Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Local Division Hamburg

UPC_CFI_685/2024
UPC_CFI_157/2025

Decision of the Court of First Instance of the Unified Patent Court delivered on 27/04/2026

HEADNOTES:

1. The inclusion of 51 auxiliary claims in the counterclaim for revocation may be justified in individual cases where the legal basis of the patent in suit is subject to multiple challenges.
2. An amendment to the counterclaim for revocation, adding a further claim to be revoked, must be rejected if the patent proprietor otherwise would be put in a situation where he/she would not be given sufficient time to properly address the new attack.

CLAIMANT:

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,

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

DEFENDANT:

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

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: Infringement action and counterclaim for revocation

PANEL/DIVISION:
Panel of the Local Division Hamburg

DECIDING JUDGE/S:
Full Panel

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

ORAL HEARING:
23.01.2026, 10:00

SUMMARY OF FACTS

1 The Claimant 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.

2 The Claimant claims to be the proprietor of the European Patent EP 2 077 811 B1 (hereinafter: patent in suit or the 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).

3 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.

4 The patent consists of 15 claims. The Claimant has based its present infringement action on claim 1, especially claims 2, 3, 7 and 9 and auxiliary on claim 1 in conjunction with claim 9.

5 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.

6 Claim 2 reads as follows:
The device of claim 1, wherein said clay material (14) is kaolin.

7 Claim 3 reads as follows:
The device of claim 1, wherein said clay material (14) is selected from the group consisting of attapulgite, bentonite, kaolin, and combinations of the foregoing materials.

8 Claim 7 reads as follows:

The device of claim 1, wherein said gauze substrate (62) is fabricated from a material selected from the group consisting of cotton, silk, wool, plastic, cellulose, rayon, polyester, and combinations of the foregoing.

9 Claim 9 reads as follows:
The device of claim 1, wherein said binder is chitosan.

10 With its submission of November 11, 2024, the Claimant filed an infringement action directed against the marketing of the Defendant's contested embodiment SpeedM emergency hemostatic dressing. One week later, on November 18, 2024, the Claimant submitted an application for provisional measures. On 21 February 2025, the Local Division Hamburg dismissed the application for provisional measures.

11 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 Durtec GmbH, 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 Durtec at that time and also took over the management of the Defendant. [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.

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

13 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:

Infringement action

14 With its Statement of Claims November 11, 2024, the Claimant 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, ltaly, 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, within a period of 30 days after service of the notification within the meaning R. 118 (8) S.1 RoP and, if applicable, the certified translation,

1. to provide the Claimant with written information in an electronic editable form on the extent to which they have committed the acts described in section I. since November 11, 2019 stating in each case

(a) origin and distribution channels of the products referred to under section I.;
(b) the quantity produced, manufactured, delivered, received, or ordered, and the prices paid for the products referred to under section I.;
(c) the identity of all third parties involved in the production or distribution of products referred to under section 1.;
(d) the quantity and the data of products offered;
(e) the advertising carried out, broken down by advertising media, their circulation figures, distribution period and distribution area, including evidence for theses advertising activities;
(f) the costs broken down by the individual cost factors and the profit generated,

whereby the relevant supporting sales documents (namely invoices, alternatively delivery notes) must be submitted in copy with the proviso that details requiring confidentiality and outside the data subject to disclosure and notification may be redacted;

2. to recall the products referred to under section I. by informing the third parties from whom the infringing products are to be recalled that this court has found that the

products infringe the European Patent EP 2 077 811 B1, whereby the defendants have given the third parties a binding undertaking to reimburse the costs incurred, to bear the packaging and transport costs incurred, to reimburse the customs and storage costs associated with the return of the products and to take back the products;

3. to permanently remove the products referred to under section I. from the distribution channels by informing third parties who are industrial customers, but not end users, with regard to the products referred to in section I. that this court has found that the products infringe the European Patent EP 2 077 811 B1 and by inviting those to cancel all orders relating to the products referred to in section I.,

   to destroy the products referred to under section |. which are in the possession of the defendant and to submit to this court and the claimant written evidence of the action taken, and

   to submit to this court and the claimant within the aforementioned period of 30 days from the service of the notification within the meaning of Rule 118 (8) sentence 1 RoP and, if applicable, the certified translation, written evidence of the actions taken, as referred under section II 3 p.1 and 2.

III. In each case of non-compliance with
a. the order pursuant to section I. and
b. the orders pursuant to section II

the Defendant shall pay a repeated penalty payment to the court, the amount of which shall be determined by the court.

IV. The Defendant is obliged to compensate the Claimant for all damages which he has suffered and will suffer as a result of the acts described in section I. and committed since November 11, 2019 during the term of the European patent EP 2 077 811 B1.

The Defendant is also ordered to provisionally pay EUR 50,000.00 as flat-rate compensation for damages.

V. The orders in sections I, II and IV sentence 2 are only enforceable after the claimant has informed the court which part of the orders he intends to enforce and has submitted a certified translation of the orders into the official language of the contracting member state in which enforcement is to take place and after the notification and the (respective) certified translation have been served on the defendant.

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

15 In its Reply to the Statement of Defence (25 April 2025) the Claimant amended its requests and introduced an amended request in **item II.2. and 3**.

II. The Defendant is ordered within a period of 30 days after service of the notification within the meaning of R. 118 (8) S.1 RoP and, if applicable, a certified translation (…)

2. to recall the products referred to under section I. by informing the third parties, who are industrial customers from whom the infringing products are to be recalled, that this court has found that the products infringe the European Patent EP 2 077 811 B1, whereby the defendants have given the third parties a binding undertaking to reimburse the costs incurred, to bear the packaging and transport costs incurred, to reimburse the customs and storage costs associated with the return of the products and to take back the products;

3. to permanently remove the products referred to under section I. from the distribution channels by informing third parties who are industrial customers, with regard to the products referred to in section I. that this court has found that the products infringe the European Patent EP 2 077 811 B1 and by inviting those to cancel all orders relating to the products referred to in section I.,

to destroy the products referred to under section I. which are in the possession of the defendant, and

to submit to this court and the claimant within the aforementioned period of 30 days from the service of the notification within the meaning of Rule 118 (8) sentence 1 RoP and, if applicable, the certified translation, written evidence of the actions taken, as referred under section II 3 sentence1 and 2.

16 The Defendant requests:

I. to dismiss the infringement action;

in the alternative, if the Local Division grants motion II.1, set a deadline of 90 days after service of the notification pursuant to R. 118 (8) 1 RoP and proof for the provision of enforcement security;
further in the alternative, if the Local Division grants motion II.1: order that the information be subject to adequate confidentiality measures;
further in the alternative, if the Local Division grants motion IV. regarding an interim award of damages: to limit the payment obligation to EUR 3,000.00 and to make the payment obligation subject to the condition that the Claimant initiates damages proceedings against the Defendant;
in the further alternative, to make the payment obligation subject to the condition that

a payment made upon a respective order of the Court is to be paid back if the Claimant does not initiate damages proceedings or the reimbursable costs of the damages proceedings is lower than the awarded provisional damages, and
that the Defendant may pay the interim damages to a trust account of attorneys-at-law Wildanger Kehrwald Graf v. Schwerin & Partner mbB, Düsseldorf, (in a further alternative: attorneys-at-law Grünecker, Munich) and to authorize and oblige the latter to pay the amount to the plaintiff only upon proof that proceedings for dam-ages have been initiated; further in the alternative: to make enforcement of the decision subject to provision of a security or equivalent guarantees in the amount of at least EUR 25 million;

II. order the Claimant to bear the legal costs and other expenses incurred by the Defendant.

The Defendant further requests,

that exhibits originally in German do not need to be translated.

Counterclaim for revocation

With its Counterclaim (24 February 2025) the Defendant requests:

I. that the EP 2 077 811 B1 be revoked to the extent of claims 1, 2, 3, 7, and 9 for the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark (without Faroe Islands and Greenland), the Republic of Finland, the French Republic (without New Caledonia and French Polynesia), the Federal Republic of Germany, the Italian Republic, the Kingdom of the Netherlands (without Aruba), the Portuguese Republic and the Kingdom of Sweden;
II. that the Claimant and Revocation Counterdefendant be ordered to pay the costs.

17 With its submission of 25 April 2025, the Claimant requests

The Counterclaim for Revocation is dismissed;

The Defendant (Revocation Counterclaimant) bear the costs of the Revocation Proceeding.

The Claimant further requests,

to maintain the patent-in-suit in amended form with the claims according to any Auxiliary Requests 1, 1a to 26a, 27 (in this order), submitted in Annex K69.1 and K 69.2 (Reference is made to the wording of the Auxiliary Requests submitted in Annex K69.1 and K 69.2).

18 With Rejoinder to the Reply of Statement of Defence dated 30 July 2025, the Defendant requests that the amendment to the case be rejected because at least one of the specified grounds for admission in R. 263(2) RoP is not met.

19 With application for leave and to further amend the patent of 1 September 2025, the Claimant seeks permission to amend the patent stepwise in the following conditional manner:

a) In a first step, amend the set of 51 auxiliary requests already submitted by completely deleting Amendment C. This entails:

Retaining the originally submitted Auxiliary Requests AR 1, 1a, 2, 2a, 3, 10, 10a, 11, 11a, 12, 19, 19a, 20, 20a, and 21.

Deleting Auxiliary Requests AR 3a, 4, 12a, 13, 21a, and 22.
Revising and substituting the remaining Auxiliary Requests with the Auxiliary Requests Aux 4a, 5, 5a, 6, 6a, 7, 7a, 8, 8a, 9, 13a, 14, 14a, 15, 15a, 16, 16a, 17, 17a, 18, 22a, 23, 23a, 24, 24a, 25, 25a, 26, 26a, and 27, as submitted in Annex K72.1 and K72.2.

b) In a second step, additionally or alternatively, add Auxiliary Requests Aux MR+, 9a, and 18a, as submitted in Annex K73.1 and K73.2. Specifically:

Auxiliary Request MR+ would become the new first Auxiliary Request.
Auxiliary Request 9a would be inserted between Auxiliary Requests 9 and 10.
Auxiliary Request 18a would be inserted between Auxiliary Requests 18 and 19.

Alternatively, the Claimant requests that the patent in suit be maintained in an amended form according to any of the revised or newly added Auxiliary Requests MR+, 4a, 5, 5a, 6, 6a, 7, 7a, 8, 8a, 9, 9a, 13a, 14, 14a, 15, 15a, 16, 16a, 17, 17a, 18, 18a, 22a, 23, 23a, 24, 24a, 25, 25a, 26, 26a, and 27, as submitted in: Annexes K72.1, K72.2, K73.1, and K73.2.

Reference is made to the wording of the Auxiliary Requests submitted in Annex K72.1 and K 72.2 and K73.1 and K 73.2.

20 With submission dated 1 October 2025, the Defendant requests:

I. that the European Patent EP 2 077 811 B1 be revoked to the extent of claims 1, 2, 3, 7, and 9 and 15 for the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark (without Faroe Islands and Greenland), the Republic of Finland, the French Republic (without New Caledonia and French Polynesia), the Federal Republic of Germany, the Italian Republic, the Kingdom of the Netherlands (without Aruba), the Portuguese Republic and the Kingdom of Sweden;

II. that the Claimant and Revocation Counterdefendant be ordered to pay the costs.

21 With submission of January 15, 2026, the Claimant applied for the grant of an opportunity to adjust the Claimant's requests in the infringement proceeding in case the court allows the second amendment of the claims of the patent in suit as requested by the Claimant with writ of September 1, 2025.

POINTS AT ISSUE

22 The Claimant asserts that it is entitled to enforce the claims at issue. The application for the patent in suit was filed by Z-Medica Corporation. Z-Medica Corporation merged in Z-Medica LLC as of August 31, 2012, for which a confirmation of the State of Delaware and the Certificate of Formation of Z-Medica LLC was submitted (Exhibit K 5), issued by the State of Delaware. Z-Medica LLC assigned the patent in suit on December 10, 2021 to TFX Equities Incorp., and TFX Equities Incorp. on the same day to Teleflex Medical Devices S.A.R.L (Exhibit K 6). On December 10, 2021, Teleflex Medical Devices S.A.R.L. assigned the patent in suit to Teleflex Life Science Ltd (Exhibit K 7). In Exhibit K 8 an agreement between Z Medica 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 (Exhibit K 9), to Teleflex Life Sciences II LLC. On December 18, 2023, Teleflex Life Sciences II LLC merged into Teleflex Technologies LLC, as proven by the Merger Certificate of the State of Delaware (Exhibit K 10). Teleflex Technologies LLC changed its name to Teleflex Life Sciences II LLC, as shown by the Certified Confirmation of the State of Delaware of December 19, 2023 (Exhibit 11). The Claimant 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.

23 The Claimant asserts further that the Defendants attacked embodiment infringes the patent in suit. It is of the opinion that the term "flexible gauze substrate" does not include felt material, but it must have the ability to get in contact with clay material by means of adhering clay material using a binder. In addition, 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. "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 Claimant is further of the opinion that the term "binder" is to be understood in a broad way und defined by its function to adhere the clay to the gauze substrate. The term is not limited by the type of bond between the clay material and the binder.

24 The Claimant claims in the statement of claim 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 Claimant asserts that the direct comparison proves that the rinsate contains chitosan.

25 With its Reply to the Statement of Defence the Claimant presented tests of the Technical University of Munich and expert opinions. The Claimant asserts that the attacked embodiment contains Polypropylen glycol (PPG) and Polyacrylnitrile (PAN) as binding material.

26 The Defendant argues that the Claimant's requests must be denied.

27 It disagrees with the Claimant's construction of the claim. "Clay" in the meaning of the patent is an aluminium silicate with an H_2O binding ability 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 bound per se. Due to the structural flexibility of the layered plates of silicon tetrahedra (SiO_4) and aluminum octahedra ($Al(OH)_6$), 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. The meaning of the term "binder" is disclosed in the patent with regard to a rather specific technology for applying clay to the gauze substrate, namely a kind of bonding by means of a binder or adhesive. The Defendant reasoned that, according to all embodiments that describe the claimed invention, particlized kaolin is to be attached to one side of the gauze substrate using a "binding agent", whereas on the opposite side of the gauze substrate, a "release agent" is to be applied to prevent the wound contacting side of the gauze from adhering to the device, and whereby said release agent can be chosen from e.g. PVA, silicone, gelatinized starch or produced as "a slurry of release agent and clay material". Since the very same substances can, thus, be interchangeably used both either as binding agents or release agents, the patent requires differentiation based on the specific technology with which it is applied to the device.

28 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.

29 The Defendant does not dispute the assertion in the further tests that the attacked embodiment contains Polypropylenglycol (PPG) and Polyacrylnitrile (PAN). It further adds that it contains urea. But the Defendant states that the compounds do not function as binders; they stabilize the fibres. The secure attachment of HNTs is purely by physical and mechanical means, without the use of binders or chemical bonding agents. The images and spectral findings submitted by the

Claimant do not prove the use of a chemical bonding agent, but rather make the physical adhesion phenomena plausible (hydrogen bonds, electrostatic attraction, Van der Waals forces, mechanical interlocking, capillary forces caused by thermal processes).

30 Regarding the validity of the patent the Defendant is of the opinion that the subject matter of the claims 1, 2, 3, 7 and 9 of the patent in suit is exceeding the disclosure of the application as originally filed (Exhibit K 4). Furthermore, the alleged invention of the patent in suit cannot even remotely be carried out in the entire claimed breadth of claim 1. At no point in the description is it explained how the binder must be used in order to achieve the alleged objective. The selection of the combination of binder, clay and gauze material will also play a decisive role here. However, the patent specification is also completely silent on this point. The only combination mentioned is that of kaolin with chitosan or polyvinyl alcohol. However, the substrate to which such a combination can be bound is not mentioned.

31 In addition, the patent is not novel. The disclosures in each of the documents EP 0 116 240 A1(N2 = Exhibit WKS H 12), EP 1 107 051 A2 (D1 = Exhibit WKS H3), WO 2006/088912 A1 (D3 = Exhibit WKS 1) and WO 2007/074326 A1 (N24 = Exhibit WKS H6) are novelty destroying.

32 Furthermore, the patent in suit is not based on an inventive step. The combination of WO2006/102008A1 (N1 = Exhibit WKS H9) with D3 (attack 1), D3 with N2 (attack 2), WO 02/30479 A1 (D2 = Exhibit WKS H 8) alone (attack 3) and D2 with WO 2006/102008 A1 (N1 = Exhibit WKS H 9) (attack 4) would lead the person skilled in the art to the invention, i.e. makes the invention obvious. The same applies to the numerous auxiliary requests.

33 The Claimant disputes these entire arguments and, with regard to the disclosure in D3, contends that the argument is based on hindsight. D3 discloses a vast number of different options and a long list of potential additives. The person skilled in the art would have to select from quite a few examples in order to obtain the technical teaching according to the patent in suit.

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

GROUNDS FOR THE DECISION

35 Both the Counterclaim for revocation and the infringement action are admissible. The Counterclaim is successful on the merits, the infringement action is therefore unfounded.

INTERNATIONAL JURISDICTION

36 The UPC's international jurisdiction and the LD Hamburg's competence is not disputed. According to R. 19.7 RoP this shall be treated as a submission to the jurisdiction of the Court and the competence of the division chosen by the claimant.

ADMISSIBILITY

37 The Infringement action and the Counterclaim for revocation are admissible.

A. Infringement action

38 The Claimant is entitled to bring the Infringement action before the Unified Patent Court pursuant Art. 47 (1) UPCA, because the Claimant is deemed to be the proprietor of the patent-in-suit.

39 The patent proprietor is entitled to bring actions before the Court (Art. 47.1 UPCA). According to Rule 8.5 (c) RoP, there is a rebuttable presumption that the person shown in each national patent register and the European Patent Register is the person entitled to be registered as proprietor.

40 The rebuttable presumption means that the burden of substantiation and proof now lies with the Defendant (UPC_CFI_463/2023, decision by LD Dusseldorf of 30 April 2024). He must substantiate that the Claimant is not the proprietor of the patent-in-suit and that the entry in the register is therefore incorrect. It is not sufficient to simply dispute the ownership of the patent or the effectiveness of a patent assignment. Rather, the Defendant must present specific facts from which it can be concluded that the Claimant is not the patent proprietor.

41 In the case at hand, all the national patent registers list Teleflex Life Sciences II LLC, the Claimant, as the registered proprietor of the patent in suit (see Exhibit K 13 and K 40). As far as the Defendant alleges that this is not the Claimant but the previous Teleflex Life Sciences II LLC, this is just an allegation without any proof.

42 Moreover, even if one would assume that the old Teleflex Life Sciences II LLC was still registered in one or more national patent registers, with the merger of this old Teleflex Life Sciences II LLC into Teleflex Technologies LLC in December 2023 (Annex K10), all assets of the old Teleflex Life Sciences II LLC automatically passed to the second-named company. Teleflex Technologies LLC was the legal successor to the old Teleflex Life Sciences II LLC. Teleflex Technologies LLC changed its name to Teleflex Life Sciences II LLC just one day after its merger with Teleflex Life Sciences II LLC (cf. in this respect Annexes K10 and K11).

43 That the merger and the transfers before are not valid, is not sufficiently disputed by the Defendant. Furthermore, that the complete chain of transfers in the respective national patent registers is valid, is not of relevance. All parties involved in the transfer acts of December 2021 as members of the same company group have again confirmed the transfer of the patent-in-suit within this chain in writing in a Recordable Assignment Agreement dated 10 December 2021 (Exhibit K 8). Thus, they have confirmed the transfer of the patent within the described chain of transfer by means of a written declaration. This strengthens the effect of presumption of the register according to Rule 8 (5) RoP.

44 Therefore, the Claimant is entitled to sue. The Defendant did not present any further convincing arguments in its rejoinder after the Claimant had stated that it is now registered in all national

patent registers. As far as the Defendant alleges the Belgian patent register would show that the former Teleflex Life Sciences II LLC is registered because the change of the name was registered as a sale and not as a merger, this is not of relevance. Even if the former Teleflex Life Sciences II LLC is still mentioned, with the merger all assets of the old Teleflex Life Sciences II LLC automatically passed to the second-named company. Both companies are therefore a unity.

45 Admissibility of the infringement action is clear and undisputed.

B. Counterclaim for revocation

46 The admissibility of the counterclaim for revocation is clear and undisputed.

Application to amend the patent

47 The Claimant's application to amend the patent is admissible. The Defendant has challenged the admissibility with respect of the number of auxiliary requests (hereinafter: AR). The Claimant has introduced 51 AR and the Defendant is of the opinion that this number is not appropriate within the meaning of R. 30(1) RoP and therefore inadmissible. The Defendant argues that the question is how many attempts the Claimant should be allowed to find a patentable claim. In answering this, all relevant circumstances of the case and the interests of the parties must be taken into account. To ascertain what constitutes a reasonable number of auxiliary requests, several factors must be considered: the complexity of the technology involved, the number of prior art documents, the nature and number of the validity attacks, as well as the presentation and structure of the auxiliary requests (cf. CD Munich, UPC_CFI_526/2024, order of 18 April 2025).

48 In order to determine whether the number of AR conditionally submitted is reasonable, the Court must weigh all the relevant circumstances of the case and the interests of the parties. In the present case, the proposals made by the Claimant are deemed reasonable in number given the circumstances of this case.

49 The arguments provided by the Claimant explaining the high number of requests are convincing. The objections by the Defendant are quite numerous in terms of number of documents and grounds for revocation. The Defendant argues lack of novelty, lack of inventive step, lack of clarity, enablement and inadmissible extension of subject matter. Furthermore, several prior art documents were introduced. The Claimant has to have the opportunity to defend its patent in an appropriate way against this backdrop.

50 Furthermore, the claimed technology and therefore the AR addressing the objections are relatively similar, which reduces the burden for the Defendant in replying to the AR. The set of Auxiliary Requests include two major lines of defence, AR 1 to 27 and AR 1a to 26a. The first subset is addressing the clay material and its medical use. In the second subset of auxiliary requests, the claims are directed to a hemostatic device.

Application to further amend the patent

51 On the other hand, the application to further amend the patent of 1 September 2025 is not allowable. The new AR result from two main amendments:

- Addition of feature K ("for use in treating a severely bleeding wound") and
- the deletion of feature C ("the gauze initially exists separately from said clay material").

52 With order of 11 November 2025 the judge-rapporteur held that the decision on whether to allow the amendments is reserved for the oral hearing and invited the Defendant to comment on the merits of the auxiliary requests. The Defendant submitted its brief on 11 December 2025.

53 The application to further amend the patent, R. 30.2 RoP, has to be dismissed.

54 R. 30.2 RoP states that "Any subsequent request to amend the patent may only be admitted into the proceedings with the permission of the Court". The provision confers to the Court the discretionary powers to admit an amendment of the patent even after a previous application to amend that patent has been submitted and even after the expiration of the time period for amending the patent, that is the time period for lodging of a defence to revocation. While using these discretionary powers the Unified Patent Court judges have to observe the principles of proportionality, flexibility, fairness and equity, mentioned in the preamble 2 and 4 of the Rules of Procedures (see, CD Paris, UPC_CFI_412/2023, order of 9 February 2024; UPC_CFI_255/2023, order of 27 February 2024). With particular regard to the admission of a subsequent request to amend the patent, the Court has to take into account, on one hand, the fact that a subsequent amendment of a patent may lead to more efficient proceedings, narrowing the subject-matter and simplifying the procedural activities, and to a proper safeguard of the interest of the patent proprietor in controlling the scope of protection of its exclusive rights. On the other hand, the admission of subsequent requests to amend the patent may affect the purpose of delivering an expeditious decision, forcing an extension of the time of the written procedure in relation to the right of the other parties to arrange the consequent defence, and may undermine the right of defence of these latter parties. In order to enable the Court to strike a fair balance between the opposed interests involved in the request to amend the patent the applicant has to offer a justification of its request, explaining why it has decided to change the original request to amend the patent (LD Dusseldorf, UPC_CFI_733/2024 and 255/2025, order of 12 September 2025, LD Mannheim, UPC_CFI_210/2023, order of 27 June 2024).

55 The Claimant argues that the request is being made to address objections made by the Defendant in the defence to the application to amend the patent and after re-evaluation of the validity situation of the previous auxiliary requests in light of these objections. The first amendment is a pure deletion of Amendment C. The second amendment is the introduction of the feature "severely bleeding", which has already been discussed.

56 The requested amendments are, according to the Claimant, necessary to address the Defendant's objections under Article 84 EPC concerning the clarity and conciseness of the claims in Auxiliary Requests 4-9, 13-18, 20-27, as well as AR 3a-8a, 12a-17a, and 21a-26a. The deletion of Amendment C from the relevant AR resolves several objections raised by the Defendant under Article 84 EPC. The second step of the amendment is necessary to address the ongoing dispute over claim construction, particularly regarding the "suitable for" argumentation. This

step introduces a functional feature - “for providing a hemostatic effect on a severely bleeding wound” - to clarify the intended purpose of the claimed invention. This addition avoids premature and exhaustive discussions on the allowability of second medical use claims, which are not central to the current stage of proceedings. The Claimant is of the opinion that the request complies with Rule 30(2) RoP as it does not unduly delay the proceedings or prejudice the Defendant. The amendments have been proposed in a timely manner during the written procedure, allowing the Defendant sufficient opportunity to respond. Specifically, the Defendant can address the amendments in their rejoinder to the Claimant’s reply, with a minimum response period of one month. The proposed amendments directly address the issues in dispute and improve the legal position of the Claimant. Furthermore, the amendments do not introduce new subject matter or fundamentally alter the scope of the claims. The Defendant has already addressed the substance of Amendments A to J, including Amendment C, in their arguments. If the Defendant had identified specific combinations of amendments as being of primary importance, it had the opportunity to raise such arguments earlier but did not do so. As such, the amendments do not create any new or unforeseen issues for the Defendant. The proceedings will therefore not be unduly delayed, and the Defendant’s procedural rights remain fully safeguarded.

57 According to the Claimant, these amendments simplify the case, resolve key objections, and focus the proceedings on the most relevant issues, thereby improving the efficiency and fairness of the process. The requested amendments are proportionate and do not impose unnecessary burdens on the Court or the Defendant.

58 In the court’s opinion the Claimant was not able to justify its subsequent request to amend the patent. The Claimant's reasoning is not convincing. It remains unclear which aspects of the Defendant's submission in the reply are actually new and how they relate to the changes made in the auxiliary requests. The Claimant does not establish a connection between the changes made in the auxiliary requests and specific arguments of the Defendant in the proceedings.

59 Furthermore, the application to further amend the patent does not simplify the proceedings, as there is already a set of numerous (51) auxiliary requests, divided up into two times three subgroups, using a recast of claim 1 and 10 additional features in various combinations. It would be a huge burden on the Defendant and in the end the court to examine the prior art and to work through all grounds for invalidity. To understand that this is not a simple addition or deletion of requests, one need only to look at the Claimants reasoning in its motion of September 1, 2025, starting on page 11. Here, there is both an overview of the deletions and a table showing the changes, resulting in an elaborate scheme. This does not constitute a simplification.

Application to extend the counterclaim for revocation to claim 15

60 The Defendant’s application for leave to amend the counterclaim for revocation of the patent of 1 October 2025 to extend the scope of the counterclaim for revocation to claim 15 must be dismissed.

61 Under R. 263.1 RoP, a party may at any stage of the proceedings apply for leave to amend its case. The Court shall not grant leave if, all circumstances considered, the party seeking the amendment cannot satisfy the Court that (a) the amendment in question could not have been made with reasonable diligence at an earlier stage; and (b) the amendment will not unreasonably hinder the other party in the conduct of its action, R. 263.2 RoP.

62 In the case at hand, it would have been reasonable to include claim 15, which is now the focus of attention, in the counterclaim for revocation from the beginning. By failing to do so, the Defendant may have not acted with reasonable diligence. In any event, the fact that the application was not filed until 1 October 2025 suggests that the Defendant has not acted with such diligence, as the scope of the Claimant's defence has been known since 25 April 2025. In this submission, the Claimant asserted extensive auxiliary requests, including those which, in the Defendant's view, have now provided the grounds for extending the counterclaim for revocation to claim 15. However, as this was not done until the written statement of 1 October 2025, the Defendant have not acted with reasonable diligence.

63 Furthermore, allowing the amendment would unreasonably have hindered the Claimant in the course of its action. This is because, for reasons of time, it was no longer possible for the Claimant to properly address the attacks on claim 15 prior to the oral hearing.

THE PATENT

A. Subject matter of the patent in suit

64 The invention of the patent in suit 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]).

65 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, 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 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.

66 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.

67 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.

68 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.

69 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.

70 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.

71 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.

72 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.

73 The patent in suit refers to several prior art documents. 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.

74 Based on the foregoing, the patent in suit defines as 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.

75 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.

Claim 2 adds the feature:

4. wherein said clay material is kaolin.

Claim 3 adds the feature

5. wherein said clay material is selected from the group consisting of attapulgite, bentonite, kaolin, and combinations of the foregoing materials.

Claim 7 adds the feature

6. wherein said gauze substrate is fabricated from a material selected from the group consisting of cotton, silk, wool, cellulose, rayon, polyester, and combinations of the foregoing.

Claim 9 adds the following feature:

7. wherein said binder is chitosan.

B. Claim construction

1) Person skilled in the art

76 The Claimant was in the preliminary measures' proceedings of the opinion that the skilled person is defined by a technician or technical college engineer with several years of experience in materials science, especially with regard to medical engineering. The Defendant is of the opinion that the skilled person can be defined by a multidisciplinary team with a mineralogical and pharmaceutical background

77 The particular relevance of one definition over the other is not clear. In the opinions of both parties, the skilled person has knowledge in two fields, on the one hand material or mineralogical knowledge, on the other hand medical or pharmaceutical knowledge. The court concludes that the skilled person should have both a mineralogical and a pharmaceutical background.

2) Interpretation of claim 1

a) Legal principles

78 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, - 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) Assessment

aa) Feature 2.1: *a flexible gauze substrate*

79 This feature is without relevance for the infringement, but of relevance for the invalidity attacks.

80 The term flexible gauze substrate specifies the material without imposing specific requirements. The substrate has to have the ability to get in contact with the clay material by means of an adhering binder. The claim does not impose any further requirements.

81 In the specification in para. [0038] the gauze substrate is described as follows:

> “Referring now to FIG. 3, another embodiment of a hemostatic device of the present invention is a kaolin gauze, which is shown generally at 20 and is hereinafter referred to as "gauze 20." Kaolin is coated onto a gauze substrate using any suitable method to result in the gauze 20. One exemplary method of coating kaolin onto the gauze substrate is to immerse the substrate in a kaolin/water slurry. The kaolin material used for the slurry is preferably finely ground kaolin powder, although the present invention is not limited in this regard as kaolin particles, flakes, chips, beads, rods, granules, or the like may alternatively or additionally be used. The gauze substrate may be any suitable woven or nonwoven fibrous material including, but not limited to, cotton, silk, wool, plastic, cellulose, rayon, polyester, combinations of the foregoing, and the like. The present invention is not limited to woven or non-woven fibrous materials as the gauze substrates, however, as felts and the like are also within the scope of the present invention.”

82 The list of various exemplary embodiments illustrates that the patent has a broad scope.

83 The Claimant is of the opinion that the gauze substrate does not include felt materials. This opinion is not supported by the patent specification. It also contradicts the references to the claim wording (claims 32 and 33) in the original application. Although felt may not be a woven substrate, it is nevertheless a non-woven fiber material and thus a gauze substrate within the meaning of the patent.

84 The flexibility of the gauze substrate ensures that it can adapt to the shape of the bleeding wound during treatment and retain this shape (para. [0041]).

bb) 2.2: *a clay material disposed on said gauze substrate*

85 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).

86 Paragraph [0023] 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.”

87 The paragraph might propose preferred clay material in the light of the technical teaching of the patent in suit, hydrated aluminum silicate. But a person skilled in the art would not necessarily assume that the invention is limited to hydrated aluminum silicate as clay material mentioned in para. [0023]. This paragraph belongs to the description of 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].

88 Para. [0024] describes 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.”

89 It is undisputed between the parties that the chemical formula in para. [0025] refers to clay, especially kaolin, that is not hydrated, means without any additional amount of bonded H_2O.

90 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. The patent in suit refers to kaolin, consisting of 50% aluminum and 50% silicon, that is not a hydrated material.

91 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 clay materials, such as 7 Å halloysite or kaolinite, that do not have additional bonded water.

92 This is also apparent from para. [0024] and [0025] of the patent in suit, cited above, 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.

93 Furthermore, the patent in suit refers in section [0029], [0031] and [0032] to how the clay material Edgar's plastic kaolin (EBK) in dehydrated. After the multiple drying cycles of 600°C, dehydration is definitely present. The Defendant argued in the Rejoinder to the Reply of Defence (mn. 22) that EBK is carcinogenic and not suitable for wound treatment. Its preferred use was claimed in the original application (claim 3). This was not disputed by the Claimant. In this respect, it may be that EBK is not suitable for anticoagulation due to its carcinogenic properties. However, the reference to EBK in the description shows that the patent in suit does not require

a specific condition of the clay material. This view is not contradicted by the Defendant's argument that EBK is heated multiple times and is no longer clay material at 900 degrees Celsius. This is because the patent in suit only describes heating to 600 degrees Celsius.

94 As far as the Defendant argues, that the functionality of the clay material depends on the suitability of “clay material” to be able to absorb its liquid phase on contact with blood and thereby brings about the demanding effect of a hemostatic agent and the skilled person knows that the absorption capacity of clay material does not depend on whether water of crystallization is bound in the structure of the mineral bound by hydroxyl groups. Rather, the skilled person knows that the absorption capacity of a “clay material” depends largely on how well it can incorporate or attach loosely bound water molecules (as H_2O). The person skilled in the art therefore understands the term “hydrated” as the attachment of H_2O molecules to organic substances.

