Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Hamburg - Local Division

UPC_CFI_701/2024
Final Order of the Court of First Instance of the Unified Patent Court delivered on 21/02/2025

HEADNOTES:

The burden of presentation and proof establishing a patent infringement lies with the Applicant. This is only reversed if the Applicant has at least provided reasonable indications and/or facts that an infringement has occurred.

KEYWORDS:
Preliminary injunction; Art, 62(2) UPCA; Rule 209(2) RoP.
Infringement of the patent in suit

PARTIES OF THE PROCEEDINGS:

Teleflex Life Sciences II LLC, represented by the executive management, Mr. Jesper Kristian Jacobsen and Mr. Mogens Vedel Hestbæk, and the board of directors, 251 Little Falls Drive, Wilmington, Delaware, USA,

Applicant,

Representatives:

all attorneys-at-law of Grünecker PartG mbB admitted in the Federal Republic of Germany and to the UPC, especially Mr. Ulrich Blumenröder, Mr. Sebastian Ochs and Ms. Elvira Bertram, Leopoldstrasse 4, 80802 Munich,

European patent attorneys of Grünecker PartG mbB who have the necessary qualifications pursuant to Article 48 (2) of the Agreement on a Unified Patent Court (UPCA), especially Mr. Thomas Laubenthal and Mr. Alexander Stumvoll, Leopoldstrasse 4, 80802 Munich

Electronic address:
Rechtsanwaltspostfach@grunecker.de

versus

Speed Care Mineral GmbH, represented by Siegfried Kruse and Ulf Peer-Ole Pommerening, Genzkowerstraße 7, 17034 Neubrandenburg, Germany,

Defendant,

Representatives: Attorney-at-law Peter-Michael Weisse, Dr. Alexander Reetz, Dr. Eva-Maria Thörner, Jan-Caspar Maiers, Wildanger Kehrwald Graf v. Schwerin & Partner mbB, Couvenstraße 8, 40211 Duesseldorf,

Electronic address:

Teleflex-speedcare-ep811@wildanger.eu

PATENT AT ISSUE: **EP 2 077 811**

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS: Application for provisional measures

DECIDING JUDGE:

Full Panel

Presiding Judge and JR	Sabine Klepsch
Legally qualified Judge	Dr. Stefan Schilling
Legally qualified Judge	Stefan Johansson
Technically qualified Judge	Jeroen Meewisse

SHORT SUMMARY OF FACTS:

The Applicant is – as member of the Teleflex Group – a global provider of medical technologies designed to improve people's health. Teleflex' portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. One of the Applicant's main product groups is that of emergency medical products, which include, among other things, hemostatic products that promote clotting in the event of bleeding.

The Applicant claims to be the proprietor of European Patent EP 2 077 811 B1 (hereinafter: patent in suit or patent, Exhibit K 12), entitled "Clay-based hemostatic agents and devices for the delivery thereof". The application for the patent in suit was filed on 20 July 2007 with a priority date of 30 October 2006. On 10 November 2010, the European Patent Office (EPO) granted the patent. The patent in suit has survived an opposition proceeding before the EPO on September 25, 2023 (Exhibit K 14).

The patent in suit protects clay-based hemostatic agents and devices incorporating such agents for the delivery thereof to bleeding wounds. The liquid phase of blood is plasma, which includes acids, lipids, solubilized electrolytes and proteins. The proteins are suspended in the liquid phase and can be separated out of the liquid phase by any of a variety of methods. One particular protein suspended in the liquid phase is fibrinogen. When bleeding occurs, the fibrinogen reacts

with water and thrombin to form fibrin, which is insoluble in blood and polymerizes to form clots. In case of substantial bleeding, specialized equipment and materials are generally required as well as personnel trained to administer aid. Otherwise, excessive blood loss can occur. Severe wounds can often be inflicted in remote areas or situations; in such situations, it is important to stop bleeding long enough to allow the injured persons to receive medical attention.

The patent consists of 15 claims. The Applicant has based its present application for provisional measures on claim 1, especially claims 2, 3, 7 and 9 and auxiliary on claim 1 in conjunction with claim 9.

Claim 1 reads as follows:

> A hemostatic device for providing a hemostatic effect on a bleeding wound, said device comprising: a flexible gauze substrate (62); a clay material (14) disposed on said gauze substrate (62); and a binder to adhere the clay (14) to the gauze substrate (62); wherein when treating a bleeding wound, application of said device causes at least a portion of said clay material to come into contact with blood.

Claim 9 reads as follows:

> The device of claim 1, wherein said binder is chitosan.

With regard to the wording of the merely in especially asserted claims 2, 3 and 7, reference is made to the patent-in-suit.

The Defendant is a German company, which develops, produces and distributes medical products in the field of hemostasis and also offers various mineral-based technologies for manufacturers in other industries, as shown by excerpts from the Defendant's website under www.speedcaremineral.de. It was founded in 2017 as a spin-out from [redacted] a Neubrandenburg-based engineering, consulting and laboratory company. The long-standing Managing Director and current Chief Technology Officer Dr. rer. nat. habil. [redacted] was managing director of [redacted] at that time and also took over the management of the Defendant. Dr. [redacted] studied geology, obtained his doctorate in the field of technical mineralogy and habilitated in 1985. He is the author of more than 90 scientific publications and has been researching so-called halloysites and their fields of application, including hemostasis, since 2002.

The Defendant produces medical devices against bleeding, especially the SpeedM emergency hemostatic dressing (hereinafter: attacked embodiment). The attacked embodiment contains halloysite-7Å (hereinafter also HNT), a dehydrated clay mineral of the kaolinite group, as a hemostatic agent.

The Applicant was informed on October 11, 2024, that the attacked embodiment was granted CE certification. The German Federal Army has arranged for a call for tender regarding wound dressings, and also such applying hemostatic agents. The Applicant is participating in this call and expects that – after having been granted the CE-certification – the Defendant will certainly also participate. On November 11, 2024, the Applicant initiated an action for infringement against the Defendant at the UPC (Local Division Hamburg). One week later, on November 18, 2024, the Applicant submitted this Application for provisional measures.

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 from manufacturing and/or offering, placing on the market or using or exporting or possessing for the purposes referred to in Belgium, Denmark, Germany, Finland, France, Italy, the Netherlands, Austria, Portugal and Sweden,

1. a hemostatic device for providing a hemostatic effect on a bleeding wound, said device comprising:

a flexible gauze substrate; a clay material disposed on that gauze substrate; a binder to adhere the clay to the gauze substrate; where in, when treating a bleeding wound, application of said device causes at least a portion of said clay material to come into contact with blood; (direct infringement of claim 1 of EP 2 077 811 B1),

2. especially if said clay material is kaolin; (direct infringement of claim 2 of EP 2 077 811 B1),

3. especially if said clay material is selected from the group consisting of attapulgite, bentonite, kaolin, and combinations of the foregoing materials; (direct infringement of claim 3 of EP 2 077 811 B1),

4. especially if said gauze substrate is fabricated from a material selected from the group consisting of cotton, silk, wool, plastic, cellulose, rayon, polyester and combinations of the foregoing; (direct infringement of claim 7 of EP 2 077 811 B1),
5. especially if said binder is chitosan; (direct infringement of claim 9 of EP 2 077 811 B1).

