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Datasheet for the decision of 10 January 2023

Case Number: T 2892/19 - 3.2.02

Application Number: 07802770.3

Publication Number: 2073862

IPC: A61M1/36, G01N33/49, B01D21/26, B01L3/14

Language of the proceedings: EN

Title of invention:
METHOD FOR THE PREPARATION OF PLATELET RICH PLASMA FOR UNPROCESSED USE AND COMBINATION THEREOF WITH SKIN AND BONE CELLS

Patent Proprietor:
Regen Lab SA

Opponents:
Estar Technologies Ltd.
PromoItalia Group S.p.A.

Headword:

Relevant legal provisions:
EPC Art. 56, 104(1)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:
Late-filed facts (no)
Inventive step over prior use - (no)
Apportionment of costs - abuse of procedure - (no)

Decisions cited:
T 0818/93, T 0952/00, T 0906/01, T 0152/03, T 1464/05, T 0474/13, J 0014/19

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2892/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 January 2023

Appellant: (Patent Proprietor)	Regen Lab SA En Budron B2 1052 Le Mont-sur-Lausanne (CH)
Representative:	Sach, Greg Robert Valet Patent Services LLP Siedlungsstrasse 4a 85253 Erdweg (DE)
Respondent: (Opponent 1)	Estar Technologies Ltd. P.O. Box 2150 15 Ha'merkava Street 5812101 Holon (IL)
Representative:	Pearl Cohen Zedek Latzer Baratz UK LLP The Gridiron Building One Pancras Square London N1C 4AG (GB)
Respondent: (Opponent 2)	PromoItalia Group S.p.A. Via San Gregorio 44 20124 Milano (IT)
Representative:	Sarpi, Maurizio Studio Ferrario S.r.l. Via Collina, 36 00187 Roma (IT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 October 2019 revoking European patent No. 2073862 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	N. Obrovski
	A. Martinez Möller
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor appealed against the Opposition Division's decision to revoke the European patent. The Opposition Division considered that the subject-matter of claim 1 of auxiliary request II lacked novelty over a prior use related to sales to and by a company called Levi Medical S.r.l ("Levi Medical").

II. Oral proceedings before the Board took place on 10 January 2023, in the absence of respondent 2, which had been duly summoned but had declared that it would not attend, without submitting any requests or arguments.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of auxiliary request II as considered in the decision under appeal or that the case be remitted to the Opposition Division.

Respondent 1 ("the respondent") requested that the appeal be dismissed.

III. The following documents are relevant to this decision:

D9: Regen Lab brochure entitled "RegenPRP- Kit " available at www.regenkit.com as of 26 September 2004, copy obtained from archived version of 12 March 2005 on the Wayback Machine

D51: Supply agreement between Regen Lab SA and Becton Dickinson AG signed 28 and 30 October 2003

D61: Witness statement (EPO) of Kama Levi, 20 September 2018

D62: Witness statement of Kama Levi,

6 April 2018
D63: Annexe KL1 to witness statement D62 of Kama Levi
D64: Annexe KL2 to witness statement D62 of Kama Levi
D65: Annexe KL3 to witness statement D62 of Kama Levi
D67: Annexe KL5 to witness statement D62 of Kama Levi
D68: Annexe KL6 to witness statement D62 of Kama Levi
D126: Second witness statement (EPO) of Kama Levi, 2 October 2018
D127: Second witness statement (EPO) of David Paul Sant, 2 October 2018
D129: Instructions for Regen Kit, 2006
D130: Third witness statement (EPO) of Kama Levi, 6 March 2019
D137: Decision in case HP-2017-000018 - UK High Court of Justice
D200: Witness statement of Antoine Turzi, 14 November 2022
D201: Legal opinion by Adelchi d'Ippolito, 7 December 2022

IV. Claim 1 of auxiliary request II reads as follows:

"A process for the preparation of a cell composition for wound or tissue healing or regeneration treatments, comprising the steps of:
(a) Centrifuging whole blood in a separator tube selected from:
- a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M; and
- a polyethylene terephthalate separator tube containing a highly thixotropic gel formed by a polymer mixture and an anhydrous sodium citrate at 3.5 mg/mL;
(b) Separating enriched platelet rich plasma from full plasma by removing half of the supernatant containing platelet poor plasma;

(c) Re-suspending the enriched plasma;
wherein the centrifugation step a) is performed at a force of or about 1500g up to about 2000g in a sufficient length of time to form a barrier between plasma containing platelets, lymphocytes and monocytes and a pellet containing erythrocytes; the separation step b) is made by collecting the supernatant from atop of said barrier and wherein the enriched plasma is enriched in leucocytes, thrombocytes and adhesion proteins as compared to native whole blood."