95 This might be true but the patent in suit does not differentiate between different clay materials regarding hydrated or not. Dependent Claim 2 protects kaolin as clay material and para. [0025] describes kaolin without any bonded water. Therefore, the patent in suit does not differentiate between the functional properties of the various clay materials. Even the scientific statements cited by the Defendant (in mn. 37 to 39 in the Statement of Defence) do not show a relevant difference in the ability to bind water or plasma between 7 Å-halloysite and 10 Å-halloysite. It can remain undisputed that structural differences exist between hydrated and dehydrated clay materials. TBut there is no indication in the patent in suit that the structural differences lead to significant differences in how they work.

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

cc) Feature 2.3: *a binder to adhere the clay to the gauze substrate*.

97 The term binder is to be understood in a broad way and defined by its function. It has to adhere the clay to the gauze substrate. The term is not limited by the type of bond between the clay material and the binder.

98 The patent in suit provides examples of binders and further relies on the general knowledge of a skilled person to understand what is meant by the term “binder.” There are no restrictions or limitations disclosed in the patent as to how this is achieved.

99 The patent in suit describes in para. [0046] preferred embodiments, but there is no indication that the technical teaching of the patent in suit is limited hereto:

> “In embodiments according to the present invention, the kaolin is attached to the gauze substrate using a binder. The material of the binder is biocompatible. Preferred binders include chitosan as well as polyvinyl alcohol, both of which have adhesive qualities, are compatible with biological tissue, and also exhibit hemostatic properties.”

100 Further, the patent lists several examples for a binder in para. [0058]:

> "By using a binder to bind the particlized kaolin 14 to the substrate 62, the binder material provides additional functionality to the sponge 60. Materials from which the binder may be fabricated include, but are not limited to, chitosan, polyvinyl alcohol, guar gum, gelatinized starches, polysaccharides, cellulose (e.g., carboxymethyl cellulose), calcium alginate, and the like, as well as combinations of the foregoing."

101 Some examples, mentioned in the patent in suit as possible binders – such as chitosan, polyvinyl alcohol, polysaccharides, and cellulose – primarily function through physical binding mechanisms, such as hydrogen bonding, Van der Waals forces, or electrical interactions. These interactions enable effective adhesion of clay particles to the gauze substrate without the need for covalent or ionic bonding.

102 Furthermore, the patent in suit does not require the binding agent solely act as a binder without any other possible function. PVA, described in the patent, is identified as a binder, but is also a release agent and a dust suppressant. Chitosan, that is protected in the dependant claim 9 as a binder, also has coagulant properties (see Exhibit WKS 1 = D3).

103 The patent in suit leaves it to the skilled person whether the clay is mixed with the binder or positioned between the clay material and the gauze, as long as the adhesive qualities of the binder are not affected and the clay is able to come into contact with the blood (feature 3) to provide a hemostatic effect on the bleeding wound.

104 The Defendant contests this broad understanding of the term binder and is of the opinion that the disclosure is rather limited to a specific technology for applying clay to the gauze substrate, namely the bonding of particulate clay by means of a binder or adhesive. The Defendant reasoned that this is, according to all embodiments that describe the claimed invention, particlized kaolin is to be attached to one side of the gauze substrate using a "binding agent" (see paragraphs [0054], [0058]), whereas on the opposite side of the gauze substrate, a "release agent" is to be applied to prevent the wound contacting side of the gauze from adhering to the device, and whereby said release agent can be chosen from e.g. PVA, silicone, gelatinized starch or produced as "a slurry of release agent and clay material" (see para. [0061], claims 12, 13). Since the very same substances can, thus, be interchangeably used both either as binding agents or release agents, the patent requires differentiation based on the specific technology with which it is applied to the device: The binding agent is applied as an adhesive to attach particlized clay to the gauze substrate, thereby carefully preserving the hemostatic effect of the particlized clay which is not dispersed within the binder. The release agent shall facilitate easy removal of the substrate from the wound tissue after the formation of blood clots whereby it allows dispersing clay within such release agent.

105 The Defendant is correct in stating that the patent in suit distinguishes between a binder and a release agent. However, this view overlooks the fact that the distinction is made in the context

of the description of preferred embodiments and does not say anything about the manner in which the binding is effected. Furthermore, it fails to take into account that the wording of the feature merely provides that a binder is provided which adheres the clay to the gauze substrate. The feature does not provide for any function beyond this.

COUNTERCLAIM FOR REVOCATION

106 The Counterclaim for revocation is successful on the merits. Regarding the claims as granted ("Main Request"), the patent in suit lacks novelty, alternatively inventive step. The application to amend the patent in suit based on Auxiliary Request 1a to 26a is refused because the Auxiliary Requests extends beyond the content of the application as filed or lack novelty or inventive step.

A. Claims as granted

1) Inadmissible extension of the subject-matter of claim 1 as filed

107 The patent is not inadmissibly extended, Art. 138 (1) (c), 123 (2) EPC.

a) Legal principles re. added matter

108 Article 138(1)(c) EPC provides that a European patent may be declared invalid with effect for a contracting state if the subject-matter of the European patent extends beyond the content of the application as originally filed or, if the patent was granted on the basis of a divisional application, beyond the content of the earlier application as originally filed (Art. 123 (2) EPC). In order to determine whether there is an inadmissible extension, it is necessary to ascertain what a person skilled in the art, using their general technical knowledge and objectively, could derive directly and unambiguously from the entire application as filed at the time of filing application, whereby an implicitly disclosed subject matter, i.e. a subject matter that clearly and unambiguously results from what is expressly stated, is also to be regarded as part of the content (Court of Appeal, UPC_CoA_764/2024, Decision of 02.10.2025; UPC_CoA_382/2024, Order of 14.02.2025; Local Division The Hague, UPC_CFI_131/2024, Order of 19.06.2024; Local Division Düsseldorf, UPC_CFI_363/2023, Decision of 10 October 2024; Central Division Paris, UPC_CFI_316/2023, Decision of 17 January 2025: Local Division Mannheim, UPC_CFI_471/2023, Decision of 6 June 2025; Local Division Hamburg, UPC_CFI_173/2024 and 424/2024, Decision of 10 July 2025; Local Division Munich, UPC_CFI_248/2024, Decision of 22 August 2025). Further, it is not required that a claim uses the exact same wording as used in the original application, as long as the skilled person would derive the combination of features from the whole application.

b) Present case

aa) Feature 2.1

109 Feature 2.1 can directly and unambiguously be derived from the patent application. The person skilled in the art would expect a gauze substrate to be flexible, as the flexibility is a necessary and highly useful feature in wound treatment and allows to get the clay to contact the blood to provide a hemostatic effect and further for easy packaging and handling.

110 On page 9, lines 2-6 of the original application (Exhibit K 4, patent application), a number of examples for the gauze substrate are mentioned,

> "(…) Woven or non-woven fibrous material including, but not limited to, cotton, silk, wool, plastic, cellulose, rayon, polyester, combinations of the foregoing (…)"

111 These kinds of materials would the skilled person expect to have an inherent flexibility. Even though the feature flexibility was broadened in claim 1 of the patent with respect to claim 21, this broadening falls within the scope of what the skilled person would derive directly and unambiguously from the application as filed.

112 As the Defendant is of the opinion that in the original claim 14, the "gauze substrate" was not designated as "flexible", the reasoning is not convincing. The technical attribute is used in the original claim 21 in the following form:

> 21. The device of claim 14, wherein said gauze substrate is flexible to allow said gauze substrate to form to a shape of said bleeding wound and to retain a shape of said bleeding wound.

113 The Defendant asserts that the original disclosure in the original claim 21 is thus limited to such flexibility which allows the "gauze substrate" to be adapted to the shape of a bleeding wound without changing the shape of this bleeding wound. This limitation is not found in feature 2.1 of claim 1 as granted, since it merely refers to "a flexible gauze substrate".

114 It is further of the opinion that the passage on page 9 line 12 (Exhibit K 4, patent application) is not suitable to support and permit an abstraction to any flexibility; moreover, it refers to a gauze to which kaolin is applied and dried by wet technique. The originally filed documents thus do not provide a disclosure for the feature of "general flexibility". Rather, flexibility is only disclosed in combination with the additional feature "to allow said gauze substrate to form to a shape of said bleeding wound and to retain a shape of said bleeding wound", so that "flexibility" in the sense of the patent application was to be understood as this functionality. However, this additional feature was not included in claim 1, so that the addition of the feature "flexible" is an inadmissible intermediate generalization.

115 These arguments are not convincing. A skilled person would automatically expect such a flexibility to be present in a gauze substrate that is used in a device capable of providing a hemostatic effect on a bleeding wound. The device needs to be adaptable to certain types and sizes of bleeding wounds, which is of course also an important aspect of the main substrate that forms the basis of the device. It is also common in this type of device for the gauze substrate to be flexible enough to be folded, rolled, or otherwise manipulated for packaging (e.g. [0040]). In this area of technology, any gauze substrate is flexible.

116 The flexibility of the gauze substrate is also taught explicitly in claim 21. Claim 21 might add additional information ("said gauze substrate to form a shape of said bleeding wound and to retain a shape of said bleeding wound"). But the skilled person would not expect this kind of flexibility in this field of technology.

bb) Claims 2, 3, 7 and 9 - binder

117 The Defendant is of the opinion that the combination of the features of the now granted subclaims 2 - 8 with the feature “binder” is not disclosed in the originally filed claims. Firstly, because of their reference back to claim 1. Secondly, the further features of the granted claims 3 to 8 are formally mentioned as such in the original claims 15 to 21; however, these claims are each only related back to the original claim 14, which means that they are not related to feature 2.3 “a binder”, which is only mentioned in the original claim 22, which in turn was only related back to claim 14. It is precisely this combination of the respective features of the original claims 15 to 21 that is not originally disclosed together with feature 2.3 “binder” (see list p. 13, mn. 30 counterclaim).

EP2077811B1 Claim	Referred to claim	Corresponds to claim in **WO 2008/054566**	Referred to claim
1	Independent	14 + 22	
2	1	15	14
3	1	16	14
4	1	17	14
5	1	18	14
6	1	19	14
7	1	20	14
8	1	20	14
9	1	23	22
10	1	23	22
11	Independent	35	Independent
12	1	44 + 22	Independent (44)
13	12	50	44
14	12	52	44
15	1		

118 A reference back to the original claim 22 can only be found in the original claim 23. All other sub-claims do not contain any reference back to the binder in claim 22. The combination of the features of the now granted subclaims 2 - 8 with the feature “binder” is therefore not disclosed in the originally filed claims. As far as the Claimant refers in the examination (letter dated February 25, 2010, Exhibit K 18) to page 4, line 4 and page 5, line 29-31, this view cannot be followed because the combination is not disclosed in the description, at least for claims 3 – 8. This is because the binder in only mentioned in three places in the patent application (Exhibit K 4), namely p. 10, lines 4-8, page 12, lines 7-15, page 13, lines 26-31. these disclosure passages are not general disclosures that apply to the entire invention. Rather, these passages refer to very specific embodiments, namely for the selection of kaolin as clay material.

119 The Defendant adds that the only disclosure in K 4 which discloses the binder in the general combination with clay in general is claim 22. This explicitly refers only to claim 14. By referring claims 3 – 8 back to claim 1, these claims infringe Art. 138 (1)(c) EPC and represent an inadmissible intermediate generalization.