II. The Defendant is ordered to pay to the court a penalty payment (which may be repeated) of up to EUR 250,000 for each infringement of the order under section I.

III. The Defendant shall bear the costs of the proceedings.

IV. The above orders are directly enforceable.

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

Auxiliary request (submission 6 January 2025):

I. 1. with the amendment "wherein said binder is chitosan".

The Defendant requests,

1. reject the application for provisional measures;

2. order the Applicant to pay the costs; in the alternative:

3. allow the Defendant to continue the acts in dispute against the provision of security; further in the alternative:

4. make enforcement dependent on the provision of appropriate security, whereby the security should amount to at least EUR 25 million.

5. that exhibits originally in German need not be translated.

POINTS AT ISSUE:

The Applicant asserts that it is entitled to enforce the claims at issue. The application for the patent in suit was filed by [redacted] merged in [redacted] LLC as of August 31, 2012, for which a confirmation of the State of [redacted] and the Certificate of Formation of [redacted] LLC was submitted, issued by the State of [redacted] LLC assigned the patent in suit on December 10, 2021 to [redacted] and [redacted] on the same day to Teleflex [redacted] On December 10, 2021, Teleflex [redacted] assigned the patent in suit to Teleflex Life [redacted] Ltd. In Exhibit K 8 an agreement between [redacted] LLC and Teleflex Life Sciences Ltd of December 10, 2021 is submitted, signed by the CEOs of all affected companies. On December 11, 2023, Teleflex Life Sciences Ltd. assigned the patent in suit, as shown by the Intellectual Property Assignment Agreement of December 11, 2023, to Teleflex Life Sciences II LLC. On December 18, 2023, Teleflex Life Sciences II LLC merged into Teleflex [redacted] LLC, as proven by the Merger Certificate of the State of [redacted] Teleflex [redacted] LLC changed its name to Teleflex Life Sciences II LLC, as shown by the Certified Confirmation of the State of [redacted] of December 19, 2023. The Applicant therefore claims to be the proprietor of the patent in suit and its national parts and by that to be entitled to assert any rights based on the patent in suit.

The Applicant asserts further that the Defendants attacked embodiment infringes the patent in suit. It is of the opinion that the term “clay” does not require the clay material to be halloysite 10 Å or any other hydrated clay material. The feature “clay” in the claim has a broad meaning. Only in the specification of preferred embodiments does the patent in suit mention both, hydrated and dehydrated "clay materials" or other aluminium silicates. Para. [0023] of the patent in suit is located under the headline indicating that the following pertains to preferred embodiments. "Clay material" in the form of a hydrated aluminium silicate is a preferred embodiment, but not a definition of the "clay material" which is intended to apply to the invention of the patent in suit as a whole.

The Applicant claims that the attacked embodiment comprises further a binder and that binder is chitosan. The tests conducted by the Cambridge Polymer Group (CPG) on a sample of the attacked embodiment, namely a Fourier-Transform Infrared Spectroscopy (FT-IR) and a Scanning Electron Microscopy-Energy Dispersive Spectroscopy (SEM-EDS) (Exhibit K 22) are indicating chitosan. The CPG conducted tests before and after rinsing of the gauze of the sample in water (see CPG test report, Exhibit K 22, p. 2). The rinsate, obtained after rinsing the gauze with the deionized water, was evaluated by CPG in a FT-IR analysis (also see CPG report, Exhibit K22, p. 2 and 3). The Applicant assertsthat the direct comparison proves that the rinsate contains chitosan. The CPG report states (Exhibit K 22, p. 3):

> "The rinsate was also scanned, with the spectrum shown in figure 5, and the spectrum is distinctly different from the Halloysite reference material. The rinsate spectrum was compared to spectra from the Know-It-All spectral library, including chitosan (match of 73,8%). Chitosan crosslinked with glutaraldehyde was used by some to coat Halloysite to improve drug release, and the peak at 1120 cm-1 could be associated with glutaraldehyde."

The KnowItAll-Database, used by CPG, is the "KnowItAll" library from Wiley. There can be a variation between the reference source and the sample, caused e.g. by the purity of the sample or the source of the sample. It considers, taken that into account that the spectrum shown in figure 6 in black lines is quite close to the spectrum for pure chitosan of the Know-It-All-library.

Furthermore, test samples were provided to [redacted] for testing their elements (Exhibit K 29). [redacted] tested samples of the attacked embodiments, namely the coated and the uncoated sides of the samples. [redacted] conducted on the filtered solution firstly a Fourier-Infrared Spectroscopy to identify the species at present in the test samples of the attacked embodiment, the coated and the uncoated sides of the samples. Secondly, [redacted] conducted an Inductively Coupled Plasma–Optical Emission Spectroscopy (ICP-OES). The ICP-OES is an analytical technique of the state of the art used to determine how much of certain elements are in a sample. This principle uses the fact that atoms and ions can absorb energy to move electrons from the ground state to an excited state. In ICP-OES, the source of that energy is heat from an argon plasma. The [redacted] team digested the samples to isolate the coated material from the gauze and then tested the residual solution using ICP-OES, where it was confirmed that aluminum and silicon were present. This implies that the coating material contains an aluminosilicate clay mineral. The samples contain silicon (Si) and aluminum (Al), which are the main components of halloysite, a clay mineral of the kaolinite group.

The Applicant states to have demonstrated that the attacked embodiment contains clay in the meaning of the patent in suit and chitosan as a binder. The same can be derived from the Defendant's intellectual property rights.

The Defendant argues that the Applicant's requests must be denied because no provisional measures are justified in the present case.

It disagrees with the Applicant on the construction of the claim. "Clay" in the meaning of the patent is an aluminium silicate with an H_2O bond and resulting absorption capacity as "clay material" in the claimed hemostatic device. Each of the preferred groups of clay minerals mentioned in claim 3 has at least one clay mineral with H_2O bonding or incorporation (in the group of kaolins it is halloysite-10 Å), the other minerals have a water bond per se. Due to the structural flexibility of the layer plates, the montmorillonites of the bentonite group can even swell when interlayer water is stored and are therefore particularly suitable for absorbing the liquid phase of blood.

It is of the opinion that the patent in suit is not infringed, as the attacked embodiment does not contain clay in the meaning of the patent. It further does not contain chitosan or any other binder. The Defendant avoids the use of chitosan and of a binder in its product because of its negative properties (risk of allergic reactions in patients). It does not require a binder due to the manufacturing process and properties of halloysite-7 Å used. The Applicant's allegation of infringement is based, inter alia, on serious methodological errors in the investigation of the attacked embodiment.