V. The appellant's arguments relevant to the decision can be summarised as follows.

Admissibility of D200 and D201

D200 and D201 should be admitted into the appeal proceedings as they had been submitted in response to a number of points raised in the preliminary opinion of the Board provided before the oral proceedings. These documents only shifted, if at all, the emphasis of arguments which had been submitted previously.

Prior use - availability to the public

The respondent's substantiation of a prior use of products of the appellant which had been allegedly sold to and by Levi Medical was based on unreliable and biased testimonies built for the circumstances. The respondent was involved in a criminal complaint in Switzerland. Kama Levi did not even have legal representation capacity as she had been a manager of a company, Levi Medical, which went bankrupt and was a debtor of the appellant. Kama Levi was also liable for patent infringement. Hence, she had a vested interest in invalidation of the patent and could not be

considered a credible witness. Her statements were false, deliberately misleading and, as such, an abuse of the EPO. Moreover, the appellant had had an agreement with Levi Medical but no commercial relationship with Kama Levi. She had no authority to be heard in proceedings on the patent in suit before the EPO. It followed that D61, D62, D126 and D130 should be disregarded. The fact that Kama Levi's witness hearing before the UK Court of Justice had not been challenged by the appellant was not decisive as that hearing had not been on the Regen kit shown in D127, its alleged sales according to D126 or the instructions for use according to D129. This evidence had not been considered in the UK proceedings which led to decision D137.

The witness statements of Kama Levi were not accurate and did not provide an uninterrupted chain of proof. On their basis, it was impossible to establish what had actually been delivered to Levi Medical. D63 was an agreement representing a first stage for future cooperation. Attachment C of D63, concerning sale forecasts for 2005, was blank. Contrary to what Kama Levi had stated in point 6 of D61, D63 was not binding for sales and did not provide any evidence of them. Attachment D of D63, concerning the distribution of the appellant's products by Levi Medical, was also blank. The reference to surgeons as potential customers in point 9 of D62 was therefore wrong. The price list referred in attachment A of D63 was not the one provided as D64. It was therefore unclear which products were available at the date of signing of D63. It was impossible to clearly identify the products listed in the invoices of D65, D67 and D68. There was no evidence that they corresponded to the single Regen kit referred to in D127, fortuitously discovered in

Kama Levi's home. There was no evidence either that the shipping documents in D126 related to the Regen kit referred to in D127 or the instructions according to D129. The fact that the same lot number was found in D127 and D129 was not decisive.

Moreover, the appellant's products that had allegedly been sold to Levi Medical had to have been sold for test purposes because their public sale without prior regulatory approval was prohibited by law in Italy. Medical devices to be placed on the Italian market had to be notified to the Ministry of Health via registration in an online database and bear the CE marking. The first announcement of publication/ commercialisation in Italy of the appellant's products according to the official database of the Italian Ministry of Health was dated May 2009, i.e. after the priority date of the patent. D63 could not circumvent provisions of Italian law. Accordingly, confidentiality and pending regulatory approval clauses were implicitly included in the agreement of D63. Moreover, there was a large body of evidence that the appellant, which had a significant interest in obtaining patent protection to monopolise the new technology, was undergoing clinical evaluations in Italy at the time around and after the priority date of the patent. D126 comprised transport documents which did not declare a value for insurance and related to small numbers of items, which were neither practical nor allowed for commercial purposes. This meant that D126 concerned prototypes for clinical evaluation purposes. No evidence of sale by Levi Medical to an end consumer for public use was provided by the respondent. The instructions according to D129 were unclear. For example, they wrongly mentioned 10% CaCl2 in the preparation of platelet rich plasma ("PRP") before application and referred to components

not present in the Regen kit. It was apparent that D129 was a work in progress and thus that the Regen kit according to D127 had to be a prototype. The Regen kit did not have the required regulatory approval and should not have borne a CE marking. The appellant had obtained a first CE marking in 2003 for a single product with specific instructions for use. D129 concerned a different product, the CE marking of which was not valid.

Accordingly, as considered in decision T 906/01 (and T 818/93), the development and test phases of products or devices in the medical field were necessarily surrounded by secrecy as long as the products or devices had not been approved and commercialised. In the medical field, there was a *prima facie* assumption that any person involved in a medical process was obliged to maintain confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices (T 152/03).

Prior use - novelty and inventive step

The Regen kit according to D127 and the instructions for use according to D129 neither anticipated nor rendered obvious the subject-matter of claim 1. First of all, because of their inconsistencies, the instructions according to D129 were so unclear that the person skilled in the art would not know how to use the Regen kit content. According to the instructions, a Regen THT® Vacutainer tube containing blood was centrifuged and 5 ml of PRP were obtained and could be transferred to a Z tube. It was unclear whether a second centrifugation step was carried out. According to one option, 2 of the 5 ml were drawn off. It was not

clear either whether the 2 ml were drawn off the Regen THT® Vacutainer tube or the Z tube. Since the Z tube did not have a barrier, there was no direct and unambiguous disclosure of the feature of claim 1 "collecting the supernatant from atop of said barrier". Furthermore, removing 2 out of 5 ml did not anticipate the feature of claim 1 "removing half the supernatant containing platelet poor plasma". Moreover, the Regen kit according to D127 and the instructions for use according to D129 did not directly and unambiguously disclose a glass separator tube containing a buffered sodium citrate solution at 0.10 M. Although D127 and D51 concerned the same reference number 368924 of the separator tube, this number had also been used for a previous version of such tubes of the appellant, as shown in D9. In this previous version, anticoagulant acid-citrate-dextrose ("ACD-A") was included instead of a buffered sodium citrate solution at 0.10 M. All the distinguishing features rendered the subject-matter of claim 1 also inventive over the Regen kit according to D127 and the instructions for use according to D129.

Apportionment of costs

Apportionment of costs in the appellant's favour was requested since the respondent had asserted numerous untrue facts, knowing that they were untrue. The respondent had repeatedly asserted that the appellant had sold Regen kits which had not been notified to the Ministry in Italy and, as such, this would have been illegal.

VI. The respondent's arguments relevant to the decision can be summarised as follows.

Admissibility of D200 and D201

D200 and D201 should not be admitted into the appeal proceedings. They had been filed very late for no cogent reasons and changed the nature of the proceedings as they referred to Italian law, which the respondent had not been given sufficient time to consider. Their submission was contrary to Article 13(2) RPBA.

Prior use - availability to the public

When the supporting evidence was not all within the power and knowledge of the opponent, the applicable legal standard for assessing a public prior use originating from the patent proprietor was the balance of probabilities.

Kama Levi's evidence related to her company's sale of the appellant's products in Italy before the priority date of the patent. She had put her name to a witness statement in UK High Court proceedings with a statement of truth and had been willing to be cross-examined on her statement under oath. Her evidence had remained unchallenged before the UK Court. Afterwards, Kama Levi had put her name to witness statements in the opposition proceedings, again with a statement of truth. Her testimony had been corroborated by documentation of sales. It was irrelevant whether there was a business relationship between the respondent and Kama Levi. Such a relationship between a witness and a party was typical in proceedings before the EPO. Likewise, any alleged bankruptcy or criminal proceedings did not play a role in these proceedings. Nor was it relevant whether Kama Levi represented a still existing company. Kama Levi herself had been

giving evidence, presenting her direct knowledge about past conduct. Her past activity regarding the pertinent products qualified her as a witness.

The shipping documents in D126 proved that Regen kits corresponding to the one according to D127 and D129 had been delivered to surgeons in Italy before the priority date of the patent. The shipping documents in D126, D127 and D129 related to Regen kits with the same lot production number 0011. Whether D65, D67 and D68 referred to a different lot production number or whether D63 comprised no sales forecasts or referred to a price list which had not been provided as evidence was irrelevant for the relationship between the shipping documents of D126 and the Regen kit according to D127 and D129.

The appellant's argument that the promotion and sale of the appellant's products must have been confidential could not outweigh the witness evidence and the documents submitted showing that the sales had not been confidential. What was required for medical devices to be publicly promoted and sold in Italy was a CE certification and a notification to the Ministry of Health. The only regulatory approval needed was the CE marking. The notification was a trivial requirement done either by letter or online. For the new database since 2007, notification had to be done online only. The Regen kits according to D126, D127 and D129 were CE marked. Since Levi Medical was an expert in the medical device field and understood the Italian regulations, there was no reason to assume that it did not undertake this simple notification prior to selling the Regen kits according D126, D127 and D129 before the priority date of the patent. Moreover, even if the regulatory approval had still been pending in Italy, this would

not automatically prove a confidentiality obligation on Levi Medical. The evidence of sales by the appellant proved that if it truly had been illegal to make those sales, the appellant did not know or care about the illegality. Since the prior use was by the appellant and the relevant product/technical information had been transferred to a third party, the burden of proof for establishing the existence of a confidentiality agreement lay with the appellant (T 473/13, Reasons 11.2). No evidence had been provided by the appellant for this. On the contrary, the witness statements of Kama Levi (in particular D62, paragraph 11) and the signed distribution agreement of D63 excluded any obligation of confidentiality. D63 did not mention any need to obtain regulatory approval prior to promotion and sale and was explicit in that the relationship between Levi Medical and the appellant had been that of "vendor and vendee" (section 10). There was no mention or expectation of any confidentiality in Levi Medical's signed distribution agreement with the appellant. The appellant's assertion that the Regen kits according to D126, D127 and D129 had to be prototypes was *prima facie* incorrect as the Regen kits were provided with CE markings, which made them suitable for sale. Moreover, the appellant had provided no evidence of any clinical trials in Italy. The fact that the shipping documents of D126 were for small numbers of items did not mean that the sales must have been only for clinical evaluation or testing purposes, in accordance with T 1464/05. Minor inconsistencies in the instructions according to D129 did not prove any confidentiality agreement. If the Regen kits according to D126, D127 and D129 had not been, in fact, CE-certified, applying the CE mark and selling them with the CE mark would have been illegal.

Prior use - novelty and inventive step

The appellant had disputed for the first time on appeal that the instructions for use of D129 disclosed the method as defined in claim 1 of auxiliary request II. This was an amendment to the appellant's case which should not be admitted under Article 12 RPBA.

The Regen kit according to D127 and the instructions for use according to D129 deprived the subject-matter of claim 1 of auxiliary request II of novelty or at least inventive step.

The minor inconsistencies in the instructions according to D129 did not affect their clarity for the person skilled in the art. According to D129, in all cases blood was collected into Regen THT® Vacutainer tubes and inverted gently. The tubes containing the blood were centrifuged at 1500 g for 8 minutes. According to one option, in a method not involving a Z tube, a syringe could be inserted directly into the centrifuged Regen THT® Vacutainer tube to remove 2 out of 5 ml of the supernatant (which was about half) from the Regen THT® Vacutainer tube. It would not have been possible to remove 2 ml of supernatant from the Z tube to increase the platelet concentration without a further centrifugation step. Moving the whole plasma from the Regen THT® Vacutainer tube into the Z tube involved resuspending the platelet cells into the plasma. This would have made it impossible to remove a platelet poor supernatant layer from the Z tube to increase the platelet concentration. The step of "removing half of the supernatant" in claim 1 of auxiliary request II, as properly interpreted, did not require the removal of exactly 50% of the supernatant from the tube. This would have been practically

impossible and not a reasonable expectation. If removing 2 out of 5 ml was considered a distinction compared with the claimed subject-matter, this minimal distinction could not be inventive. There was no significant effect of the difference for the increase in platelet concentration. The fact that the Regen THT® Vacutainer tubes in the Regen kits according to D126, D127 and D129 contained 0.10 M buffered sodium citrate solution was directly derivable from D51. The Regen THT® Vacutainer tubes of the Regen kits were products with reference number 368924 (paragraph 32.1 and photograph on page 15 of D127). D51 stated that Becton Dickinson AG was to manufacture the Regen THT® Vacutainer tubes for the appellant under the same reference number. Moreover, as stated in paragraph 32 of D127 and clearly visible from the pictures on pages 13 and 14 of D127, the label of the Regen THT® Vacutainer tubes in the Regen kit contained the words "NC: 1.0mL". "NC" was a well-known and commonly-used abbreviation in the field for "sodium citrate" anticoagulant – as opposed to, for example, ACD-A anticoagulant. Although D9 showed a picture of a Regen THT® Vacutainer tube with reference number 368924 (page 8) and indicated that this tube contained anticoagulant ACD-A (page 9), this could have been a mistake. Perhaps the relevant part of D9 had been prepared before the specifications according to D51 came into effect and not updated afterwards.