120 These arguments are not convincing. The original claim 22 ("The device of said claim 14, further comprising a binder to adhere said clay material to said gauze substrate") referred to clay in general, and not only kaolin. For claim 2, the Claimant points at the paragraph bridging pages 12 and 13 (claim 2) where the release agent functions not only as a release agent but also as a binder in conjunction with a flexible gauze and page 10, lines 4 and 5 refer to the use of a binder. For claim 3, the Claimant refers to page 5, lines 29 to 33, where the general use of other clays and combinations of clays is described and Claim 22, that discloses a clay material in general and a binder.

121 The inclusion of the binder feature in claim 1 does not give rise to an intermediate generalization, as the binder is not described in the embodiments in a particular order or in a particular composition; a binder is described as an option of general application for the specific embodiments of page 10, lines 4-8 (gauze embodiments) and of page 12, lines 7-15 (sponge embodiments). Also on page 5, lines 26-33, the application describes that kaolin is used as an example to describe the invention, but that other materials may be used. Therefore, the skilled person would consider a binder as a generally applicable option.

2) Lack of sufficient disclosure, Art. 138 (1)(b) EPC

122 The teaching of the patent in suit is sufficiently disclosed.

a) Legal principles re. added matter

123 Pursuant to Art. 138 (1) (b) EPC, the patent has to disclose the invention in a manner sufficiently clear and complete for it to be carried out by persons skilled in the art.

124 The overriding consideration in this context is the disclosed content of the European patent specification, that is to say what a person skilled in the art is able to derive directly and unambiguously from the explicit and implicit disclosure in the patent claims, description and drawings, if any, without using inventiveness.

125 A patented invention is insufficiently disclosed if a person skilled in the art in the field of the invention is not able, with reasonable effort, to realize the protected invention in a sufficient extent in practice in the entire claimed field on the basis of the patent specification with the aid of his technical knowledge and general technical knowledge.

b) Present case

126 The Defendants' opinion that the invention cannot even remotely be carried out in the entire claimed breadth of claim 1, is not convincing. It was argued that at no point in the description it is explained how the binder must be used in order to achieve the alleged objective. The selection of the combination of binder, clay and gauze material will play a decisive role here and the patent specification is silent on this point. The only combination mentioned is that of kaolin with chitosan or polyvinyl alcohol. However, the substrate to which such a combination can be bound is not mentioned. Furthermore, some of the available binders are water-soluble and the patent in suit, especially the patent specification, is silent on the use of water-soluble binders.

127 The Defendant misses that the patent specification includes detailed description and examples that guide the skilled person in making the hemostatic device. Specific examples of binders and their use are provided in the specification (e.g. chitosan, polyvinyl alcohol). The same applies for the use of water-soluble binders and provides context for their application. The skilled person would therefore understand that water-soluble binders can be used effectively when combined with other materials or processes that mitigate their solubility during application. For example, the slurry method and high-temperature processes described in the patent ([0038] et seq.) can be used to stabilize the binder and clay material on the gauze substrate. This is a rather common process for the application of soluble binders. The adhesive properties of such binders become effective after drying of the slurry. Hence, a skilled person will know how to use water-soluble binders and can assess the mentioned problem of loosening of particles. The skilled person would know, that it is of relevance to adhere the particles in a matrix. The skilled person can be expected to provide enough adhesive if it is water-soluble to prevent the occurrence of loose material upon blood contact. And in case a non-soluble binder is used, it is evident that the clay particle should not be completely covered by the binder as the clay should be able to get in contact with the blood.

3) Lack of Novelty, Art. 138(1)(a) EPC i.c.w. Art. 54 EPC

128 Claim 1 and claims 2, 3, 7 and 9 of the patent are found to be not novel in light of WO 2006/088912 A2 = D3 = WKS 1 (hereinafter D3).

a) Legal principles

129 According to Art. 54(1) EPC, an invention is considered new if it does not belong to the prior art. A technical teaching does not belong to the prior art if it differs in at least one of its known features from what is available in the prior art. Only that which is directly and unambiguously apparent to a person skilled in the art from the relevant publication or prior use is considered to be anticipated by the prior art (Court of Appeal, UPC_CoA_182/2024, order of 25 September 2024; UPC_CoA_382/2024, order of 14 February 2025; Central Division Munich, UPC_CFI_252/2023, decision of October 17, 2024). Findings that an expert only obtains on the basis of further considerations or the use of additional documents or uses are not prior art (Local Division The Hague, UPC_CFI_239/2024, decision of November 22, 2024; Local Division Düsseldorf, UPC_CFI_16/2024, decision of January 14, 2025).

130 The burden of proof and presentation for facts concerning the invalidity of a patent lies with the plaintiff in nullity proceedings (Court of Appeal, UPC_CoA_335/2023, order of February 26, 2024), in this case the Defendant in the infringement proceedings and Claimant in the counterclaim for revocation.

b) Present Case

131 D3 was filed by the applicant Virginia Commonwealth University, USA, and published before the priority date of the patent in suit on August 24, 2006. D3 is therefore prior art under Article 54(2) EPC for the patent in suit.

132 D3 is based on the same problem as the patent in suit and also addresses the task of providing an alternative substance for hemostasis in order to avoid the disadvantageous exothermic reaction of zeolites when used for hemostasis (page 3 point 5, lines 14-18). As a solution to this problem, D3 proposes the use of dressing materials comprising clay materials for hemostasis (page 4, lines 26-31), as clay minerals would not undergo an exothermic reaction with blood (page 4, lines 19-22). D3 discloses therefore a device for providing hemostatic effect (page 1, lines 9-12 (feature 1.)

133 Regarding the material, D3 describes on page 5, line 10 that the clay material may be in form "such as (…) impregnated in a bandage, and electrospun into a bandage." On page 10, line 27-28 it is described:

> "Bandages may also be of a type that, with application of pressure, bend and so conform to the shape of the wound site. Bandages may also be of a type that, with application of pressure, bend and so conform to the shape of the wound site."

134 D3 further discloses clay material that is disposed on a substrate (see page 6, line 3-4, page 4, line 25, page 5, line 6-6 and page 9, line 5 "kaolin"). On page 9, line 24-26 it is described:

> "The clay mineral compositions utilized in the practice of the present invention may be formulated in a variety of ways. Examples include but are not limited to liquids, foams, powders, granules, gels, hydrogels, sprays, incorporation into bandages etc."

135 Regarding the adherence of the clay material, it is described that the composition comprises one or more substances such as, chitosan, polyethylene glycol, and on page 10, line 4, cellulose. Chitosan is not explicitly described as binder in D3. On page 10, first paragraph, it is explained that other hemostatic or absorptive agents may be added. The possible agents mentioned include chitosan and cellulose.

136 Furthermore, claim 4 of D3 describes that the clay can be used in the form of a paste. Finally, on page 10, line 19-20 it is disclosed:

> "any suitable material may be added, so long as the material clay composition is still able to cause blood clotting and promote hemostasis."

137 Feature 2.1 is known from D3. The feature of a flexible gauze material in the patent in suit is to be understood in a broad way (sponge, woven structure, mesh) as described above. D3 describes that a bandage is impregnated with clay material, or clay is incorporated into the material. Also, a sponge-like material is used. D3 further refers on page 1 line 26 to a "gauze bandage impregnated with chitosan". The argument of the Claimant that D3 relates to a closed type material which would not be a gauze material can therefore not be followed. Also, the notion that "bandage" is a more broad definition than "gauze material", as there are bandages which are not open structured, cannot bring novelty over D3, as impregnation of a bandage implies an open material.

138 Feature 2.2 is disclosed too. D3 discloses "coating of bandages", see page 12, lines 16-18. This implies "on", as coating implies disposing material on a substrate.

139 D3 further discloses the usage of chitosan and cellulose. The presence of these components is enough to disclose a binder to adhere the clay to the gauze substrate. Since the patent in suit itself already mentions that the binders provide additional functionality (see [0058]), it is also in line with the patent in suit to select the binder from agents with other functionalities such as hemostatic or absorptive functionalities. Since the Claimant assumes that the presence of chitosan would already have a patent-infringing binding effect, it must also be assumed with regard to D3 that the addition of chitosan to the clay material leads to the material being adhered to the bandage. When applying such compositions as a coating of a bandage, chitosan inherently will act as a binder. Therefore, feature 2.3 is disclosed too.

140 As far as the Claimant argues that D3 discloses extensive lists of possibilities and therefore an arbitrarily selecting for the person skilled in the art, the court does not agree. Regarding the clay material, the main focus of D3 is the usage of clay material and the skilled person only has to select an application option (page 10, lines 21-30), the “binder” option (chitosan etc.), whereby other choices are made because of requirements of a particular usage and therefore are not arbitrary. This kind of selecting is not a combination of picking individual elements from several extensive lists of possibilities.

141 Document D3 further provides an enabling disclosure with regard to the use of chitosan or cellulose as binders. D3 provides an explicit explanation in this regard (see page 11, line 31 – page 12, line 2 in conjunction with page 9, line 24 – page 10, line 6). General examples are described, similar to the patent in suit. A person skilled with its general knowledge knows how to prepare a functional device.

142 Claims 2 and 3 and 7 and 9 are disclosed by D3 as well. D3 discloses kaolin and bentonite (page 4, line 25, page 5, lines 6-8; page 9, line 5) as clay materials, therefore dependent claims 2 and 3 lack novelty. Chitosan is further disclosed in D3, see page 5 lines 10-14 and page 10 line 2, therefore dependent claim 9 is not novel.

143 Cellulose is disclosed on page 9, line 27 to page 10, line 6 (claim 7).

4) Lack of inventive Step, Art. 138(1)(a) EPC i.c.w. Art. 56 EPC

144 If one would assume that D3 does not disclose feature 2.3 – binder to adhere – the relevant claims lack inventive step with regard to WO 2006/088912 A2 = D3 in combination with WO 92/16681 A2 = N2 – “attack 2” as well. Furthermore, if one would assume that claim 7 is not disclosed due to the circumstance that cellulose is disclosed in D3 only with regard to the electrospun embodiment, claim 7 lacks inventive step as the specific feature is present in N2.

a) Legal principles

145 The principles of the recent decisions of the CoA (UPC_CoA_528/2024 and UPC_CoA_529/2024, Decision of 25 November 2024, mn. 123-138 Amgen/Sanofi; UPC_CoA_464/2024 et al., decision of 25 November 2024, Meril/Edwards Lifescience, mn. 128-136) can be summarized as follows:

A European patent is only validly granted for an invention if – apart from other requirements – it involves an inventive step. An invention shall be considered as involving an inventive

step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Art. 56 EPC).
National courts of the various EPC countries have different approaches and use different guidelines when assessing whether an invention involves an inventive step. One of those approaches is the so-called 'problem-solution-approach' used by the European Patent Office (EPO) and the Technical Boards of Appeal (TBA) of the EPO. In some jurisdictions, such as France, Italy, The Netherlands and Sweden, this approach is applied as well, but not necessarily as the only possible approach. In other jurisdictions, such as Germany and the UK, other approaches – sometimes referred to as more 'holistic' – are used. Despite the differences in approach, all of these are just guidelines to assist in the establishment of inventive step as required by Art. 56 EPC, that, when properly applied, should and generally do lead to the same conclusion.
The burden and presentation of 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 claimant in a revocation action (Art. 54 and 65(1) UPCA, R. 44(e)-(g), 25.1(b)-(d) RoP). Even though proof of certain facts, if contested, may be required, the assessment of whether the legal consequence for which the facts and circumstances have been submitted is justified, is a question of law.
The approach taken by the Unified Patent Court when establishing inventive step, which can already be derived from the Order of the Court of Appeal in Nanostring/10X Genomics (supra), is as follows.
It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the skilled person (m/f – hereinafter referred to as 'it'), with its common general knowledge, as at the application or priority date (also referred to as the relevant date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in context of the description and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the skilled person on the basis of the application understands is (are) achieved with the claimed invention.
In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution.
The claimed solution is obvious when at the relevant date the skilled person, starting from a realistic starting point in the state of the art in the relevant field of technology, wishing to solve the objective problem, would (and not only: could) have arrived at the claimed solution.
The relevant field of technology is the field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art of the specific field must be expected to be aware.
A starting point is realistic if the teaching thereof would have been of interest to a skilled person who, at the relevant date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention. There can be more than one realistic starting point and the claimed invention must be inventive starting from each of them.
The skilled person has no inventive skills and no imagination and requires a pointer or motivation that, starting from a realistic starting point, directs it to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be considered not inventive / obvious when the skilled person would take the next step prompted by the pointer or as a matter of routine, and arrive at the claimed invention.

A claimed solution is obvious if the skilled person would have taken the next step in expectation of finding an envisaged solution of his technical problem. This is generally the case when results of the next step were clearly predictable, or where there was a reasonable expectation of success.

The burden of proof that the results were clearly predictable or the skilled person would have reasonably expected success, i.e. that the solution he envisages by taking the next step would solve the objective problem, lies on the party asserting invalidity of the patent.

A reasonable expectation of success implies the ability of the skilled person to predict rationally, on the basis of scientific appraisal of the known facts before a research project was started, the successful conclusion of that project within acceptable time limits.

Whether there is a reasonable expectation of success depends on the circumstances of the case. The more unexplored a technical field of research, the more difficult it was to make predictions about its successful conclusion and the lower the expectation of success. Envisaged practical or technical difficulties as well as costs involved in testing whether the desired result will be obtained when taking a next step may also withhold the skilled person from taking that step. On the other hand, the stronger a pointer towards the claimed solution, the lower the threshold for a reasonable expectation of success.

When the patentee brings forward and sufficiently substantiates uncertainties and / or practical or technical difficulties, the burden of proof that these would not prevent a skilled person from having a reasonable expectation of success, falls on the party alleging obviousness.

The fact that other persons or teams were working contemporaneously on the same project does not necessarily imply that there was a reasonable expectation of success. It may also indicate that it was an interesting area to explore with a mere hope to succeed.

b) Present Case - WO 2006/088912 A2 = D3 with WO 92/16681 A2 = N2 = WKS H 14

146 The content of D3 is explained in detail above. D3 is concerned with the same underlying problem of providing means for promoting hemostasis comprising clay as an alternative hemostatic substance that avoids the disadvantageous exothermic reaction of zeolites. D3 discloses features 1, 2, 2.1, 2.2.

147 If one assumes that feature 2.3 is not disclosed, as D3 discloses chitosan not explicitly in its function as a binder, the skilled person would come upon N2 and recognize that chitosan may also improve binding of particles with the fibres when used in wound dressing.

148 N2 was filed on March 20, 1992 by the applicant Weyhaeuser Company (US), and published on October, 1st, 1992. N2 is prior art under Article 54(2) EPC. As the patent in suit, N2 is concerned in one embodiment with the provision of bandages that may be applied to wounds (see, page 63, lines 7-20 and Figures 19-20). Figures 19-20, which are shown below,

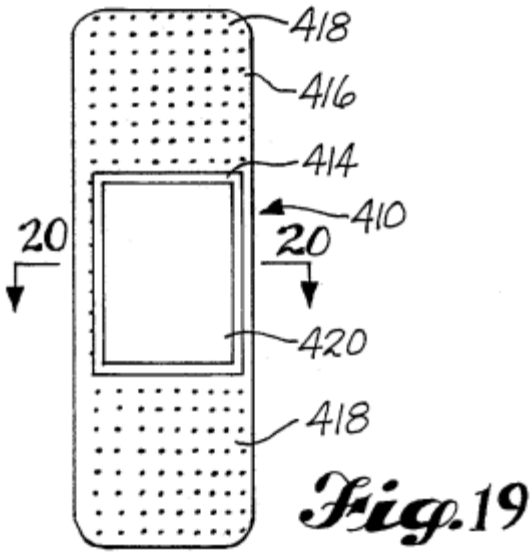

Fig. 19

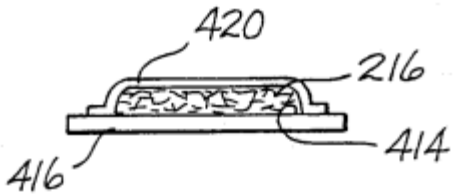

Fig. 20

149 are described on page 62, lines 15-16:

> "With reference to Figs. 19-22, absorbent structures in the form of bandages or dressings are shown. In Figs. 19 and 20, a bandage 410 for application to a wound to absorb blood and other bodily fluids is shown."

150 On page 63, lines 16-20 the material of the pad is described ("such as, for example, rayon, nylon, polyester, propylene and blends thereof.").

151 Relating to page 1 lines 13-15 and page 6, lines 27-30 ("particles may be adhered to the fibres by the binder") of N2, the skilled person would find that clay particles can be adhered to fibrous material. On page 14, lines 8-10, chitosan is mentioned as an example binder. On page 40, lines 12-18, the binder and hemostatic effect of chitosan are mentioned together, whereby the chitosan fibres are to be used in a wound dressing.

152 As far as the Claimant argues that the skilled person would not learn from N2 that chitosan is suitable for adhering a clay material to a flexible gauze substrate, as it is only disclosed to adhere particles to individual fibres, this argument is not convincing.

153 On page 40, lines 12-18, chitosan is explicitly linked to fibres in wound dressing and at the same time as a binder. It is stated:

> "Chitosan is yet another particle which may be attached to fibers. It is believed that chitosan may promote the healing of wounds. Therefore, adhering this material to fibers which are then included in a dressing for a wound or the like, would take advantage of this attribute of this material. In addition, chitosan is also soluble and useable as a binder. Given the film forming nature of a chitosan solution, it is also expected to substantially continuously coat the fibers and serve to bind particulate materials to the fiber."

154 Starting from D3, from which chitosan as a beneficial addition is already known, the skilled person would therefore come upon N2 and recognize that chitosan may improve the binding of particles with the fibers when used in wound dressing. Claim 1 is therefore lacking an inventive step in light of D3 and N2, if one assumes that D3 does not disclose feature 2.3.

155 If one further assumes, that the further features of the granted claim 7, which specify the gauze substrate in terms of all conceivable possibilities of suitable materials, are not disclosed, these features are not capable of establishing an inventive step. Cellulose itself is described in D3 with regard to the embodiment of electrospun fibers as a possible additive from which the bandage is made (see, page 9 line 27 to page 10, line 6 and page 11 line 31 to page 12 line 2). For the person skilled in the art, the use of cellulose is therefore known, and its use in impregnated bandages is also readily apparent. Rayon and polyester and blends thereof are described in N2, see page 63, lines 16-20. Cellulose and the other materials in claim 7 are therefore self-evident materials, in particular in the form of cotton, cellulose and their closest synthetic substitutes in the form of rayon or polyester.. Depending on the requirements, the skilled person will make an obvious selection and thus arrive at the subject matter of claim 7 without having to engage an inventive step.

156 The features of the dependent claims are – as described above – disclosed by D3 as well.

5. Indicators of the Presence of an inventive step

157 The Claimant relies further on secondary indications such as commercial success and a long-felt need to support the inventive step of the claims.

158 The Claimant is of the opinion that QuikClot Combat Gauze® and other QuikClot products enjoy demonstrable commercial success that is directly attributable to the technical features claimed in the patent in suit. It is of the opinion that the established EPO case law expressly confirms that secondary indicators such as (1) commercial success, (2) satisfaction of a long-felt need/failure by others, (3) an unexpected simple solution, (4) recognition of the inventors merits by the scientific community, and (5) copying by competitors may be provided as corroborative evidence once the problem-solution approach has been applied and residual doubt remains on inventive step.

159 Secondary indicia could become relevant if an inventive step objection is not that clear cut. Since all circumstances must be taken into account when assessing inventive step, secondary indicia must not be ignored. However, if the assessment is so clear on the basis of the prior art that secondary indicia would not change it, there is no need to address it in the decision because it is then no longer relevant (T 0351/93; T 0754/89). This is in the present case regardless of whether the principle of secondary indicia applies at all in the UPC.

160 The attack based on D3, where D3 is in itself already novelty destroying, is at least obvious, so that secondary indicia cannot alter the conclusion.

B. Auxiliary Requests

161 The patent in suit is even invalid taking the auxiliary requests into account.

162 The set of Auxiliary Requests includes two major lines of defence, AR 1 to 27 and AR 1a to 26a.

a) AR 1 -27, first subset of AR

163 The first set of auxiliary requests, that includes Auxiliary Requests 1 to 27, is directed to the clay material and its medical use, is inadmissible. The requirements of Art. 54 (5) EPC are not met.

164 Art. 54 (5) EPC reads as follows:

> "Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Art 53(c), provided that such use is not comprised in the state of the art."

165 The provision therefore requires that the invention teaches a new and inventive specific application. The claim must relate to a substance or mixture of substances, and the specific application must be new.

166 This cannot be determined in the present case. If the features of the device (gauze, binder) are to be included in the scope of the invention, claim 1 does not relate to a substance or composition. If the gauze substrate contributes to the medical effect, which is likely as the Claimant argues the absorbent quality, a substance claim is inadequate. If the claim should be understood as relating to the clay material as such, there is no effect that is novel, as hemostatis of clay material is already known and any beneficial effects of the invention do not relate to the clay, but to the device features. The patent does not concern a therapeutic or pharmacological insight that would make the Art. 54(5) EPC exception applicable

167 Furthermore, the application as filed aims to provide a hemostatic agent that mitigates drawbacks, and to provide devices capable of applying hemostatic agents, while the patent concerns hemostatic devices. A specific use of an agent as meant in Art. 54(5) EPC is not part of the current claims of the patent. .

b) AR 1a -26a, second subset of AR

168 In the second subset of auxiliary requests, the claims are still directed to a hemostatic device. In AR 1a to 8a, features A to H are added to claim 1. In AR 10a to 17a this is repeated, but with the addition of feature I. In AR 19a to 26a this is repeated with the addition of feature J in addition to feature I. There are no AR 9a and 18a. Reproduced below is a table of the Claimant that shows which individual Amendments A to J were made in each auxiliary request. The amendments will be discussed in detail below:

20a	X	X							X	X
21a	X	X	X						X	X
22a	X	X	X	X					X	X
23a	X	X	X	X	X				X	X
24a	X	X	X	X	X	X			X	X
25a	X	X	X	X	X	X	X		X	X
26a	X	X	X	X	X	X	X	X	X	X

20a	X	X							X	X
21a	X	X	X						X	X
22a	X	X	X	X					X	X
23a	X	X	X	X	X				X	X
24a	X	X	X	X	X	X			X	X
25a	X	X	X	X	X	X	X		X	X
26a	X	X	X	X	X	X	X	X	X	X

169 In accordance with the parties' course of action, the individual auxiliary requests will be discussed on the basis of the individual amendments. Only auxiliary request 19a and 26a, which were discussed separately by the parties during the oral hearing, will be discussed following this.

aa) Amendment A (AR 1a-8a, 10a-17a and 19a-26a)

170 Amendment A limits claim 1 with the features that the clay material is in a dry state and that application causes at least a portion of the dry clay material to come into contact with blood.

171 By way of example, the wording of claim 1 of auxiliary request 1a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

172 Claim 1 of the auxiliary request 1a 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 being in a dry state; 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 dry clay material to come into contact with blood.

173 Regardless of the objections raised by the Defendant relating to insufficient disclosure and lack of clarity, it can be established that the features added by Amendment A do not render the claim inventive. These are, just like the other features (as discussed above), disclosed in D3 alone, alternatively in conjunction with N2.

174 D3 discloses that clay can be in dry form on the bandage and can promote hemostasis in said form. On page 5, lines 8-10 it is described:

"The one or more clay minerals may be in a form such as, for example, granules, powder, micron beads, liquid, paste gel, impregnated in a bandage, and electrospun into a bandage."

175 Page 9, lines 24 to 26 describes further:

"The clay mineral compositions utilized in the practice of the present invention may be formulated in a variety of ways. Examples include but are not limited to liquids, foams, powders, granules, gels, hydrogels, sprays, incorporation into bandages etc."

176 On page 11, lines 8-10 it is described that the bandage – with the clay material – is placed directly onto a wound: "Any means of administration may be used, so long as the mineral clay makes sufficient contact with the site of hemorrhage to promote hemostasis" (see also page 12, lines 14-18: "coating of bandages with these preparations"). D3 therefore discloses that clay can be in dry form on the bandage and can promote hemostasis in said form.

177 The additional features of the Amendment A are therefore directly and unambiguously disclosed in D3 as well.

178 The features of the dependent claims are – as described above – disclosed by D3 as well.

bb) Amendment B (AR 2a-8a, AR 11a-17a and AR 20a-26a)

179 In Amendment B claim 1 of the second subset has been further limited by the feature: hemostatic device disposed in a sterilized packaging.

180 By way of example, the wording of claim 1 of auxiliary request 2a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

181 Claim 1 of the auxiliary request 2a reads as follows:

A hemostatic device disposed in a sterilized packaging; said hemostatic device is 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 being in a dry state; 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 dry clay material to come into contact with blood.

182 The additional feature does not constitute novelty or alternatively an inventive step of the amended claims. The Defendant rightly argues that the feature amounts to mere triviality. That a medical product which is used to stop a bleeding is disposed in a sterilized packaging goes without saying.

183 Furthermore, D3 at least implicitly discloses the feature of a sterilized packaging. Since the compositions comprising clay minerals in D3 may also be used for control of internal solid organ injuries and are thus also intended for use in internal wounds, a sterile packaging is implicitly disclosed in D3 or hence a mere triviality. Otherwise, there is a high risk that infections occur upon application.

184 The features of the dependent claims are – as described above – disclosed by D3 as well.

cc) Amendment C (AR 3a-8a, AR 12a-17a and AR 21a-26a)

185 In Amendment C claim 1 has been further limited by the feature whereby said gauze substrate (62) initially exists separately from said clay member (14).

186 By way of example, the wording of claim 1 of auxiliary request 3a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

187 Claim 1 of the auxiliary request 3a reads as follows:

> A hemostatic device disposed in a sterilized packaging; said hemostatic device is 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 being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); 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 dry clay material to come into contact with blood.

188 The additional feature lacks novelty/inventive step.

189 D3 discloses that clay is initially separate from the bandage. On page 5, line 10, it is described that the clay material may be (…) "impregnated in a bandage" and on page 12, lines 14-18 a "coating of bandages" is mentioned. This implies without any doubt that the clay material is initially separate from the bandage.

190 This opinion is supported by the fact that in D3 a method of manufacturing a bandage is described which is coated or impregnated with clay material, thereby implying that the bandage and the clay material exist separately.

191 Besides, in the reply to the defence, where the Claimant defends amendment C, albeit in the not allowable application to further amend the patent, amendment C is abandoned. The Claimant itself therefore does not seem to want to pursue the amendment.

dd) Amendment D (AR 4a-8a, AR 13a-17a and AR 22a-26a)

192 In Amendment D claim 1 has been further limited by the feature absorbent flexible gauze substrate and 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 through said flexible gauze substrate (62).

193 By way of example, the wording of claim 1 of auxiliary request 4a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

194 Claim 1 of the auxiliary request 4a reads as follows:

> A hemostatic device disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
> an absorbent flexible gauze substrate (62);
> a clay material (14) disposed on said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); 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 dry clay material to come into contact with blood through said flexible gauze substrate (62).

195 The features of the Amendment D do not constitute novelty over D3.

196 It is the opinion of the court interpreting the feature, that the skilled person would first think 'through' would imply a spatial feature.

197 Based on this understanding, Amendment D does not bring novelty over D3. As the clay particles of D3 are spun into, or impregnated into, this implies that blood should travel through the bandage to reach the particles. The argument that the absorbent feature is not present in D3 cannot be followed, as the provision of a gauze substrate would result in an absorbent capability, as in the patent.

198 Therefore, Amendment D does not bring novelty over D3. The same applies with regard to the dependent claims as these are disclosed in D3 as well, in the alternative an inventive step cannot be established with regard to a combination of D3 and N2.

ee) Amendment E (AR 5a-8a, AR 14a-17a and AR 23a-26a)

199 In Amendment E claim 1 is limited by the feature wherein the hemostatic device is folded into a configuration to produce a number of distinct plies attached along edges.

200 By way of example, the wording of claim 1 of auxiliary request 5a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

201 Claim 1 of the auxiliary request 5a reads as follows:

A hemostatic device disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
an absorbent flexible gauze substrate (62);
a clay material (14) disposed on said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); and
a binder to adhere the clay (14) to the gauze substrate (62);
wherein said hemostatic device is folded into a configuration to produce a number of distinct plies attached along the edges; and
wherein when treating a bleeding wound, application of said device causes at least a portion of said dry clay material to come into contact with blood through said flexible gauze substrate (62).

202 Amendment E does not bring an inventive step over claim 1. The fact that a medical gauze may be provided in a folded configuration is trivial and cannot establish patentability. The Z-folding of medical gauze is shown in prior art, for example in US 2,402,982 (N6, Exhibit WKS H16) or US 3,625,209 (N7, Exhibit WKS HH17). Starting from D3 in order to improve the handling of the bandage disclosed in D3, the skilled person would have consulted the teachings of N6 or N7. From these documents it would have been apparent (even without a need for inventive activity) that a zigzag fold is a suitable method for packaging medical gauze.

203 The same applies to the dependent claims since the alleged problem solved by the feature of Amendment E constitutes a partial problem on the patent. The packaging and provision of the hemostatic device in form of a certain folding configuration solves a different problem than the composition and provision of the hemostatic material on the device, as it does not address the hemostasis itself, but an efficient manner of packaging the device. In terms of determining the inventive step, this leads to separately assess, for each problem, whether the combination of features solving the partial problem is obviously derivable from the prior art. For each partial problem, a different document with the closest prior art may be combined with it. Therefore, a combination of documents D3 with N2 and N6/N7 leads without an inventive step to each solution.

ff) Amendment F (AR 6a-8a, AR 15a-17a and AR 24a-26a)

204 In Amendment F claim 1 has been further limited by the following feature a radiopaque component.

205 By way of example, the wording of claim 1 of auxiliary request 6a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

206 Claim 1 of the auxiliary request 6a reads as follows:

> A hemostatic device disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
> an absorbent flexible gauze substrate (62);
> a clay material (14) disposed on said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); and
> a binder to adhere the clay (14) to the gauze substrate (62); and
> a radiopaque component;
> wherein said hemostatic device is folded into a configuration to produce a number of distinct plies attached along the edges; and
> wherein when treating a bleeding wound, application of said device causes at least a portion of said dry clay material to come into contact with blood through said flexible gauze substrate (62).

207 The feature in Amendment F violates Art. 123 (2) EPC. The feature originates from claim 52 that refers to claim 44 and there to a hemostatic sponge. On page 13, lines 7-9 it is described:

> "The sponge 60 may further include a component that imparts a radiopaque characteristic to the sponge. In such an embodiment, barium sulfate may be incorporated into a slurry that includes particlized kaolin 14 and applied to the substrate 62."

208 The added feature in Amendment F is disclosed exclusively in the context of the sponge embodiment. Extracting this feature without incorporating the essential structural context of the sponge (including the release agent, absorbent matrix, spatial arrangement) results in a violation of Article 123(2) EPC.

209 The Claimant's reference that the patent application as filed makes it clear that the sponge is not a mutually exclusive concept, but rather a specific example or preferred embodiment of the

broader invention, is not convincing. The Claimant cites page 11, line 23 of the application, which states:

> "The substrate 62 is an absorbent gauze material that defines a matrix."

210 In doing so, the Claimant overlooks the fact that the sponge and the gauze are not interchangeable, but that the gauze substrate is, as it turns out, a component of the sponge. On page 11 lines 16-19 with reference to figure 6 it is stated:

> "Referring now to FIG. 6, another embodiment of the present invention is a sponge, shown at 60, which comprises a substrate 62, the particlized kaolin 14 (or some other clay material or diatomaceous earth) disposed on one face of the substrate 62, and a release agent 64 disposed on an opposing face of the substrate."

211 In line 23 it is further stated (reproducing again):

> "The substrate 62 is an absorbent gauze material that defines a matrix."

212 It is hereby made clear that the substrate, which comprises gauze material, forms part of the sponge, and that there is no free interchangeability; furthermore, no general concept is described and not a preferred embodiment of a broader invention. There is no evidence or even indication to suggest that Amendment F applies generally to all embodiments. Amendment F cannot therefore be derived directly and unambiguously from the application with regard to a flexible gauze substrate without the further requirements that relate to the sponge.

<u>gg) Amendment G (AR 7a-8a, AR 16a-17a and AR 25a-26a)</u>

213 In Amendment G claim 1 has been further limited by the feature <u>the clay material (14) is only disposed on a first surface of said gauze substrate (62)</u>.

214 By way of example, the wording of claim 1 of auxiliary request 7a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

215 Claim 1 of the auxiliary request 7a reads as follows:

> A hemostatic device disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
> an absorbent flexible gauze substrate (62);
> a clay material (14) disposed on only a first surface of said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); and
> a binder to adhere the clay (14) to the gauze substrate (62); and
> a radiopaque component;
> wherein said hemostatic device is folded into a configuration to produce a number of distinct plies attached along the edges; and
> wherein when treating a bleeding wound, application of said device causes at least a portion of said dry clay material to come into contact with blood through said flexible gauze substrate (62).

216 Like Amendment F, the feature in amendment G violates Art. 123 (2) EPC. The feature originates from granted claim 44 and not claim 1. Page 3, line 27, that was cited by the Claimant, mentions the feature only with regard to a sponge:

> "Such a sponge comprises a substrate, a hemostatic material disposed on a first surface of the substrate, and a release agent disposed on a second surface of the substrate. The release agent is disposed on the wound-contacting surface of the substrate."

217 The Claimant refers further to page 9, lines 29-31:

> "Another manner of depositing the kaolin coating on the substrate includes applying the kaolin in slurry form on one side of the gauze substrate using a spraying technique, a slot die technique, or a combination thereof."

218 However, it argues itself that the cited passages refer to embodiments involving a sponge. The Claimant argues that despite the context of a sponge, the disposition is not inherently limited to the sponge embodiment. The disposition of the clay material on a first surface of the gauze substrate is a physical configuration that can be applied to any hemostatic device that has a gauze substrate having more than one surface.

219 It might be true that the feature has no specific (technical) reference to a sponge. However, there is no indication in the application of the patent that the feature in Amendment G refers to all embodiments. Therefore, it is the opinion of the court, that the added feature in Amendment G is disclosed exclusively in the context of the sponge embodiment. The restriction to "only on a first surface" is thus functionally dependent on this spatial configuration, which is not reflected in the amended claim. There is no evidence or even indication to suggest that Amendment G applies generally to all embodiments. Amendment G constitutes an inadmissible intermediate generalisation, infringing Article 123(2) EPC.

hh) Amendment H (AR 8a, AR 17a and AR 26a)

220 In Amendment H claim 1 has been further limited by the feature a hemostatic sponge (60).

221 By way of example, the wording of claim 1 of auxiliary request 8a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests.

222 Claim 1 of the auxiliary request 8a reads as follows:

> A hemostatic sponge (60) disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
> an absorbent flexible gauze substrate (62);
> a clay material (14) disposed on only a first surface of said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14); and
> a binder to adhere the clay (14) to the gauze substrate (62); and
> a radiopaque component;
> wherein said hemostatic device is folded into a configuration to produce a number of distinct plies attached along the edges; and
> wherein when treating a bleeding wound, application of said device causes at least a portion of said dry clay material to come into contact with blood through said flexible gauze substrate (62).

223 Claim 1 with the amended feature is not inventive.

224 D3 discloses the feature introduced by Amendment H. The document describes on page 11, lines 2-5 a sponge-like material:

> "The clay minerals can be incorporated into special carriers such as liposomes or other vehicles to assist in their delivery either topically, […].
> In addition, combinations of these forms may also be used, for example, a bandage that combines a flexible, sponge-like […] material that is placed directly onto a wound, […]
> Any means of administration may be used, so long as the mineral clay makes sufficient contact with the site of hemorrhage to promote hemostasis".

225 The skilled person would derive from D3 that also bandages comprising flexible, sponge-like materials may be advantageous for applying clay materials to a wound.

226 Since the feature is known from D3, the feature cannot bring an inventive step in light of D3 with N2. The same applies with regard to the dependent claims as these are disclosed in D3 as well.

ii) Amendment I (AR 10a and AR 26a)

227 In Amendment I claim 1 has been further limited to the following feature whereby said gauze substrate (62) is flexible to allow said gauze substrate (62) to form to a shape of said bleeding wound and to retain a shape of said bleeding wound.

228 By way of example, the wording of claim 1 of auxiliary request 10a is reproduced below, without mentioning further amendments, which are included in the other auxiliary requests. The amendment is not a combination with the combined amendments A to H, but an additional feature to all of these.

229 Claim 1 of the auxiliary request 10a reads as follows:

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

230 Amendment I is lacking an inventive step. D3 discloses the feature on page 10, lines 21-28:

> "The formulations of the present invention may be administered to a site of bleeding by any of a variety of means that are well known to those of skill in the art. Examples include but are not limited to internally (e.g. by ingestion of a liquid or tablet form), directly to a wound, (e.g. by shaking powdered or granulated forms of the material directly into or onto a site of hemorrhage), by placing a material such as a bandage that is impregnated with the material into or onto a wound, […].

Bandages may also be of a type that, with application of pressure, bend and so conform to the shape of the wound site"

231 On page 12, lines 28-29 it is disclosed, that many applications of the invention of D3 are based on the known problems of getting the surfaces of bandages to conform to all surfaces of a bleeding wound.

232 The skilled person would derive from D3 that it is advantageous that flexible bandages are capable of adapting to the shape of a bleeding wound, e.g., in order to provide protection and to achieve an efficient or even improved hemostatic effect.

jj) Amendment J (AR 19a and 26a)

233 In the last amendment, Amendment J, claim 1 has been further limited to the feature whereby said clay material (14) is kaolin.

234 In Amendment J, claim 1 has been limited to kaolin as the exclusive clay material and has been newly introduced into claim 1 in auxiliary requests AR 19a and 26a.

235 The wording of claim 1 of auxiliary request 19a is reproduced below. Like Amendment I, Amendment J is not a combination with the combined amendments A to H, but an additional feature to all of these.

236 Claim 1 of the auxiliary request 19a, that was discussed explicitly in the oral hearing, reads as follows:

A hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
a flexible gauze substrate (62), whereby said gauze substrate (62) is flexible to allow said gauze substrate (62) to form a shape of said bleeding wound and to retain a shape of said bleeding wound;
a clay material (14) disposed gauze substrate (62) and being in a dry state, whereby said clay material (14) is kaolin; and
a binder to adhere the clay (14) to the gauze substrate (62); and
wherein when treating a bleeding wound, application of said device causes at least a portion of said dry clay material to come into contact with blood.

237 The additional feature of the Amendment J is known from D3 (e.g. page 9 line 5) and cannot bring novelty and inventive step of AR 19a. On page 9 of D3 it is described:

"In another embodiment of the invention, the mineral clay that is used is kaolin (anhydrous aluminum silicate)."

238 The same applies to the further in the oral hearing discussed auxiliary request 26a that implements all amendments and reads as follows:

A hemostatic sponge (60) disposed in a sterilized packaging; said hemostatic device is for providing a hemostatic effect on a bleeding wound, said device comprising:
an absorbent flexible gauze substrate (62); whereby said gauze substrate (62) is flexible to allow said gauze substrate (62) to form a shape of said bleeding wound and to retain a shape of said bleeding wound;

a clay material (14) disposed on only a first surface of said gauze substrate (62) and being in a dry state, whereby said gauze substrate (62) initially exists separately from said clay material (14), and whereby said gauze substrate (62) initially exists separately from said clay material (14), and whereby said clay material (14) is kaolin;
a binder to adhere the clay (14) to the gauze substrate (62); and
a radiopaque component;
wherein said hemostatic device is folded into a configuration to produce a number of distinct plies attached along the edges; and
wherein when treating a bleeding wound, application of said device causes at least a portion of said dry kaolin to come into contact with blood through said flexible gauze substrate (62).

239 Auxiliary request 26a violates Art. 123 (2) EPC. Not all features relating to the sponge were included in the AR 26a.The features with regard to the sponge originate – as mentioned above - from claim 52 that refers to claim 44 and there to a hemostatic sponge. On page 11 lines 16-22 the application document discloses:

"Referring now to FIG. 6, another embodiment of the present invention is a sponge, shown at 60, which comprises a substrate 62, the particlized kaolin 14 (or some other clay material or diatomaceous earth) disposed on one face of the substrate 62, and a release agent 64 disposed on an opposing face of the substrate. The sponge 60 allows for sufficient contact of the particlized kaolin 14 with blood emanating from a wound and through the release agent 64 and the substrate 62 while minimizing the adhesion of the sponge to the wound tissue. The sponge 60 is also compatible with living tissue."

240 Both in claim 44 and in the relevant passage of the description, as well as in Figures 6 to 9, the embodiment relating to a sponge is described in conjunction with other features, such as the release agent, which is, however, not the subject of auxiliary claim 26a.

241 Although the sponge is now included in AR 26a, the other characteristics associated with the sponge are not included. Extracting this feature without incorporating the essential structural context of the sponge (including the release agent, absorbent matrix, spatial arrangement) results in a violation of Article 123 (2) EPC. There is no evidence or even indication to suggest that the features of the sponge – radiopaque, release agent etc. - apply generally to an overall concept.

242 Auxiliary request 26a cannot therefore be derived directly and unambiguously without the further requirements that relate to the sponge.

5. Result:

243 There is no obligation to rule on the Claimant's application of 15 January 2026, as it was submitted only in the event that the court allows the second amendment of claims of the patent in suit as requested by the Claimant with writ of September 1, 2025.

244 The infringement action is not justified. It must be dismissed. The infringement action cannot succeed due to the revocation of the patent in suit. It is therefore unnecessary to address the question of whether a patent infringement has occurred.

Legal consequences

245 As a result of the revocation action, European Patent EP 2 077 811 B1 is revoked with effect to the requested territories.

246 The infringement action is dismissed.

247 The Claimant shall bear the costs of the infringement action and the counterclaim for revocation, Art. 69 (1) UPCA.

248 The value of dispute of the infringement action is set to 1.000.000,00 EUR. The Panel considers an amount of 1.000,000 EUR as an appropriate amount for the infringement action and 1.000.000,00 EUR for the counterclaim for revocation. In doing so, the Panel has in particular taken into account that on the one hand the Defendant is a small company but on the other hand the Claimant pursues its alleged rights in ten countries.

DECISION:

1. The European patent EP 2 077 811 is revoked to the extent of claims 1, 2, 3, 7 and 9 for the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark (without Faroe Islands and Greenland), the Republic of Finland, the French Republic (without New Caledonia and French Polynesia), the Federal Republic of Germany, the Italian Republic, the Kingdom of the Netherlands (without Aruba), the Portuguese Republic and the Kingdom of Sweden.

2. The Application of 1 September 2025 to further amend the patent in suit is dismissed.

3. The Application of 1 October 2025 to amend the counterclaim for revocation to the extent of claim 15 is dismissed.

4. The infringement action is dismissed.

5. The costs of the infringement action and the counterclaim for revocation are to be borne by the Claimant.

6. The value in dispute for the infringement action is set at EUR 1.000.000. The value in dispute for the Counterclaim for revocation is set at EUR 1.000.000.

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

Sabine Klepsch Presiding Judge und Judge-rapporteur	Sabine Maria Klepsch Digital unterschrieben von Sabine Maria Klepsch Datum: 2026.04.27 10:01:34 +02'00'
Dr. Stefan Schilling Legally qualified Judge	Stefan Schilling Digital signiert von Stefan Schilling DN: cn=Stefan Schilling, c=DE, email=stefan.schilling@unifiedpatentcourt.org Datum: 2026.04.27 09:57:55 +02'00'

Stefan Johansson Legally qualified Judge	Stefan Erik Johansson Digitally signed by Stefan Erik Johansson Date: 2026.04.27 10:05:09 +02'00'
Jeroen Meewisse Technically qualified Judge	Jeroen Willem Meewisse Digitaal ondertekend door Jeroen Willem Meewisse Datum: 2026.04.27 10:23:17 +02'00'
For the sub-registry	Sarah Brecht Digital signiert von Sarah Brecht DN: cn=Sarah Brecht, c=DE, email=sarah.brecht@lg.justiz.hamburg.de Datum: 2026.04.27 10:33:35 +02'00'

INFORMATION ON APPEAL

An appeal against this decision may be brought before the Court of Appeal by any party whose claims have been unsuccessful, in whole or in part, within two months of service of the decision (Art. 73(1) UPCA, R. 220.1 (a) RoP, 224.1 (a) RoP).

INFORMATION OF ENFORCEMENT (Art. 82 UPCA, Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP): An authentic copy of the enforceable order will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

INSTRUCTION TO THE REGISTRY

A certified copy of the decision shall be sent to the European Patent Office and the national Patent and Trademark offices as soon as the decision on the revocation action has become legally binding. This decision was read in open court on 19 December 2025.

This decision was announced in public session on 27 April 2026

Stefan Schilling
Digital signiert von Stefan Schilling
DN: cn=Stefan Schilling, c=DE, email=stefan.schilling@unifiedpatentcourt.org
Datum: 2026.04.27 14:03:00 +02'00'

Dr. Stefan Schilling

Legally qualified Judge