Furthermore, the Defendant submitted a "Report on Analytical Testing of a SpeedM and QuikClot sample and Evaluation of the CPG Report for Analytical Testing on SpeedM" by Heppe Medical Chitosan GmbH (Hereinafter: Heppe report, Exhibit WKS 9). It came to the solution that the test probe did not contain any nitrogen (N) and it asserts that the CPG report is scientifically untenable because of the alleged agreement of 73.8 % to prove the presence of chitosan. It is of the opinion that the requirements for a reliable identification should be a match over 95%. In its own investigations two gauze samples of the attacked embodiment and QuikClot, the product of the Applicant's group, were used. FT-IR spectra of the SpeedM and QuikClot samples were compared with those of chitosan and cotton. The spectra showed significant differences, especially in the regions characteristic of chitosan. The SpeedM sample showed a strong similarity to cotton. The gauze samples were also compared with chitin from crustaceans and fungi. The spectra showed differences in the relevant areas, which rules out a similarity with chitin. As a result, it was found that the FT-IR spectra and the absence of nitrogen in the samples indicate that the SpeedM gauze sample does not contain chitosan. The criticism of the Heppe report by the applicant is unfounded which the Heppe statement by Dr. rer. Nat. [redacted] and Dipl.-Ing. Richter (Exhibit WKS 20) prove.

Further, the validity of the patent is in question. It is also highly likely that the patent application will not prove to be legally valid. The opposition proceedings before the EPO do not change this, as these have been cursory proceedings.

The Applicant's conduct also clearly shows that the requirement of urgency is lacking because the Applicant was already aware of all the circumstances and all the evidence of its present application since March 2024. It took then 8 months to file the present application, without prior request for authorization (Berechtigungsanfrage) or warning letter (Abmahnung), only in order to hinder the Defendant in participating in a tender of the Dutch Ministry of Defense and to make it impossible for it to clarify the patent situation in court before the end of the (now expired) tender period.

In addition, particularly in view of the short interval of only a few months between the provisional measures and the decision on the merits, there is also no factual necessity to decide the matter by means of preliminary measures. It is therefore irrelevant that the applicant has not sufficiently proven its standing to sue. The examination of the documents submitted to explain the alleged innumerable transfers of the patent in suit makes it predominantly likely that the applicant is not (has not become) the proprietor of the patent in suit. In particular, life experience shows that it is probable that the alleged transfers of which several were concluded in one day, were not concluded in the required order.

GROUNDS FOR THE ORDER:

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

I.

The Applicant is entitled to bring actions to the court, Art. 47 (2) UPCA in conjunction with R. 8.5 (a) and (c) RoP. The Applicant, Teleflex Life Sciences II LLC, is already registered as the owner of the patent in suit in the registers of Denmark, Germany, Finland, France, Italy, Austria, Portugal and Sweden. For Denmark, Germany, Finland, France, Italy, Austria, Portugal and Sweden, the entitlement of the applicant is therefore evident from the state of the respective national patent

register (Exhibit K 13, excerpts from the relevant patent registers: Belgium, Netherland, Germany, Austria, Denmark, Finland, France, Italy, Portugal, Sweden). The excerpts indicate that the Applicant itself applied for the ownership of the patent in suit.

The Defendant did not present convincing arguments that the Teleflex Life Sciences II LLC limited referred to here is not actually the Applicant (see certified confirmation of the State of [redacted] December 19, 2023, Exhibit K 11). It did not present any indication that would cast doubt on the Applicant's registration as patent proprietor.

II.

The Court is not convinced with the sufficient degree of certainty (Art. 62 (4) UPCA in conjunction with R. 211.2 RoP) that the Applicant's right is infringed by the intended offer and distribution of the attacked embodiment within the Contracting Member States Belgium, Denmark, Germany, Finland, France, Italy, the Netherlands, Austria, Portugal and Sweden (Art. 25(a) UPCA). On summary examination, the Court finds that is not more likely than not that the attacked embodiment makes direct and literal use of the technical teaching of the patent in suit protected by patent claim 1, Art. 62 (4) UPCA in conjunction with R. 211.2 RoP (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).

On the basis of the above-mentioned principles, the Court cannot conclude that an infringement of the patent is more likely than not. In detail:

2.
The present invention relates generally to agents and devices for promoting hemostasis and, more particularly, to clay-based hemostatic agents and devices incorporating such agents for the delivery thereof to bleeding wounds (par. [0001]).

The patent-in-suit provides the technical background to the invention as follows, that blood is a liquid tissue that includes red cells, white cells, corpuscles, and platelets dispersed in a liquid phase. The liquid phase is plasma, which includes acids, lipids, solublized electrolytes, and proteins. The proteins are suspended in the liquid phase and can be separated out of the liquid phase by any of a variety of methods such as filtration, centrifugation, electrophoresis, and immunochemical techniques. One particular protein suspended in the liquid phase is fibrinogen. When bleeding occurs, the fibrinogen reacts with water and thrombin (an enzyme) to form fibrin, which is insoluble in blood and polymerizes to form clots.

In a wide variety of circumstances, animals, including humans, can be wounded. Often bleeding is associated with such wounds. In some circumstances, the wound and the bleeding are minor, and normal blood clotting functions in addition to the application of simple first aid are all that is required. Unfortunately, however, in other circumstances substantial bleeding can occur. These situations usually require specialized equipment and materials as well as personnel trained to administer appropriate aid. If such aid is not readily available, excessive blood loss can occur. When bleeding is severe, sometimes the immediate availability of equipment and trained personnel is still insufficient to stanch the flow of blood in a timely manner. Moreover, severe wounds can often be inflicted in remote areas or in situations, such as on a battlefield, where adequate medical assistance is not immediately available. In these instances, it is important to stop bleeding, even in less severe wounds, long enough to allow the injured person or animal to receive medical attention.

In an effort to address the above-described problems, materials have been developed for controlling excessive bleeding in situations where conventional aid is unavailable or less than optimally effective. Although these materials have been shown to be somewhat successful, they are sometimes not effective enough for traumatic wounds and tend to be expensive. Furthermore, these materials are sometimes ineffective in some situations and can be difficult to apply as well as remove from a wound.

Moreover, severe wounds can often be inflicted in remote areas or in situations, such as on a battlefield, where adequate medical assistance is not immediately available. In these instances, it is important to stop bleeding, even in less severe wounds, long enough to allow the injured person or animal to receive medical attention. In an effort to address the above-described problems, materials have been developed for controlling excessive bleeding in situations where conventional aid is unavailable or less than optimally effective. Although these materials have been shown to be somewhat successful, they are sometimes not effective enough for traumatic

wounds and tend to be expensive. Furthermore, these materials are sometimes ineffective in some situations and can be difficult to apply as well as remove from a wound.

Additionally, or alternatively, the previously developed materials can produce undesirable side effects. For example, one type of prior art blood clotting material is generally a powder or a fine particulate in which the surface area of the material often produces an exothermic reaction upon the application of the material to blood. Oftentimes excess material is unnecessarily poured onto a wound, which can exacerbate the exothermic effects. Depending upon the specific attributes of the material, the resulting exothermia may be sufficient to cause discomfort to or even burn the patient. Although some prior art patents specifically recite the resulting exothermia as being a desirable feature that can provide clotting effects to the wound that are similar to cauterization, there exists the possibility that the tissue at and around the wound site may be undesirably impacted.

Furthermore, to remove such materials from wounds, irrigation of the wound is often required. If an amount of material is administered that causes discomfort or burning, the wound may require immediate flushing. In instances where a wounded person or animal has not yet been transported to a facility capable of providing the needed irrigation, undesirable effects or over-treatment of the wound may result.

Bleeding can also be a problem during surgical procedures. Apart from suturing or stapling an incision or internally bleeding area, bleeding is often controlled using a sponge or other material used to exert pressure against the bleed site and/or absorb the blood. However, when the bleeding becomes excessive, these measures may not be sufficient to stop the blood flow. Moreover, any highly exothermic bleed-control material may damage the tissue surrounding the bleed site and may not be configured for easy removal after use.

WO 02/30479 discloses a bandage using molecular sieves incorporating a material for the enhancement of blood coagulation. JP 11332909 discloses an absorbent for absorption of salt-containing solution, such as a salt containing solution containing blood. WO 2006/088912 discloses a composition comprising at least one clay material for promoting hemostatis. US 2004/243043 A1 discloses a compressed sponge used for hemorrhage control comprising a hydrophilic polymer. EP 1 690 553 discloses devices and methods for the delivery of molecular sieve materials for the formation of blood clots. EP 1 810 697 discloses devices for the delivery of molecular sieve materials for the formation of blood clots.

Based on the foregoing, the patent in suit defines its object to provide a hemostatic agent that overcomes or improves upon the drawbacks associated with the prior art. It is also a general object of the present invention to provide devices capable of applying such hemostatic agents.

In order to solve this problem, the patent in suit protects, in patent claim 1, a composition, having the following features:

1. A hemostatic device for providing a hemostatic effect on a bleeding wound,
2. said device comprising:

2.1 a flexible gauze substrate;

2.2 a clay material disposed on said gauze substrate, and

2.3 a binder to adhere the clay to the gauze substrate, wherein

3. when treating a bleeding wound, application of said device causes at least a portion of said clay material to come into contact with blood.

Auxiliary request (claim 9):

4. The binder is chitosan.

3.

Some of these features need clarification, especially the disputed feature 2.2.

a)

Feature 2.2 has the following wording, a clay material disposed on said gauze substrate.

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, the term “clay” in feature 2.2 of claim 1 specifies a "clay material" without imposing specific requirements on the clay material, especially on the presence or absence of any kind of water (water of crystallisation or deposited water). The specification does not provide restrictions with regard to the clay material (see para. [0016] to [0019]). This means that the teaching of the patent in suit does not seem to require the use of a special clay material. In particular, it does not distinguish between hydrated and dehydrated clay materials. The brief specification of the drawings merely refers to "clay particles" or "clay material" (see para. [0021] of the patent in suit).

Paragraph [0023], which reads as follows:

> “As used herein, the term "clay" refers to a crystalline form of hydrated aluminum silicate. The crystals of clay are irregularly shaped and insoluble in water. The combination of some types of clay with water may produce a mass having some degree of plasticity. Depending upon the type of clay, the combination thereof with water may produce a colloidal gel having thixotropic properties.”

might propose preferred clay material in the light of the technical teaching of the patent in suit. But a person skilled in the art would not necessarily assume that the invention is limited to the clay material mentioned in para. [0023]. This paragraph belongs to the description of other preferred embodiments of the invention and is located under the heading “detailed description of the preferred embodiments”. There is not an indication in the patent that the clay material mentioned in the claim is defined as in para. [0023].

In addition, para. [0024] mentions kaolin as a preferred embodiment and para. [0025] defines kaolin:

> “[0024] In one preferred embodiment of the present invention, the clay material is kaolin, which includes the mineral "kaolinite." Although the term "kaolin" is used hereinafter to describe the present invention, it should be understood that kaolinite may also be used in conjunction with or in place of kaolin. The present invention is also not limited with regard to kaolin or kaolinite, however, as other materials are within the scope of the present invention. Such materials include, but are not limited to, attapulgite, bentonite, combinations of the foregoing, combinations of the foregoing with kaolin and/or diatomaceous earth, and the like.
>
> [0025] As used herein, the term "kaolin" refers to a soft, earthy aluminosilicate clay (and, more specifically, to a dioctahedral phyllosilicate clay) having the chemical formula $Al_2Si_2O_5(OH)_4$. Kaolin is a naturally occurring layered silicate mineral having alternating tetrahedral sheets and octahedral sheets of alumina octahedra linked via the oxygen atoms of hydroxyl groups. Kaolin comprises about 50% alumina, about 50% silica, and trace impurities.”

It is undisputed between the parties that the chemical formula in para. [0025] refers to clay, especially kaolin, without any additional amount of bonded H_2O.

Additionally, in para. [0026] another dehydrated clay material is described, Edgar’s plastic kaolin (hereinafter “EPK”). In para. [0029], [0031] and [0032] it is described how EPK is prepared: fired to about 600 degrees C for several times. The reason for the heating might be, as the Defendant explained, to achieve a glassy substance. However, it will remain undisputed that after these multiple drying cycles of 600° C, dehydration is present. An excerpt of Römpp (Exhibit K 32), a well-known chemical encyclopedia, confirms this fact.

As far as the Defendant argues that the "clay material" should be chosen from the group of kaolinites, bentonites or attapulgites and that all those are hydrated clay materials, the argument is not convincing. Yet, the patent in suit also refers to kaolin, consisting of 50% aluminum and 50% silicon, which is not a hydrated material. The comparison between different kaolin minerals, to which the Defendant refers,

Tabelle 2.1. Strukturformeln und kristallographische Daten der Kaolinminerale.

Kaolinit Dickit Nakrit 7 Å-Halloysit (Metahalloysit)	$Al_2[Si_2O_5(OH)_4]$
10 Å-Halloysit	$Al_2[Si_2O_5(OH)_4] \cdot 2H_2O$

	Raumgruppe	a_0 (Å)	b_0 (Å)	c_0 (Å)	α (°)	β (°)	γ (°)
Kaolinit [1]	$C1$	5,16	8,94	7,40	91,7	104,9	89,8
Dickit [2]	Cc	5,14	8,92	14,39		96,7	
Nakrit [3]	Cc	8,91	5,15	15,70		113,7	
7 Å-Halloysit [4]	Cc	5,14	8,90	14,9		101,9	
10 Å-Halloysit [4]	Cc	5,14	8,90	14,9		99,7	

[1] (19); [2] (130); [3] (22); [4] (138)

shows that the structure of kaolinite is to be seen in line with 7 Å halloysite, which has hydroxide groups in its structure, i.e. water derived moieties. 10 Å halloysite is merely to be distinguished from it because it comprises an additional amount of water ($2H_2O$). If the skilled person therefore considers this knowledge from the overview presented here with the statements of the patent in suit, he/she comes to the conclusion that the patent in suit also covers dehydrated clay materials, such as 7 Å halloysite or kaolinite.

This is also apparent from para. [0024] and [0025] of the patent in suit, in which examples of clay materials are listed. The chemical formula $Al_2SiO_5(OH_4)$ (see para. [0025]) also refers to clay without any additional amount of bonded H_2O. It follows that even if a limitation in the claim construction to hydrates, as made by the Defendant, is assumed, kaolinite, and by extension also halloysite (based on the fact that halloysite belongs to the same group of materials as kaolinite), is in fact a hydrate, i.e. a water-containing material from which water can be removed, i.e. dehydration. Furthermore, as stated above, the patent in suit refers in section [0029], [0031] and [0032] to how the clay material Edgar's plastic kaolin in dehydrated. After the multiple drying cycles of 600°C, dehydration is definitely present.

This view is supported by technical and functional considerations. It is undisputed between the parties that there is no difference in the ability to bind fluids between hydrated and dehydrated clay material.

The skilled person would therefore understand the term "clay material" or "clay" in the sense of claim 1 without any limitation with regard to the binding of water (H_2O), respectively without any limitation to a dehydrated or hydrated form.

Based on this understanding of feature 2.2 the attacked embodiment makes literal use of feature 2.2. It contains HNT-7 Å, a dehydrated clay mineral of the kaolinite group, a clay material in the meaning of the patent.

c)
Feature 2.3 has the following wording: a binder to adhere the clay to the gauze substrate.

The parties are basically in mutual agreement as to the understanding of the feature. However, the question of infringement by the attacked embodiment is disputed, and the Court is not convinced that it has been established. The Applicant has not been able to demonstrate, with a sufficient degree of certainty, that the attacked embodiment contains chitosan as a binder or any other binder.

aa)
In the written submissions the Applicant expressed the opinion that the tests have shown that the attacked embodiment contains chitosan. The attacked gauze material was tested by the Cambridge Polymer CPG. They rinsed the gauze with deionized water. The rinsate was evaluated by CPG in a FTIR analysis (Exhibit K 22, p.2 and 3.). The below depicted figure 5 of the CPG report shows the FT-IR spectrum obtained from this rinsate in a blue line.

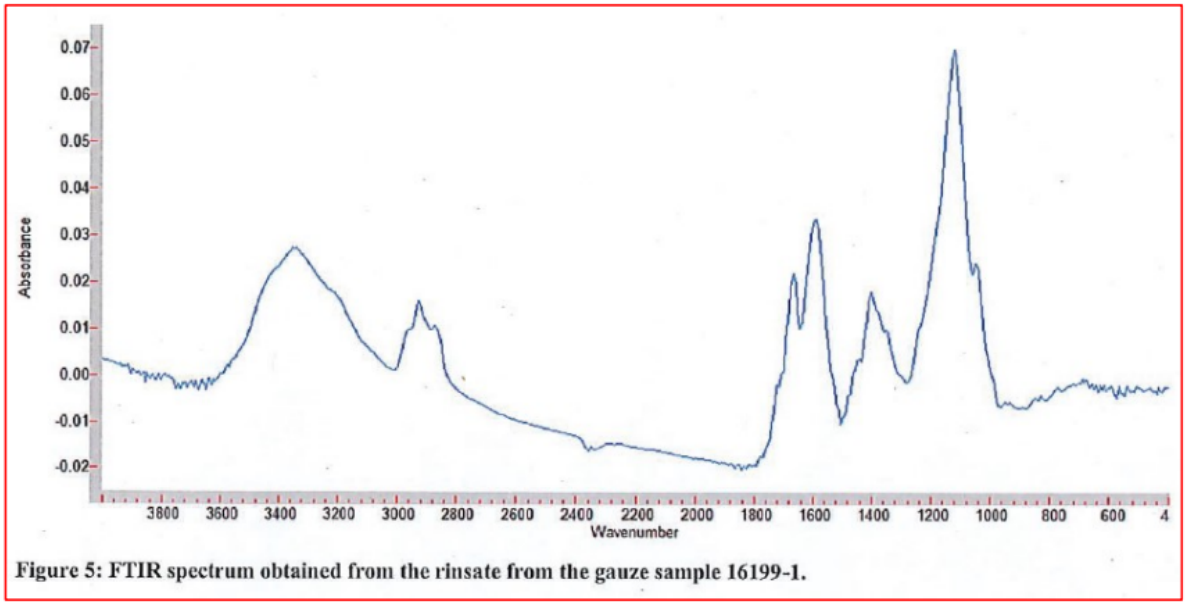


Figure 5: FTIR spectrum obtained from the rinsate from the gauze sample 16199-1.

Figure 6, following, shows this spectrum (in black) compared to the FT-IR spectrum for chitosan powder, taken from the Know-it-all database:

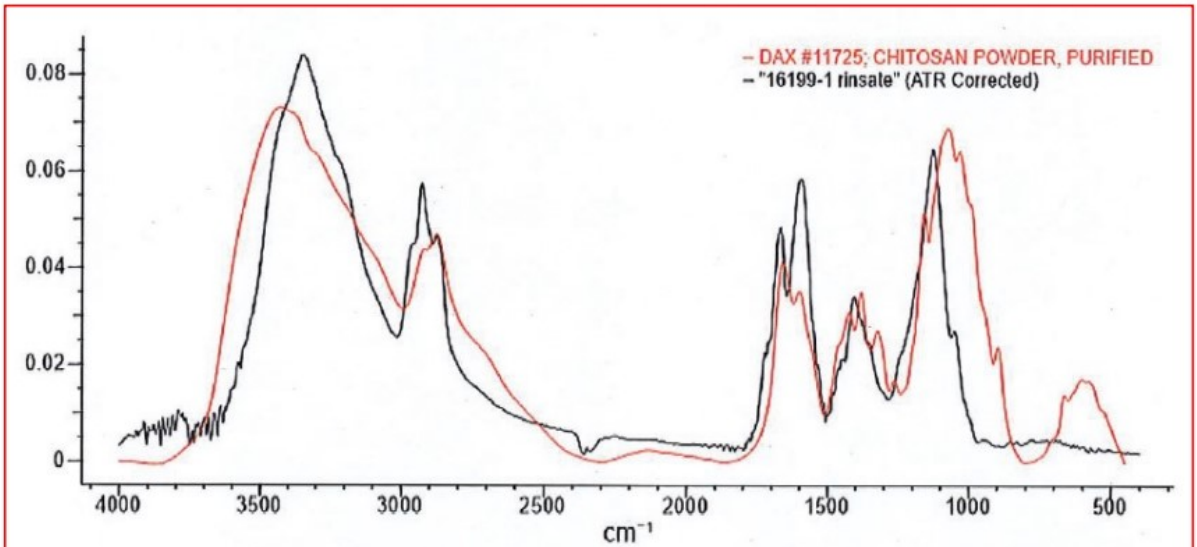


Figure 6: Overlay of FTIR spectrum of rinsate from the gauze sample 16199-1 (black) and the Know-It-All database spectral match (orange) of chitosan powder (hit quality index = 73.80).

The Applicant is of the opinion that the direct comparison in figure 6 proves that the rinsate contains chitosan. The CPG reports states in Exhibit K 22, p. 3:

> "The rinsate was also scanned, with the spectrum shown in figure 5, and the spectrum is distinctly different from the Halloysite reference material. The rinsate spectrum was compared to spectra from the Know-It-All spectral library, including chitosan (match of 73,8%). Chitosan crosslinked with glutaraldehyde was used by some to coat Halloysite to improve drug release, and the peak at 1120 cm^{-1} could be associated with glutaraldehyde."

The Defendant disputes correctly that CPG has detected chitosan.

First, the signals of the FT-IR spectroscopy are not completely overlapping. That might be normal, but there are slightly different peaks. This could be caused by other functional groups similar to the ones of chitosan having been detected.

Second, the Defendant explained convincingly via the Heppe statement (Annex WKS 20) why the central thesis of the Applicant, the presence of a "peak" at 1120 cm^{-1} in the FT-IR spectrum of the rinsate produced, which CPG had regarded as an indication of cross-linking of HNT with glutaraldehyde (see Annex K 22 p. 3), is wrong.

CPG cited insofar *Massaro et al.*, 2020. *Massaro et al.* refer in footnote [59] - to an article published in 2013 by *Zhai et al*. They compare various FT-IR spectra of HNTs with reference to Fig. 3, whereby the spectrum relevant to CPG's central thesis is labeled "(c) HNTs-CTS-GTA". Fig 3 from *Zhai et al* is reproduced below:

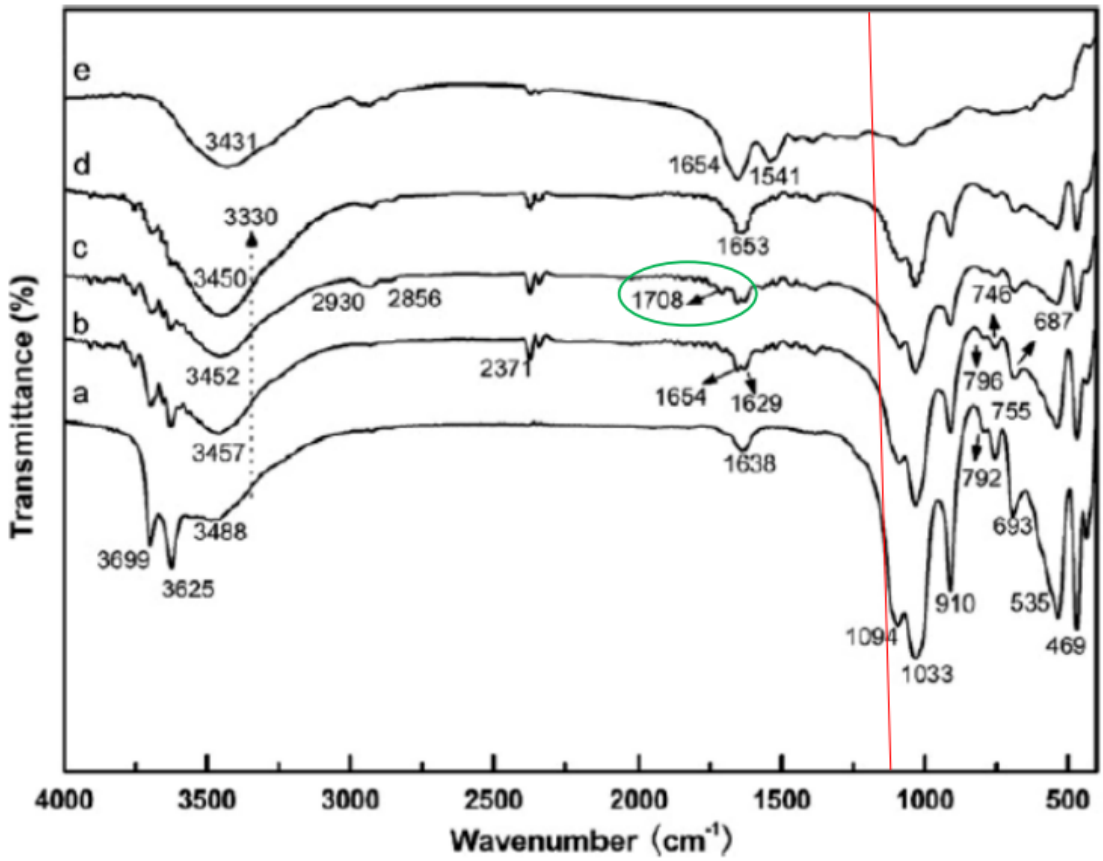


Fig. 3. FT-IR spectrum of (a) HNTs, (b) CTS–HNT (c) HNTs–CTS–GTA, (d) HNTs–CTS–GTA–HRP, (e) free HRP.

Heppe is of the opinion that - as can be seen above (red vertical line added by the Defendant, also green ellipse) - no specific peak can be recognized in Fig. 3 at the wavelength 1120 cm^{-1} of the spectrum (c) and is not even discussed in the article by *Zhai et al.* Accordingly, the assumption made by CPG seems to be the result of an unquestioned statement taken from the article by *Massaro et al* without verification.

In addition, a band of 1708 cm-1, which should be characteristic for a cross-linking of chitosan with glutaraldehyde, is not shown in the attacked embodiment (Heppe statement, Fig. 5, p. 5):

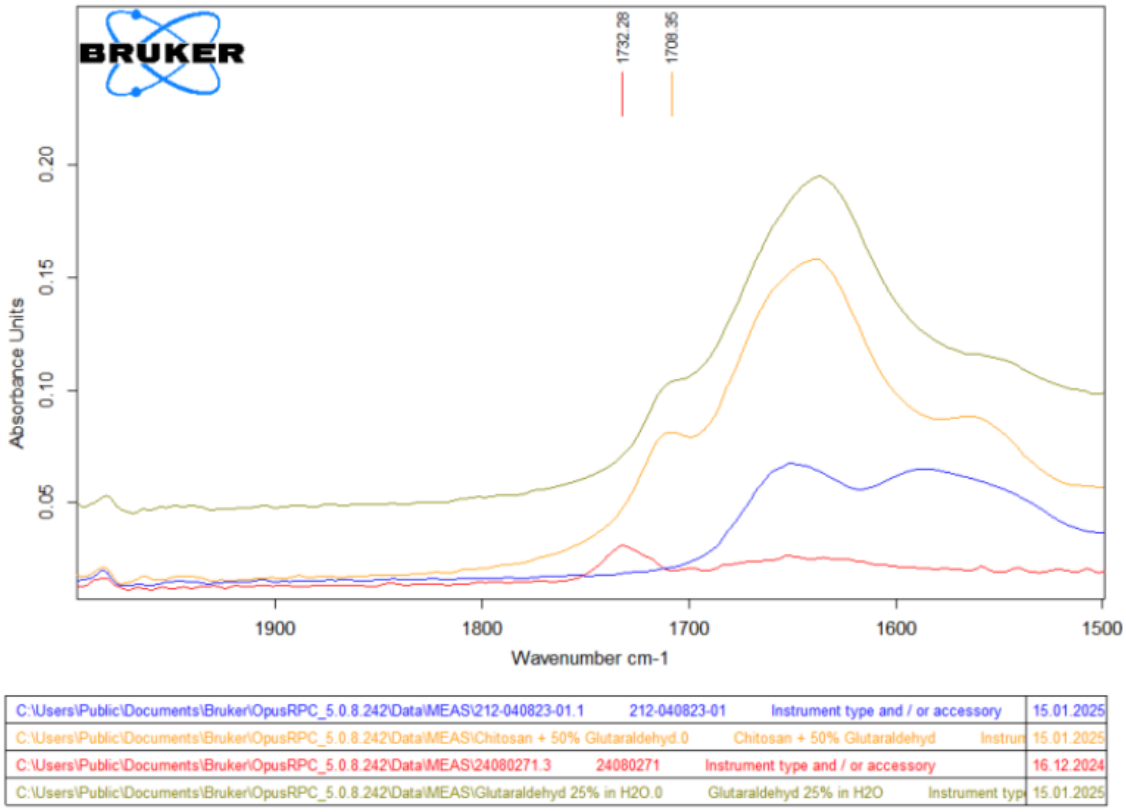


Figure 5 FTIR spectra from Glutaraldehyde (green) in comparison to Chitosan 212-040823-01 (blue), SpeedM (24080271) and crosslinked chitosan with Glutaraldehyde (orange)

It can be concluded that the cross-linking of chitosan with glutaraldehyde assumed in the CPG report could be based on the scientifically untested thesis of a characteristic band of 1120 cm^{-1}. According to the references used by the CPG, a characterizing peak would be at 1708 cm^{-1}, which the spectrum of the SpeedM product examined does not exhibit.

Furthermore, a probability of 73.8% is not sufficient for providing an indication of the presence of chitosan as a binder. The Defendant has examined the Applicant's CPG report for its scientific robustness by the expert [redacted] [redacted] graduate biologist and specialist biologist for toxicology, member of the management at BIOSERV Analytik und Medizinprodukte GmbH, Rostock (Exhibit WKS 8). As a result of her review of the CPG report, she came to the following conclusions:

> "1. The Cambridge Polymer Group laboratory is accredited to 17025, but the method used in Report 16199-1 is not part of the accreditation.
> 2. This report does not meet the requirements of 17025. Information on the clear identification of the tested test material and on sample preparation is missing. A clear assignment of the samples and the test procedure is not possible on the basis of the report.
> 3. The interpretation of the results is questionable from a scientific point of view. The database used for identification is debatable as the sole basis; furthermore, the assumption of identity with 73.8 % agreement is not state of the art.
> 4. The comparison of a finished/complete product with an individual component from this or a comparable product is not meaningful from a scientific point of view."

This confirms that identifications with probabilities below 80% are generally considered uncertain and require additional analysis or confirmation methods. Low values, such as the HQI of

73.80 % found, could indicate overlapping spectra, the presence of impurities or insufficient database entries. Therefore, further analytical techniques such as gas chromatography-mass spectrometry (GC-MS) or nuclear magnetic resonance spectroscopy (NMR) are necessary to verify the identification.

The Applicant's assertion that the Defendant's own patents demonstrate the use of chitosan is also unconvincing. None of the claims 1-5 of EP 3 655 050 B1 mention the use of a binder. They define the composition and arrangement of the halloysite and the textile substrate without specifying the need for a binder. Only dependent claim 6 claims as advantageous a device in which the halloysites are applied to the textile substrate by means of deionized water and a binder (acrylate or gelatine). It has been recognized that the hemostatic effect of the halloysite can be further improved by the addition of a binder (see EP'050 para [0029]). The low mass concentration of the optionally used binder indicates the inherent properties of halloysite to effectively develop its hemostatic and biocidal effects (e.g. EP'050 para. [0006]) even without a binder. As in the patent application, EP'050 therefore proposes the preparation of a clay or halloysite-water suspension (without binder) for application to a textile substrate as a rule, even if the suspension is applied by means of a printing technique (see claim 10, which refers back to all the preceding claims). Moreover, EP'050 assumes that a suspension of halloysite, water and binder is advantageously produced, and this suspension is "applied to the textile substrate", i.e. a "binder in between" within the meaning of feature 2.3 is not mentioned here. The application WO 2020 173 665 A1 discloses the production of a paste from barite/barium sulphate, halloysite and a water component as well as the application of such a paste by printing on a textile structure. Water is necessarily used in the production of the mineral paste (claims 1 and 10). The use of a water and binder component is only claimed as advantageous in dependent claim 2 and is described as advantageous in WO'665 from p. 6 ll. 19 ff. It can be concluded that some embodiments mention a binder, but this does not apply to all embodiments. Furthermore, there is no principle that obliges a patent holder to use his technical rights.

In contrast, the Heppe Medical Chitosan GmbH analyzed the composition of two gauze samples, SpeedM and QuikClot using FTIR spectroscopy to determine the presence of chitosan (Exhibit WKS 9). As a result, it was found that the FT-IR spectra indicates that the SpeedM gauze sample does not contain chitosan. Insofar as the Applicant contests that the tested product by Heppe was prepared in a sufficient way, that the product was not fed in its entirety to the ATR analyses carried out, the Heppe report (Annex WKS 9) describes in para 2.3 that the sample was pressed directly onto the ATR crystal, which does not contradict a proper experimental procedure.

The Defendant further presented written testimonies of its suppliers (Exhibit WKS 14 to 17, partially blackened; WKS 14’ to 17’ unredacted) stating that chitosan is not part of the supplied products: fiber material for the production of the cellulose substrate, of the cellulose nonwoven, printing paste and finished product. The statements might not be decisive to prove the absence of chitosan but provide an indication that chitosan is not used.

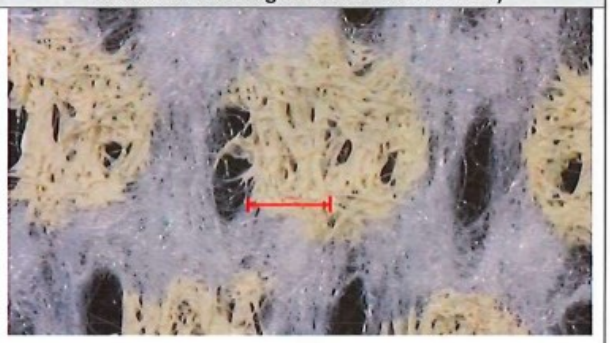
Insofar the analysis of CPG shows that according to the energy dispersive spectroscopy (EDS), the gauze sample does not contain any nitrogen (N), this fact does not support the opinion of the Defendant. Pure chitosan (deacetylated) contains 8.7 % of nitrogen, chitin (100 % acetylated) 6.9%. The absence could lead to the conclusion that the gauze samples do not contain chitosan. The Applicant has argued that nitrogen is generally not detectable by Energy Dispersive x-Ray Spectroscopy (EDS). EDS measures x-rays emitted when an electron beam interacts with the sample. Since nitrogen has only very weak x-ray emission lines, it might be very difficult to detect nitrogen at all with an EDS analysis, especially when nitrogen is present in low concentrations.

The Defendant did not contest this argument. The absence of N does not necessarily imply that chitosan is not present. The EDS analysis by itself however cannot prove its presence.

There is thus not sufficient evidence that the attacked embodiment contains chitosan as a binder.

bb)
In the oral hearing – after the introduction of the Court – no further argument has been made regarding the presence of chitosan in the attacked embodiment. Rather, the Applicant focused on that the presence of a binder is evident. It alleges that the photography on page 2 of the Z-MEDICA test report (Exhibit K 28) proves the existence of a binder since the HNT particles stick together.

The court is not convinced. Reproduced below are the photographs the Applicant referred to:

Photos of Packaged and Un-Packaged Product	Microscopic Image of Product (Red 1 mm Scale Bar Included for Magnification Reference)
	

It does not prove that the attacked embodiment contains a binder.

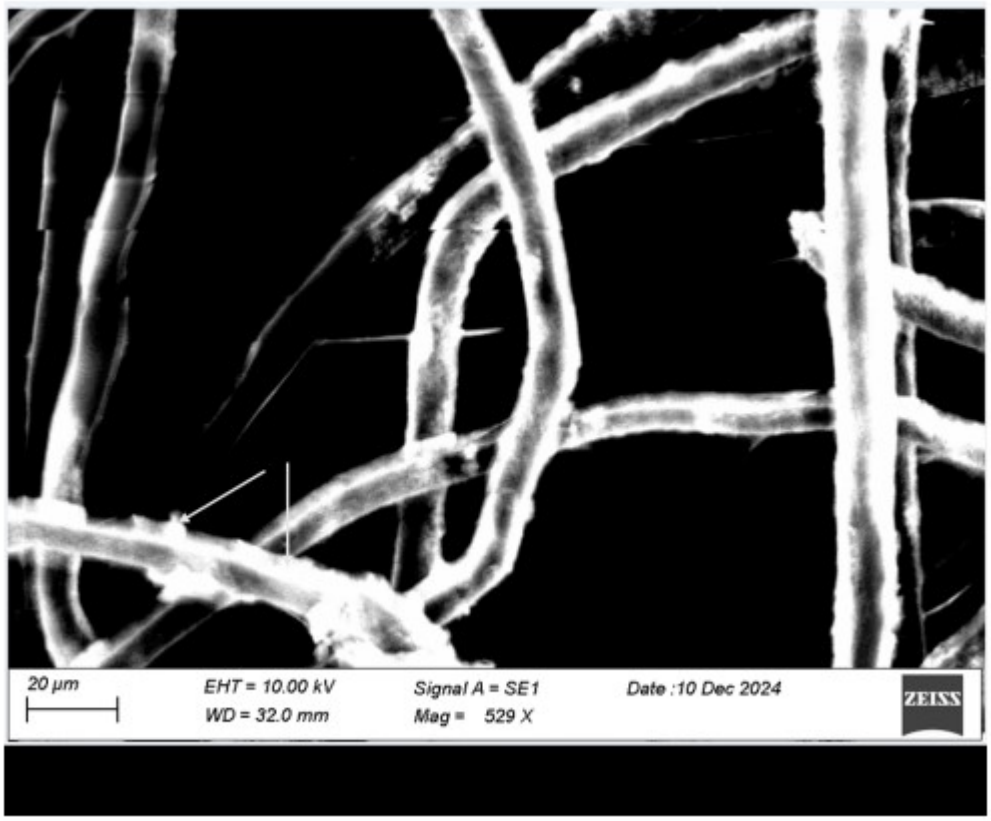
As can be seen in the photograph, in the light-yellow areas elongated fibres stick together. The Applicant is of the opinion that this proves the existence of a binder. Otherwise, the dry material would fall apart without a binder.

However, the HNT particles of the attacked embodiment would not be made visible at the selected magnification. The particles have a size of 0.00005 mm. By contrast, the magnification in the photograph is 1 mm, as the red arrow makes apparent. Due to the size differences, the HNT particles of the attacked embodiment could not be made visible using the selected magnification. Therefore, it is very difficult to draw any conclusions based on the photograph.

The Applicant has also not provided any other evidence that the attacked embodiment contains a binder. The explanations remain on the surface and are merely assumptions. Insofar as the Applicant alleges that the presence of a release agent, which can also perform the function of a binder, is sufficient, the Court finds that this position is not convincing. The patent in suit states in paras [0046] and [0060] that, for example, polyvinyl alcohol (which also has release characteristics) can be used as a binder. However, there is no evidence that the attacked embodiment contains polyvinyl alcohol or any of the other binders mentioned in the patent in suit. The sup-

plementary written testimony of Mr. [redacted] (Exhibit WKS 18) confirms this in point 3. The Applicant has not presented any evidence to the contrary.

In this respect, the Applicant has not shown sufficient evidence that the attacked embodiment contains a binder. On the contrary, the Defendant alleges that mechanical-physical properties of the HNT-7 Å nanotubes are used to securely attach the halloysite to the Lycocell material of the gauze by means of interlacing and electrostatic processes. Reproduced below is a scanning electron microscope image from the University of Greifswald:



The image shows, the Defendant alleges, halloysite agglomerations with mechanical adhesion to the cellulose fiber (see arrows). The cellulose carrier matrix produced using the hydroentanglement process is given a roughened surface during the production process, into which the specially processed halloysite/halloysite agglomerations hook directly. In this way, a mechanical bond with the carrier is achieved. Palladium sputtering provides contrast for the images. The exact process is a trade secret of the Defendant.

Regardless of whether this allegation is true, in any case the Applicant was unable to demonstrate with the necessary certainty that the attacked embodiment contains a binder. In this respect, a reversal of the burden of proof does not apply.

4.
As the Court cannot establish, with a sufficient degree of certainty, an infringement of the patent in suit by the attacked embodiment, there is no need to discuss the validity of the patent and the other requirements for ordering preliminary measures.

5.

The amount of interest of € 500.000,- is not in dispute between the parties and appears appropriate.

6.
In view of the urgency of the proceedings, a translation of the exhibits is not deemed necessary. The submissions reflect the essential content.

ORDER

1. The Application for provisional measures dated November 18, 2024 is dismissed.

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

3. The value of the dispute is set to € 500.000.

4. It is ordered that exhibits originally in German do not need be translated.

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_701/2024
Order number	ORD_68880/2024
Related proceeding no.:	61342/2024
Application Type:	Application for provisional measures

Sabine Klepsch Presiding Judge und Judge-rapporteur	Sabine Maria Klepsch Digital unterschrieben von Sabine Maria Klepsch Datum: 2025.02.20 09:32:01 +01'00'
Dr. Stefan Schilling Legally qualified Judge	Stefan Schilling Digital unterschrieben von Stefan Schilling Datum: 2025.02.20 10:23:27 +01'00'
Stefan Johansson Legally qualified Judge	Stefan Erik Johansson Digitally signed by Stefan Erik Johansson Date: 2025.02.20 10:05:41 +01'00'

Jeroen Meewisse Technically qualified Judge	Jeroen Willem Meewisse Digitaal ondertekend door Jeroen Willem Meewisse Datum: 2025.02.20 15:17:47 +01'00'
For the sub-registry	Carolin Bauch Digital unterschrieben von Carolin Bauch Datum: 2025.02.20 15:22:40 +01'00'