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Datasheet for the decision of 23 September 2024

Case Number: T 2118/21 - 3.3.10

Application Number: 07736621.9

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Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL AND COSMETIC USE OF SILICA

Patent Proprietor:
Blaa Lonid Hf.

Opponent:
Beiersdorf AG

Headword:
SILICA / Blaa Lonid

Relevant legal provisions:
EPC Art. 54(5)

Keyword:
Novelty - second (or further) medical use - (no)
Homeopathic treatment as prior art

Decisions cited:
T 0116/85, T 1457/09, T 1859/08, T 0385/07, T 0158/96, T 0715/03

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 2118/21 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 23 September 2024

Appellant: (Patent Proprietor)	Blaa Lonid Hf. Nordurljosavegi 9 241 Grindavik (IS)
Representative:	Arnason Faktor Intellectual Property Consulting Gudridarstig 2-4 113 Reykjavik (IS)
Respondent: (Opponent)	Beiersdorf AG Unnastrasse 48 20253 Hamburg (DE)
Correspondence address:	Beiersdorf AG Patentabteilung Beiersdorfstraße 1-9 22529 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 September 2021 concerning maintenance of the European Patent No. 2026880 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	M. Kollmannsberger
	F. Blumer

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the decision of the Opposition Division to maintain its patent in amended form under Article 101(3)(a) EPC, based on the first auxiliary request.

II. The patent deals with the pharmaceutical and cosmetic use of silica. The patent describes that silica (silicon dioxide, SiO_2) in different forms, e. g. in the form of silica mud as obtained from the Blue Lagoon geothermal basin in Iceland, but also in the form of colloidal silica, may stimulate collagen biosynthesis. Therefore, silica is described as being useful in the treatment of various skin related diseases as well as for cosmetic purposes.

III. The patent had been opposed, among other grounds, on the basis of Article 100(a) EPC for lack of novelty, Article 54 EPC. The Opposition Division decided that claim 1 of the granted patent lacked novelty over documents D1 and D3. An amended version of the patent in the form of the patent proprietor's first auxiliary request was considered to fulfil the requirements of the EPC. In claim 1 of this request two therapeutic indications which are present in granted claim 1 are omitted.

IV. Claim 1 of the patent as granted has the following wording (the two indications deleted in claim 1 of the auxiliary request are marked as underlined).

"*Silica for use in the treatment of skin conditions selected from the group consisting of skin damage due to cortico steroids, skin atrophy, structural weakness of the connective tissue, wound healing, atopic dermatitis, eczema, psoriasis, rosacea.*"

V. Relevant documents are:

D1: Hunnius Pharmazeutisches Wörterbuch. 9. Auflage, Walter de Gruyter Verlag, Berlin, Seite 1386. Stichwort: Siliciumdioxid, 2004

D3: Prof. em. Prof. med. Karl Hecht: "*Gesund sein und gesund werden mit der Ursubstanz Siliziumdioxid Synonym Kieselsäure*", 15.02.06

S3: "*KBV ruft nach Erstattungsverbot für Homöopathie*", aerzteblatt.de, 6. September 2019

S4: Maibach-Nagel, Egbert, *"Homöopathie: Kein Sommerlochthema"*, Dtsch Arztebl 2019; 116(29-30)

S5: Deutsche Welle, "*German health insurers urged to end homeopathy refunds"*, 11.07.2019

VI. In its statement setting out the ground of appeal, and throughout the appeal proceedings the appellant submitted that the novelty objections against claim 1 as granted were unfounded. Neither D1 nor D3 were disclosures adhering to scientific standards. The alleged therapeutic uses of silica described therein were unsubstantiated. No relevant therapeutic activity had been proven. A person skilled in the medical field would not take these disclosures at face value. These disclosures lacked credibility and should not be

considered novelty destroying prior art for the granted claim. In particular, novelty of the disputed claim 1 over D1 was provided by the feature "*treatment*", since the homeopathic treatment described in D1 was without effect, and was thus not a treatment of a therapeutic nature as required by the claim.

VII. The opponent (respondent) defended the Opposition Division's decision. It submitted that D1 and D3 were novelty destroying disclosures. D1 was a pharmaceutical handbook and D3, although not peer-reviewed, was a review article published by a renowned scientist. There was no reason to assume that the therapeutic activity of silica as reported in these documents did not exist and thus no reason to disregard the disclosure of these documents when assessing novelty.

VIII. The parties' requests were the following:

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted.

The respondent (opponent) requested that the appeal be dismissed.

IX. Oral proceedings were held on 23 September 2024. The decision was announced at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 of the patent is drafted as medical use claim under Article 54(5) EPC and is directed to silica (silicium dioxide, SiO_2) for use in the treatment of skin conditions selected from i. a. "*structural weakness of the connective tissue*" and "*wound healing*". The Opposition Division's decision states that the use of silica for these therapeutic indications is anticipated by the disclosures of D1 and D3.

3. Novelty over D1, Articles 100(a) and 54(5) EPC.

3.1 D1 is an excerpt of a pharmaceutical handbook. For silica (SiO_2) various homeopathic uses are listed. In particular it is stated that pure precipitated SiO_2 in hydrated form (75-90%) is prescribed ("*verord.*") in case of problems with wound healing processes or against weakness of connective tissue. Thus, from this handbook it is known that silica is used in homeopathic treatments for the two disputed therapeutic indications defined in claim 1 of the granted patent.

D1 is a well-known pharmaceutical handbook and there is no reason to doubt its disclosure.

3.2 The appellant argued that homeopathic treatment was not covered by the claim. The claim defined a therapeutic treatment. Homeopathy was not a medical, therapeutic treatment since the underlying mechanisms did not adhere to established scientific standards. Such a therapy could not be, and in fact was not, effective

and had never been proven effective in any clinical study. Both basic principles of homeopathy, i. e. the doctrine of "like cures like", and the idea that an active ingredient increased its curative power the more it is diluted, possibly down to a non-detectable concentration or even theoretically being absent, contravened fundamental, well-established scientific concepts. In fact, it was general consensus in the medical field that homeopathic treatment provided, if at all, at most a placebo effect. The appellant referred to documents S3-S5 in this respect. Thus, the treatment disclosed in D1 was not therapeutic in the sense of the disputed claim.

3.3 The respondent considered the fact that D1 described a treatment using silica against pathological conditions included in claim 1 of the granted patent to be enough for a novelty destroying disclosure. A technical teaching corresponding to the granted claim was already known before the patent was filed.

3.4 In the Board's view D1 discloses a therapeutic treatment in the sense of the EPC which is included in claim 1 as granted.

3.4.1 Claim 1 of the patent is drafted as a medical use claim under Article 54(5) EPC. Under Article 54(5) EPC a substance may be claimed for a specific use in a method which would itself be excluded from patentability under Article 53(c) EPC. In the present case, the relevant method is a method for treatment of the human or animal body by therapy. Thus, the Board agrees with the appellant that the claim necessarily relates to silica for use in treatment by therapy, i. e. for use in *therapeutic treatment* of the conditions defined in the

claim, although therapy is not literally mentioned therein.

3.4.2 Claim 1 of the patent as granted does not contain any limitation as to which type of therapeutic treatment the claim is directed to. Under Article 84 and Rule 43(1) EPC the subject-matter for which protection is sought is defined in the claims in terms of technical features of the invention. Granted claim 1 does not define any technical feature that could distinguish the claim from the treatment mentioned in D1, such as the nature of the silica used, the mode of administration, a dosage form or a dosage regimen. For defining novel subject-matter, be it in the classical way under Article 54 (1)-(3) EPC or under the exceptional provisions for substances or compositions for use in therapeutic methods under Articles 54(4)(5) EPC it is however a prerequisite that some (combination of) technical feature(s) defined in the claim provide(s) a distinction over the prior art.

3.4.3 The feature "treatment" does not provide a distinction over D1.

The Board is not in a position to decide whether homeopathy, in general, is an effective treatment of a pathological condition or not. However, this is not the decisive point here; the appellant's submissions arguing lack of scientific basis or lack of proven efficacy of homeopathic treatments being correct or not. The treatment described in D1 is therapeutic in that silica is intentionally administered by medical practitioners to patients in the expectation of curing or at least improving a pathologic condition. Methods with such a curative purpose are therapeutic methods in the sense of the EPC; they are methods which themselves

would be unpatentable under Article 53(c) EPC. The idea behind the exclusion of therapeutic methods from patent protection under Article 53(c) EPC is to keep anyone practising such methods as a part of a medical treatment free from patent considerations, see e.g. T 116/85 (OJ 1989, 13), reasons 3.6-3.8. Thus, a method prescribed as a treatment of a pathological condition by medical practitioners, as the one disclosed in D1, must be considered therapeutic in the sense of the EPC, independent of its proven or not effectiveness.

3.5 The appellant argued that according to established jurisprudence of the Boards of Appeal a document only takes away the novelty of a claim if its disclosure is reproducible, see Jurisprudence I.C.4.11. With respect to medical treatments the appellant referred in particular to decisions T 715/03, T 1457/09, T 1859/08, T 385/07 and T 158/96. All these decisions concerned a situation where a medical use defined in a claim in the appropriate format was considered novel over prior art documents disclosing clinical trials investigating the same use, but not disclosing any results as to whether the therapy under investigation was effective or not. Thus, in the appellant's view, claim 1 of the granted patent should be considered novel over D1 in an analogous way, since D1 likewise did not contain any experimental proof as to the effectiveness of the therapy, and such an effectiveness was unlikely following general scientific considerations.

3.6 However, the Board does not consider the situation underlying the cited case law to be comparable with the present case. The cited decisions essentially conclude that a therapeutic effect shown for the first time by the patentee may provide novelty of a medical use claim over a disclosure in which the same therapeutic effect

is investigated and may have been hoped for, but had not yet been proven.

In the present case the prior art is not a disclosure investigating a possible effect of a certain therapeutic method defined or included in a claim under assessment. D1 is not a clinical study investigating the effectiveness of homeopathic treatment of the pathological conditions concerned using silica. D1 is a pharmaceutical handbook describing a method that is or has been used in practise which, as outlined above, must be considered therapeutic in the sense of the EPC and is covered by the claim. Whether the disclosure of D1 is credible ("reproducible") concerns thus rather the question of whether the therapeutic use disclosed in D1 is or has been in fact in practical use or whether it isn't. Since D1 is a well-known pharmaceutical handbook and its disclosure as such was explicitly undisputed by the parties the Board has no reason to doubt that it does.

3.7 The normative purpose of the novelty requirement codified in Article 54 EPC is to avoid granting patents on subject-matter that has already been disclosed to the public or is even in the public domain. Treatment of "*structural weakness of the connective tissue*" and "*wound healing*" using silica is clearly in the public domain, as evidenced by D1. Claim 1 of the patent as granted is indistinguishable therefrom in terms of technical features of the claim. Thus, granted claim 1 lacks novelty over D1.

4. In view of granted claim 1 lacking novelty over D1 novelty over D3 needs not be decided upon.

5. The opponent did not appeal the Opposition Division's interlocutory decision that the patent as amended during opposition proceedings complies with the requirements of the EPC, Article 101(3)(a) EPC. Thus, following the principle of the prohibition of *reformatio in peius* (G 9/92) this finding is unaffected by the present appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated