually presented to potential customers.

(1)
The Applicants first asserted that Defendants of UPC_165/2024 stated that they have initiated the pricing process for the challenged embodiment at the EAACI Congress in Spain and also in France. According to the written witness statement of […] – […] – he listened to a conversation between one of Celltrion´s marketing personnel and a visitor at Defendant´s booth at the EAACI congress. In this conversation, the Celltrion representative explained that Celltrion was actively negotiating prices across countries. Due to patent issues in many EU countries, Celltrion´s omalizumab biosimilar was expected to be available in October/November 2024 (cf. exhibit FBD 38). With regard to France, the Applicants only allege that employees of the French Novartis subsidiary were contacted by the French Economic Committee for Health Products (CEPS) in the context of a pricing request for XOLAIR®.

The Defendant contested these allegations and stated that there are no price negotiations at all in any UPC country. This is confirmed by the written witness statement of […] of the Defendant (Exhibit BB 39), who states that no Celltrion entity is actively negotiating prices for the challenged embodiment with the competent authorities in any UPC member state. Preparatory activities are happening to be in the position to initiate Pricing & Reimbursement on a country-by-country basis once the patent situation is resolved. Regarding the conversation at the booth on the EAACI congress, […] states that he overheard the mentioned conversation at the booth and intervened because he thought that the visitor could gain a misleading understanding as regards the challenged embodiment. He joined the conversation and clarified that there was a patent issue that was being discussed and unresolved. When asked about the timing of the launch, he said that they responded that the exact timing of the launch is not yet known due to patent and settlement issues with the original developer as well as the need to go through the P&R process for each country after approval.

As regards the activities in France, the Defendant also disputes any price discussions. The responsible Director of Defendant 4) of UPC_165/2024 only inquired about the patents relevant to the product XOLAIR®. They did not initiate the Pricing & Reimbursement Mechanism, which consists of several steps starting with an application to the CEPS. The written witness statement of […], […] with Defendant 4) of UPC_165/2024, (exhibit BB 43) attests to this. He further states that he informed the relevant officer of CEPS by email that Celltrion was currently involved in litigation with Novartis before the UPC and that they would have the result in August 2024, but that the Celltrion laboratory has no intention of commercialising it as long as the patents are valid. The witness explains his statement regarding the UPC litigation in detail and states that he is not a lawyer and not typically involved with patents or patent litigation. At the time he wrote the email to the CEPS, he was assuming that Novartis/Genentech had asserted all of the patents mentioned in the email correspondence with the CEPS against Celltrion and that the UPC would rule on these patents in August 2024. He subsequently learned that this was legally incorrect, but underlined again in his written statement of 19 June 2024 that Defendant 4) of UPC_165/2024 will not proceed with a launch if a relevant Novartis patent or relevant patents are valid.

In view of the fact that the witnesses are themselves employees of both parties or of group entities of the parties and are therefore naturally influenced in some way, the Court is not convinced that price negotiations have already taken place or are in progress. The statement of the Applicant's witness is only one word and is contradicted in detail by the Defendant´s witness statements. In addition to the contradictory witness statements, the Court's conclusion follows from the fact that, contrary to their announcement in their Reply that they would make further submissions on the pricing process in France, the Applicants no longer alleged the commencement of pricing and reimbursement at the oral hearing.

(2)
There is also no allegation of, or evidence of, a specific situation in which there was an actual presentation or exchange of samples to potential customers. The only disputed allegation is an optional provision of samples in the future.

The Applicants asserted that the Defendant allegedly announced to the […], that it would provide a sufficient number of samples of this biosimilar. This is confirmed by the written witness statement of […] (Exhibit FBD 37), a sales representative of […]. According to the statement, she participated in a dermatology staff meeting in May 2024, where, among other things, the supply of samples of the medication omlizumab (Xolair) was discussed. […], indicated to the witness that the biosimilar company Celltrion had already approached them and informed them about Celltrion´s new omalizumab biosimilar. According to […], Celltrion announced straight away that they will make available ample number of samples of that biosimilar. The staff explained that they will not refrain from using the samples to form an opinion about the product and to use it on a regular basis.

Apart from the fact that the statement is only hearsay, as the witness was not present at any meeting between [….] and any employee of Celltrion, it is contradicted by the written witness statement of […] (Exhibit BB 40), who is a […] of the Defendant 3) of UPC_165/2024. In his statement, the witness reports a meeting with […] on 8 March 2024. In the context of the mentioned barriers in the reimbursement conditions, he asked […] how she manages this and where she requests samples from Novartis. […] then asked whether they offers samples. The witness responded that they provide samples on request for their existing products and that this probably would also be the case for future biosimilars. A specific launch date was not mentioned, but the witness replied that they hope to be available by the end of the year after the patent issues have been resolved.

In view of the contradictory statements, the Court cannot conclude that the defendant announced the availability of samples in the near future.

(3)
The other alleged approaches to dermatologists in Dutch hospitals and to customers, including health insurance company representatives, in Germany in April 2024, concerning information as to when the accused embodiment was expected to be on the market, are not in themselves sufficient to constitute imminent infringement in the absence of the circumstances referred to above. Moreover, the exact content of each incident is disputed between the parties and is evidenced by contradictory written statements of witnesses (cf. Exhibit FBD 36, Exhibit FBD 39, Exhibit BB 41, Exhibit BB 42). The same applies to the presentation at the booth at the Belgian Dermatology Days at the end of March 2024, where the announcement of the challenged embodiment was even more vague, since it was mentioned in the context of a pipeline intended as future planning.

At the time of the Court's order, there is not yet sufficient evidence that the infringement is imminent.

## VI. Security of cost of the proceedings

The Defendant´s request for security for costs was admissable but unfounded.

Contrary to the Order of the Court of 30 April 2024 (CFI, LD Düsseldorf, UCP_CFI 463/2023), which concerned a request by the applicant, the Defendant´s request for security of costs is admissable

according to Art. 69 (4) UPCA, R. 158 RoP.

As the requirements of R. 158 RoP are not met, the request is rejected.

The order for security of costs requires a substantiated presentation of facts concerning the financial situation of the other party which give rise to a legitimate concern about a risk of insolvency or indications of a lack of assets (see inter alia CFI, LD Munich, Order of 23 April 2024, UPC_CFI 514/2024; RD Nordic-Baltic, Order of 20 August 2024, UPC_CFI_380/2023).

The Defendant has not provided any facts indicating an alarming financial situation of the Applicants. The Applicants rightly argue that the provisions are not primarily intended to protect against the difficulties of enforcing a cost decision abroad. Furthermore, the Defendant has not provided any substantiated arguments as to why it assumes that the Applicants will be unwilling to pay substantial interim costs without significant enforcement efforts. The mere fact that the enforcement of a cost claim outside the territory of the UPC is practically burdensome is not sufficient. In the light of the figures provided by the Applicants concerning the alleged sales situations and expected losses, there is no further indication that the Applicants would be not able to bear the costs of the proceedings.

## VII. Interim award of costs

The Defendant may claim interim costs pursuant by analogy with R. 211.1 (d) RoP.

1.
According to R. 211.1 (d) RoP, the Court may order provisional reimbursement of costs as an interim measure. If the applicant fails to commence the main proceedings in due time after the provisional measure has been ordered, the order shall be revoked upon request pursuant to R. 213.1 RoP. As a rule, therefore, the order for provisional measures is followed by proceedings on the merits. For the decision on the merits, R. 118.5 RoP requires a basic decision on costs. Where the main proceedings are preceded by an application for provisional measures, the Rules of Procedure therefore provide for a two-stage procedure:

In order to avoid having to advance the costs arising from the application for provisional measures over a longer period of time and thus to avoid the risk of the other party's insolvency, the applicant has the possibility of having the defendant obliged to reimburse the provisional costs included in the provisional measures order. In the main proceedings, the Court will then decide on the basis of R. 118.5 RoP, which forms the basis for any subsequent assessment of costs (R. 150 et seq. RoP). As long as the proceedings for interim relief are followed by proceedings on the merits, there is no (unintentional) gap.

Art. 69 UPCA does not require a different assessment, even taking into account the precedence of the Agreement over the Rules of Procedure. The latter determines the content of the decision on costs, namely who is to bear the costs of the proceedings and the other costs of the unsuccessful party, and to what extent. It does not, however, deal with the procedure by which the decision on costs is made. This is the subject of R. 118.5 RoP (see Tilmann/Plassmann/Dold/Tilmann, Unitary Patent, Unified Patent Court (german version), Art. 69 para. 1 and 3).

However, in the reverse situation – as it is in the present case – there is an unintended regulatory gap. If the application for provisonal measures is unsuccessful, the applicant is likely to refrain from filing an action on the merits. The obligation to file an action, which is standardised in R. 213.1

RoP, will then not apply. This means that in such a situation there is no decision on the merits in the sense of R. 118.5 RoP and therefore no possibility to decide on the costs. In the absence of alternatives, this is likely to be an unintended gap that opens the way to the corresponding applicability of R. 118.5 RoP.

If, by the way of exception and despite the obligation to file an action within the time limit laid down in R. 213.1 RoP, no action is brought on the merits after the order for provisional measures has been made or confirmed, two situations must be distinguished:

If the applicant has failed to file the main action within the time limit and the order for provisional measures is to be revoked. If there are proceedings on the merits, Art. 118(5) RoP shall apply. If there are no proceedings on the merits, the defendant's costs of proceedings may be claimed as part of the damages to be reimbursed pursuant to R. 213.2 RoP (for the scope of the claim for compensation see v. Falck/Dorn in Tilmann/Plassmann, Unitary Patent/Unified Patent Court (german version), para. 213.13). Alternatively, proceedings on the merits may be dispensed with if the defendant accepts the out-of-court order for provisional measures as a final settlement. In such a case, it is likely that the defendant will regularly undertake to pay the costs out of court, whereby a corresponding obligation may be imposed in accordance with R. 360.1 RoP in conjunction with R. 11.2 RoP if necessary. There is then no need to apply R. 118.5 RoP by analogy.

2.
The calculation of the Defendant´s preliminary costs on the basis of the RVG is undisputed between the parties and cannot be objected to by the Court (cf. CFI, Local Division Düsseldorf, UPC_CFI 452/2023, Order of 9 April 2024).

## VIII. No order to file action on the merits

As long as the Court has not ordered any provisional measures there is no need to take such measures according to the clear wording of Rule 213.1 RoP.

*ORDER:*

I. The Application for provisional measures is rejected.

II. The Court orders the Applicants to pay interim costs of the proceedings in the amount of EUR 138,562,80.

III. In all other respects, the Defendant’s requests are rejected.

IV. The value in dispute is set at EUR 7,500,000.

*DETAILS OF THE ORDER:*

Main file number: ACT_18551/2024

UPC-Number: UCP_CFI_166/2024

Proceeding: Application for provisional measures

Delivered in Düsseldorf on 6 September 2024

NAMES AND SIGNATURES

| | |
|---|---|
| Presiding Judge Thomas | Ronny Thomas<br>Digital unterschrieben von Ronny Thomas<br>Datum: 2024.09.06 07:41:06 +02'00' |
| Legally Qualified Judge Dr Thom | Anna Bérénice Dr. THOM<br>Digital unterschrieben von Anna Bérénice Dr. THOM<br>Datum: 2024.09.04 11:20:00 +02'00' |
| Legally Qulified Judge Zana | Alima ZANA<br>Firmato digitalmente da Alima ZANA<br>Data: 2024.09.04 12:05:03 +02'00' |
| Technically Qualified Judge Peterson | John Meidahl Petersen<br>Digitalt signeret af John Meidahl Petersen<br>Dato: 2024.09.04 22:38:17 +02'00' |
| for the Sub-Registrar Boudra-Seddiki | Rachida Boudra-Seddiki<br>Digital unterschrieben von Rachida Boudra-Seddiki<br>Datum: 2024.09.05 08:15:25 +02'00' |

*INFORMATION ABOUT APPEAL*

An appeal to this order may be brought in accordance with Art. 73 UPCA and R. 220.1 RoP within 15 calendar days of the notification of this order.