Apportionment of costs

Apportionment of costs in the respondent's favour was requested due to the appellant's abusive behaviour. The entire case set out by the appellant was based on assertions surrounding the sale of its own products which were untrue and which the appellant knew or

should have known to be untrue. Examples of false statements were the fabrication of a quotation from Lord Justice Floyd of the UK Court of Appeal and Antoine Turzi's statement that "at the priority date of the patent [i.e. in August 2006], Regen Lab had no commercial relationship with Ms. Levi, as she was not our partner". In accordance with T 952/00, the Board should grant the respondent an apportionment of costs.

Reasons for the Decision

1. The invention

The invention relates to a process for the preparation of a cell composition for wound or tissue healing or regeneration treatments from whole blood.

Platelet rich plasma ("PRP") is obtained from the whole blood by discarding platelet poor plasma.

According to the patent, the PRP, possibly with the addition of certain specific cells of the body, may be used as an autologous treatment, i.e. a treatment of a person from whom the whole blood and the specific cells are obtained, for many kinds of diseases (paragraphs [0028] to [0039]) by promoting tissue regeneration. According to the patent, diseases which may be effectively treated include myocardial deficiencies, peripheral nerve damage or spinal cord injury, diabetes, urinary and anal incontinence, and gastroesophageal reflux.

According to claim 1 of auxiliary request II, the whole blood is centrifuged in a separation tube containing a thixotropic gel (a gel that becomes more fluid as a

result of agitation or pressure - paragraph [0049] of the patent) and sodium citrate (an anticoagulant).

As a result of the centrifugation, performed at a given force for a sufficient length of time, a pellet containing erythrocytes (red blood cells) is formed at the bottom of the separation tube, on the top of which a supernatant (plasma) is gathered. The claim defines the separation between the red blood cells and the plasma as "a barrier". According to the claim, half of the plasma from atop of the barrier is removed to obtain "enriched platelet rich plasma". This is because the blood cells other than the red blood cells tend to gather towards the bottom of the plasma, proximate to the red blood cells (due to their weight). Table 1 of the patent provides an overview of how "enriched" the "enriched platelet rich plasma" may be compared to the complete plasma.

2. Admissibility of D200 and D201

D200 and D201 were filed by the appellant after the summons to oral proceedings. The respondent requested that they not be admitted into the appeal proceedings.

Under Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The Board notes that D200 and D201 comprise legal arguments on the credibility of Kama Levi's witness statements which can be seen as a repetition or refinement of the appellant's arguments provided in the

statement of grounds of appeal (points 25 to 27). The Board considers the references to foreign law in D200 and D201 an attempt to corroborate the alleged universal applicability of the legal arguments previously presented, rather than as a stand-alone analysis of that law.

In conclusion, in line with J 14/19 (point 1.11 of the Reasons), the Board does not see the filing of D200 and D201 as an amendment of the appellant's appeal case. Hence, D200 and D201 are taken into account in the appeal proceedings.

3. Prior use - availability to the public

In view of the conclusions in the impugned decision, the Board has to consider first whether Regen kits and instructions for use according to D127 and D129 belong to the state of the art.

More specifically, it has to be established whether such Regen kits and instructions were delivered to Levi Medical and from this company to clinicians in Italy before the priority date of the patent and, if so, whether the deliveries made these Regen kits part of the state of the art.

3.1 Evidence for the deliveries of the Regen kits and instructions does not lie exclusively within the sphere of the respondent. Rather, both the appellant and the respondent had access to this evidence since the deliveries under scrutiny are for material which originated from the appellant and which was the subject of a distribution agreement between the appellant and Levi Medical (D63). Hence, the applicable standard of proof is the balance of probabilities (see "Case Law of

the Boards of Appeal", 10th edn., III.G.4.3.2 a)).

3.2 Concerning whether Regen kits and instructions for use according to D127 and D129 were delivered to Levi Medical and from this company to clinicians in Italy before the priority date of the patent, the respondent provided a witness statement by Kama Levi (D126) according to which a Regen kit as shown in D127 including instructions for use according to D129 had been found at her home. In D126, Kama Levi produced shipping documents as evidence of the delivery of nine Regen kits to different clinicians in Italy before the priority date of the patent. The shipping documents concern Regen kits identified as lot 0011, which is the same lot number appearing on the Regen kit in D127 (page 12) and in the instructions for use according to D129 (page 1). Contrary to the appellant's view, this is strong evidence that the Regen kits according to the shipping documents in D126 had to be the same as the one shown in D127, with instructions of use D129. The same lot number normally indicates a unique product, and the appellant failed to provide any evidence that this was not the case for the kits that it delivered to Levi Medical. The alleged contradictions in D62, D63, D64, D65, D67 and D68 relate to deliveries other than those of Regen kits and instructions for use according to D127 and D129 on the basis of the shipping documents in D126. Hence, these arguments are not relevant.

The appellant alleged that Kama Levi was an unreliable witness, also on the basis of D200 and D201, mainly because she had an interest in the invalidation of the patent in suit and was involved in criminal proceedings.

The Board has noted Adelchi D'Ippolito's statements in

D201. His considerations about Kama Levi's status and interests are to be considered in the evaluation of the submitted evidence under the principle of free evaluation of evidence applicable to the boards. However, such considerations do not render evidence or witness statements automatically inadmissible or unreliable in proceedings before the EPO. Rather, it is not exceptional in opposition proceedings that a piece of evidence or a witness statement stems from an interested person or even a party to the proceedings.

In view of the strong documentary evidence provided in addition to Kama Levi's witness statements and the fact that the appellant has not pointed to any substantial contradictions in these witness statements about the deliveries of Regen kits and instructions for use according to D127 and D129, the Board is convinced, on the balance of probabilities, that Regen kits according to D127 and instructions for use according to D129 were delivered to Levi Medical and clinicians in Italy before the priority date of the patent.

3.3 Concerning whether the deliveries of Regen kits according to D127 and instructions for use according to D129 made those Regen kits part of the state of the art, the Board notes that it is the appellant which initially has the burden of proof to establish the existence of a confidentiality agreement (T 473/13, point 11.2 of the Reasons).

The respondent provided Kama Levi's witness statements to the EPO and the UK High Court of Justice, according to which purchases and sales by Levi Medical of the appellant's products were not confidential. The witness hearing before the UK High Court of Justice remained unchallenged (points 20 and 88 of D137). The witness

statements are supported by distribution agreement D63, which does not include or hint at any confidentiality agreement for the Regen kits. On the contrary, D63 clearly indicates that these kits were normal items of trade, explicitly defining the relationship between the appellant and Levi Medical as one of vendor and vendee, the latter of which has to maximise the sales of the product and actively demonstrate it to potential customers (paragraphs 3, 8 and 10). There is no reason to assume that the lack of confidentiality derivable from D63 should not extend to the deliveries of the Regen kits to Levi Medical and clinicians in Italy, especially because the appellant provided no explicit evidence that those deliveries had been made under a confidentiality obligation.

The appellant only argued that the deliveries had implicitly been confidential as the Regen kits had not been approved for commercialisation in Italy and therefore were for test purposes only. To support this argument, the appellant referred to T 906/01 and T 818/93.

The Board in T 906/01 held that "a device having an investigational status, being implanted and tested within the restricted area of an hospital, under the responsibility of a surgeon operating within the frame of an investigator's agreement provided with a clause of confidentiality, must be regarded as a prototype device. Usually the development and testing phases of such products or devices are necessarily surrounded by secrecy as long as said products or devices have not been approved and commercialized" (point 3.5 of the Reasons). T 818/93 comes to similar conclusion in the case of a research project aimed at the fabrication and testing of an expandable graft (point 4.1 of the

Reasons).

The appellant's line of reasoning is neither convincing nor in line with the conclusions in T 906/01. The statement in T 906/01 cited above, which refers to a lack of approval and commercialisation, only concerns devices as defined in the preceding sentence ("said products or devices"), i.e. to devices for which it has been established have "an investigational status" and are "tested within the restricted area" of a hospital. In the current case, the appellant has failed to establish such a prototype status. As the Board noted, the distribution agreement D63 supports the opposite, namely that the Regen kits were regular items of trade. For the same reasons, T 152/03 is not relevant to the current case either.

Even if the Italian Ministry of Health had to be informed before the selling of the kits in Italy and even if this information had not been provided, this does not imply that the Regen kits were prototypes. The fact that the appellant may have had a significant interest in obtaining patent protection does not render the kits prototypes either. Mistakes in this respect happen. As regards the allegedly small number of deliveries according to D126, this is not evidence that the Regen kits were prototypes. As concluded under similar circumstances in T 1464/05 cited by the respondent (point 4.2 of the Reasons), the deliveries could have been for promotional purposes, for instance. The alleged lack of clarity due to mistakes in the instructions for use according to D129 does not make the kits prototypes either.

Most importantly, however, as the respondent argued, the Regen kit shown in D127 and the instructions for

use according to D129 bear a CE marking, which conveys the information that the kit was a final product that could be sold in the EU. Even if the Regen kit should, as argued by the appellant, not have had such a CE marking for legal reasons, the mere fact that this marking was actually on the product speaks strongly against customers considering it a prototype.

For these reasons, the Board is convinced that the deliveries of Regen kits according to D127 and instructions for use according to D129 to Levi Medical and clinicians in Italy before the priority date of the patent made those kits part of the state of the art.

4. Prior use - novelty and inventive step

4.1 The respondent argued that the appellant's arguments according to which the instructions for use according to D129 did not disclose the method as defined in claim 1 of auxiliary request II should not be admitted into the appeal proceedings.

Under Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020, the Board has discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings. The Board considers the appellant's arguments an appropriate reaction to the conclusions in the impugned decision, which deviated from the preliminary opinion sent in advance of the oral proceedings before the Opposition Division, and admits them into the appeal proceedings.

4.2 D127 and D129 refer to a separator tube called a Regen THT® Vacutainer. As the respondent correctly argued, D51, a general supply agreement between the

appellant and Becton Dickinson AG, discloses that a Regen THT® Vacutainer tube as manufactured after October 2003 and with reference number 368924 (corresponding to the one visible on pages 14 and 15, annexes DPS-E5 and DPS-E6 of D127) contained a polyester-based thixotropic gel and 1.0 mL of an anticoagulant in the form of a buffered sodium citrate solution at 0.100 M (Schedule 2 of D51).

In D127 (pages 14 and 15, annexes DPS-E5 and DPS-E6), it is also visible that the Regen THT® Vacutainer tube contains sodium citrate ("NC") 1.0 mL. Hence, there is no reason to doubt that D127 is in accordance with the specifications of D51, i.e. the Regen THT® Vacutainer tube in D127 was manufactured according to the specifications valid at the time of its production. Whether D9, a brochure available on the internet in 2004, discloses that an anticoagulant other than sodium citrate could have been present in a Regen THT® Vacutainer tube with the same reference number, as argued by the appellant, is not decisive. As the respondent argued, D9 may have referred a theoretical version of a Regen THT® Vacutainer tube contemplated before the signing of D51, or it could simply contain a mistake.

4.3 The appellant argued that the instructions according to D129 were so unclear that the person skilled in the art would not know how to use the Regen kit. However, the inconsistencies in D129 to which the appellant pointed, such as the wrong mention of 10% CaCl2 in the preparation of PRP before application and of components not present in the Regen kit, are no real hurdle for the person skilled in the art in possession of the Regen kit and wanting to obtain PRP according to the instructions. Based on common general knowledge and the

other instructions, which pertain to the use of components all present in the kit, the person skilled in the art would immediately recognise such inconsistencies as minor mistakes and ignore them.

4.4 Considering D129 in view of D51 and D127, the public prior use discloses a process for the preparation of a cell composition for wound or tissue healing or regeneration treatments (PRP according to the instructions) comprising the steps of centrifuging whole blood in a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M (Regen THT® Vacutainer tube and section "Centrifuging" in D129), separating enriched platelet rich plasma from full plasma by removing part of the supernatant containing platelet poor plasma (by drawing off 2 ml supernatant after centrifugation - section "Preparation of PRP before application", point "a"), re-suspending the enriched plasma (homogenisation by inversion - section "Preparation of PRP before application", point "a"), with the centrifugation step being performed at a force of 1500 g in a sufficient length of time to form a barrier between plasma containing platelets lymphocytes and monocytes and a pellet containing erythrocytes (section "Centrifuging" and Figure 2 of D129), and with the enriched plasma being enriched in leucocytes, thrombocytes and adhesion proteins as compared to native whole blood.

4.5 The appellant submitted that D129 did not disclose a separation step made by collecting the supernatant from atop of the barrier in the separator tube. The appellant argued that, according to D129, the separation step did not necessarily take place by removing the supernatant from the Regen THT® Vacutainer

tube where the barrier would have formed after centrifugation. The supernatant could first be entirely transferred to a Z tube, from which the removal of a part could take place afterwards.

However, according to D129, there are two possible options for obtaining PRP. The first involves only one centrifugation, and the second involves a second centrifugation of the Z tube. According to the first option, described in the section "Preparation of PRP before application", point "a", PRP may be transferred from the Regen THT® Vacutainer tube using a syringe ("to draw it directly in the Regen THT tube"). The same section discloses the removal of part of the supernatant to obtain PRP ("draw off 2 ml supernatant after centrifugation"). Hence, according to the first option, the removal of the supernatant is done from the Regen THT® Vacutainer tube. Hence, the appellant's argument that the whole content of the Regen THT® Vacutainer tube could be transferred to the Z tube before removing part of the supernatant must fail. This is all the more so because removing platelet poor plasma from the Z tube without a further centrifugation step would only be possible after an unreasonable waiting time needed for the plasma to set, as the respondent pointed out. It follows that D129 also discloses a separation step made by collecting the supernatant atop of the barrier in the separator tube, as defined in claim 1 of auxiliary request II.

4.6 The only remaining feature of claim 1 of auxiliary request II to be considered is the one according to which half of the supernatant is removed. The appellant argued that D129 taught to remove 2 out of 5 ml, and hence the removed part would not be half of the total.

The Board's view is that this claim feature is at least obvious in view of D129. Half of 5 ml is very close to 2 ml, especially in view of the necessary tolerances involved. According to D129, the removal is done by hand, and the user has to visually identify the removed quantity. Moreover, the patent provides no teaching that the precise rate of removal of the supernatant could bring about any unexpected effect. Clearly, the more platelet poor plasma removed, the higher the platelet concentration in the remaining PRP. Hence, based on the teaching of D129, the person skilled in the art would have removed half of the supernatant containing platelet poor plasma whenever circumstances made it desirable, without exercising any inventive activity.

4.7 It follows that the subject-matter of claim 1 of auxiliary request II, i.e. the only claim request on file, is not inventive (Article 56 EPC) over the prior use of Regen kits and instructions for use according to D127 and D129.

Hence, the patent cannot be maintained for lack of inventive step (Article 101(3)(b) EPC).

5. Requests for apportionment of costs

Each party requested apportionment of costs in its favour due to alleged abusive behaviour of the other party.

The Board is of the view that each party must bear its own costs in line with the usual situation set out in Article 104(1) EPC. Persistently pursuing own interests in proceedings before the EPO does as such not amount to an abuse of procedure, and an abuse of procedure

must be established without doubt (J 14/19, Reasons 13).

Each party argued that the other party made untrue statements, knowing that these statements were untrue. However, the Board notes that parties must enjoy ample freedom to put forward interpretations of quotations, legislation and business relations as they deem appropriate to make their cases. In the case at hand, both parties have made statements which are attempts to interpret facts from a perspective favourable to them, i.e. attempts to pursue their own interests. The Board cannot establish without doubt that a party has made an untrue statement knowing that it was objectively untrue, hence T 952/00 referred to by the respondent is not relevant here. Antoine Turzi's statement in D200 that "at the priority date of the patent, Regen Lab had no commercial relationship with Ms. Levi, as she was not our partner" may reflect Antoine Turzi's view that Regen Lab did not have direct commercial relations with Kama Levi in person but instead with the company Levi Medical. As regards the appellant's quotation from Lord Justice Floyd of the UK Court of Appeal and the respondent's submissions about the sales of Regen kits, these are also matters of subjective interpretation.

In conclusion, the requests for apportionment of costs must be rejected.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The requests for apportionment of costs are rejected.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated