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Datasheet for the decision of 3 November 2023

Case Number: T 0638/21 - 3.3.06

Application Number: 13703739.6

Publication Number: 2804940

IPC: C11D7/32, C11D7/50, A01N25/02

Language of the proceedings: EN

Title of invention:
Use of improved N-alkyl pyrrolidone solvents

Patent Proprietor:
Taminco

Opponent:
BASF SE

Headword:
Non-reprotoxic solvent / TAMINCO

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty (main request and auxiliary requests 1-6) - (no) - purpose of use inherently disclosed
Inventive step (auxiliary request 7) - (no)

Decisions cited:
G 0002/88, G 0006/88, G 0001/92, T 0892/94, T 0186/98, T 1523/07

Catchword:

Europäisches Patentamt
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Case Number: T 0638/21 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 3 November 2023

Appellant: (Opponent)	BASF SE 67056 Ludwigshafen (DE)
Representative:	Jacobi, Markus Alexander Patentanwälte Isenbruck Bösl Hörschler PartG mbB Eastsite One Seckenheimer Landstraße 4 68163 Mannheim (DE)
Respondent: (Patent Proprietor)	Taminco Pantserschipstraat 207 9000 Gent (BE)
Representative:	Gevers Patents Intellectual Property House Holidaystraat 5 1831 Diegem (BE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 25 March 2021 rejecting the opposition filed against European patent No. 2804940 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	J.-M. Schwaller
Members:	L. Li Voti
	O. Loizou

Summary of Facts and Submissions

I. The opponent's appeal is against the decision of the opposition division to reject the opposition against European patent no. 2804940, independent claim 1 thereof reading:

"1. *Use of N-n-butylpyrrolidone as a non-reprotoxic solvent*."

II. The appellant submitted in its grounds of appeal and in letter of 17 December 2021 that claim 1 as granted and of auxiliary requests 1 to 6 filed during opposition lacked novelty and/or inventive step inter alia over **D1** (FR 2001768). Further it filed document **D22** (Forth/ Henschler/Rummel, "*Allgemeine und spezielle Pharmakologie und Toxikologie*", 8th ed., 2001, pages 996-1002 and 1084).

III. In its reply, the respondent/patent proprietor cited inter alia **D6a** (US Environmental Protection Agency, Action Memorandum, 20 June 2006), **D7a-c** (Web pages: N-(n-octyl)-2-pyrrolidone - Registration Dossier - ECHA) and **D12** (Regulation (EC) No 1272/2008, European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures), and defended the patent as granted. It also submitted auxiliary requests 1 to 6 dated 30 July 2020 and filed during opposition.

IV. In reply to the board's preliminary opinion, the respondent submitted an auxiliary request 7 and documents **D23** to **D26** with a letter dated 29 September 2023.

V. At the oral proceedings held on 3 November 2023 the final requests of the parties were the following:

The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed (main request) or, in the alternative, that the case be remitted to the opposition division to maintain the patent in amended form on the basis of the claims according to one of auxiliary requests 1 to 6 filed with letter dated 30 July 2020, or of auxiliary request 7 filed with letter of 29 September 2023.

VI. Claim 1 according to auxiliary requests 1 and 5 differs from that as granted in that it additionally recites the feature "*wherein the solvent is used as a dissolution agent, a dilution agent, an extraction agent, a cleaning agent, a stripping agent, a removing agent, an extraction agent, a cleaning agent, a stripping agent, a removing agent, a degreasing agent, an absorption agent and/or a dispersion agent*."

Claim 1 according to auxiliary requests 2 to 4 and 6 is identical to claim 1 as granted.

Independent claim 1 of auxiliary request 7 reads as follows:

"1. *A solvent comprising N-methylpyrrolidone (NMP) and at least 50 vol% of N-n-butylpyrrolidone.*"

Reasons for the Decision

1. *Main request (patent as granted) - Novelty (Article 54 EPC)*

1.1 The board preliminary notes that claim 1 at issue relates to the use of N-n-butylpyrrolidone (**NBP**) as a non-reprotoxic solvent, without however explicitly identifying the means of realisation for the claimed use, which thus encompasses any means of application of a solvent being part of common general knowledge.

1.1.1 As to the meaning of the term "non-reprotoxic" the patent states (paragraph [0029]) that it identifies a chemical substance which results to be non-reprotoxic following the evaluation according to the EC regulation no. 1272/2008 of 16 December 2008 (document D12), and its amendments up to November 2012.

D12, which classifies chemical substances which are a hazard to the human health (see page 1, paragraph 1 and page 6, paragraph 54), discloses at page 107, paragraph 3.7.7.1, that **reproductive toxicity** concerns adverse effects on sexual function and fertility in adult males and females as well as developmental toxicity in the offspring.

A similar definition for "reprotoxicity" is found in the common general knowledge shown in D22 (page 999, table 34.8, point 7), filed with the grounds of appeal by the appellant, and for which no objection under Article 12(4) RPBA against the admissibility was raised by the respondent. The board has also no reason to disregard it as it represents common general knowledge.

D12 further explains (page 108-110, paragraphs 3.7.2.1.1 to 3.7.2.2.3; page 112, paragraph 3.7.2.5) that a given chemical compound (or mixture) is classified as reprotoxic on the basis of the total weight of evidence provided (see also Chapter 1, pages 11-13), following the evaluation based on

internationally accepted test methods (see also Chapter 2, pages 13-15). As stated in D12 (page 109, paragraph 3.7.2.2.1), classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction, and substances shall not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

It was further established from the documents D23 to D26 that the definition of a "reprotoxic" substance and the criteria used for classification have not changed in the versions of D12 amended up to November 2012.

1.1.2 It follows from the above considerations that the term "non-reprotoxic" used in claim 1 at issue can only be understood as relating to a solvent which is **not classified** as reprotoxic according to an evaluation carried out within the terms of D12. This however does not exclude that a solvent could be classified as reprotoxic at a later stage, since the tests used for evaluation or the established threshold at which the potentially toxic substance is considered to be a hazard may vary in the course of time.

This is confirmed by the patent in suit (paragraph [0007]) which discloses that N-methylpyrrolidone (NMP) was classified as "reprotoxic category 2" only from 1st December 2010 as shown in D26 (page 702), whilst it was not classified as such in the older document D12 (page 520), so that from that date mixtures containing 3% or more of NMP had to be labeled as being reprotoxic (see D26, page 162 and D12, page 113).

1.2 As regards the claimed use, it is undisputed that document D1 (claims 1 and 5; examples 3, 9 and 14) already discloses the use of NBP as a solvent.

The respondent argued that D1 did not disclose that NBP was on-reprotoxic, and so the purpose "non-reprotoxic solvent" defined in the claimed use would represent a technical feature within the terms established by decisions **G 2/88** (OJ 1990, 93, catchword 3) and **G 6/88** (OJ 1990, 114, catchword) reading :"*A claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Article 54(1) EPC provided that such technical feature has not previously been made available to the public*".

The respondent argued that the technical effect related to "non-reprotoxicity" consisted in allowing a group of persons such as pregnant women or would-be parents, which are potentially affected by reprotoxic substances, to be exposed to the solvent without the need for additional protective measures against a possible hazard arising from it, thus saving e.g. costs in the management of a chemical plant wherein the solvent is used since more stringent safety measures do not need to be implemented. Therefore, the thus defined purpose was a technical feature which provides novelty over the use disclosed in D1.

1.3 The board notes that D1 (page 1, lines 1-7) discloses compositions intended for topic application, with the solvent used (for example NBP) facilitating the absorption by the skin of ingredients having cosmetic or medical properties. In the board's view, such

solvated compositions were implicitly held non-toxic at the filing date of D1, since they were supposed to be absorbed by the skin.

Since NBP was moreover not classified as being reprotoxic at the publication date of D1, the skilled reader would at this date have understood from D1 that the solvent used was also inherently non-reprotoxic and could be commercialised without any warning label and freely used by any possible group of users. This understanding remained unchanged till the contrary **is discovered**, as explained above in the case of NMP. This conclusion is further in agreement with D12 and its amended versions up to 2012, which documents were used in the patent for defining non-reprotoxicity and which in fact do not list NBP as a reprotoxic substance. In the board's view it can also be derived from D12, used in the patent for defining the word "non-reprotoxic", that all chemical substances not classified therein were still to be considered at the publication date of the above regulations not to be a hazard and thus to be non-reprotoxic within the meaning of the patent.

1.3.1 The respondent additionally argued that the non-reprotoxicity of NBP was hidden in D1 and was thus a feature not available to the public. The present case was in particular similar to the use of a compound for achieving a therapeutic effect which can only be discovered by clinical testing and that therefore the non-reprotoxic feature was hidden in accordance with the conclusions in **G 1/92** (OJ 1993, 277, reasons 3).

1.3.2 The board cannot follow this argument because, as explained above, NBP was not held reprotoxic by the skilled person at the publication date of D1 or even later at the publication date of D12 and its amended

versions. The present case thus differs from a new therapeutic application wherein an unknown therapeutic effect can be discovered by clinical trials. This conclusion in line with established case law, for example **T 1523/07**, reasons 2.4, according to which "*implicit disclosure means disclosure which any person skilled in the art would objectively consider as necessarily implied in the explicit content*".

And even though the non-reprotoxicity of a solvent manifests only when a particular group of persons (pregnant women or would-be parents) is exposed to it, being an intrinsic property of said solvent, it is still present therein irrespective of the group of persons exposed to it. Claim 1 at issue being furthermore not limited to a use by a specific group of persons or to a particular application which would need additional safety requirements or not, in the board's view, the property of NBP being non-reprotoxic was inherently available to the public in view of the specific use of the solvent in D1 requiring the solvent to be non-toxic.

As to the tests in the patent, which are supposed to show the non-reprotoxicity of NBP, they merely confirm what was already the understanding of the skilled person at the priority date of the patent taking into account the prior art and common general knowledge. Moreover, the fact that there was an interest to confirm the non-toxicity of N-alkyl pyrrolidone derivatives since NMP was found to be reprotoxic underlies only the known striving of the concerned authorities to classify chemical substances which are a hazard to the human health in order to provide adequate protection.

1.3.3 In the board's view, differently from the uses considered in decisions **G 2/88** and **G 6/88** that clearly concerned a technical effect (namely friction reduction and fungi control, respectively) different from those already known for the substance in question, and wherein the known chemical substance was purposively applied to achieve the new technical effect, the use of NBP as a non-reprotoxic solvent, even if considered to be a purposive application, underlies that already disclosed in D1.

This conclusion is supported by case law, for example that in **T 892/94** (OJ 2000, 1, notes II) which concluded that "*... a newly discovered technical effect does not confer novelty on a claim directed to the use of a known substance for a known non-medical purpose if the newly discovered technical effect already underlies the known use of the known substance*." or **T 186/98** (reasons 3) according to which "... *there must be a new technical application or use which is not necessarily correlated with the known application or use and can be clearly distinguished therefrom .... The mere* ***explanation*** *of an effect obtained when using a known compound for a known purpose cannot confer novelty on a claim...*".

1.3.4 For all the above reasons, the board concludes that the label of the use of NBP as "non-reprotoxic" solvent is merely an explanation of the non-toxicity already inherently known from D1 by means of its use for absorption by human skin, which use cannot distinguish the claimed use from the known one.

1.4 The board thus concludes that D1 already discloses the use of NBP as a non-reprotoxic solvent so that the

subject-matter of claim 1 at issue lacks novelty under Article 54 EPC.

2. Auxiliary requests 1 to 6 - Novelty (Article 54 EPC)

2.1 Claim 1 of auxiliary requests 2 to 4 and 6 being identical to that of the main request, its subject-matter lacks novelty for the same reasons.

2.2 As also submitted by the appellant, the use of the solvent in D1 implies at least its use as a dissolution or dilution agent, and so a purpose encompassed by the amended wording of claim 1 of auxiliary requests 1 and 5, the subject-matter of which thus also lacks novelty for this reason.

3. Auxiliary request 7 - Inventive step (Article 56 EPC)

Claim 1 of this request relates to a solvent comprising NMP and at least 50 vol% of NBP.

3.1 According to paragraph [0023], one of the goals of the patent is to provide alternative solvents for NMP which are not reprotoxic and have at least similar properties for their normal applications as a solvent. Moreover, as stated in paragraph [0034], mixtures of NBP with other solvents such as NMP are supposed to improve the toxicological properties of the resulting solvent mixture.

3.2 As a suitable starting point for the evaluation of inventive step, the appellant cited D1 whilst the respondent was of the opinion that D6 (in particular D6a) or D7 (in particular D7c) represented the closest state of the art.

3.2.1 As discussed hereinbefore, D1 concerns a composition comprising an N-lower alkyl pyrrolidone and which is rapidly and effectively absorbed by the skin; in consequence of this behaviour it was held non-toxic and non-reprotoxic by the skilled person at the publication date of D1. D1 (page 2, lines 3-5) offers in particular NBP as an alternative solvent to NMP and N-ethylpyrrolidone (NEP). Therefore, in the board's view, this document deals with at least part of the technical problem addressed to in the patent in suit and is a suitable starting point for the evaluation of inventive step.

In contrast, D6 concerns the reassessment of the toxicity (also reprotoxicity) of the solvents N-(n-octyl)-2-pyrrolidone (NOP) and N-(n-dodecyl)-2-pyrrolidone (NDP) by the US Environmental Protection Agency, whilst D7 concerns the chemical safety and toxicity (also reprotoxicity) assessment of NOP by the European Chemical Agency. But differently from D1, these documents do not concern the use of NBP as a replacement for NMP, and therefore, in the board's view, they are less relevant than D1.

3.2.2 Among the embodiments disclosed in D1, the solvent mixture of example 9 of D1, which comprises 30 parts by weight of NBP and 69.9 parts by weight of water, is considered to represent the closest prior art to the subject-matter of claim 1 of this request.

3.3 As regards the technical problem underlying the claimed subject-matter, the respondent formulated it as the provision of a solvent mixture which is less reprotoxic.

3.3.1 The board notes in this respect that claim 1 at issue includes solvents comprising up to 50 vol% of NMP, i.e. a mixture which according to the D12 regulation as amended up to 2012 has to be classified as reprotoxic, the threshold limit for NMP in a liquid mixture being of 3 wt% (see D26, page 162 and D12, page 113). In contrast the solvent mixture of the above identified closest prior art does not contain NMP and was thus already inherently held non-reprotoxic for the skilled person as explained above, so that the claimed formulation cannot be considered to have less reprotoxicity than those of the closest prior art.

3.3.2 The respondent argued that a reduction of the NMP content in the solvent mixture, which in D1 may consist mainly of NMP, would nevertheless provide an unexpected reduction of the reprotoxicity of the mixture, so that the group of persons affected by such toxicity could be longer exposed thereto without being negatively affected.

The board cannot accept this argument because the toxicity of a substance at an amount above the threshold at which it is known to constitute a hazard (here the reprotoxicity) cannot, in the absence of evidence to the contrary, be held to be more or less severe. It is in particular known, as discussed in the oral proceedings with respect to cancerogenic substances, that the toxic effect cannot be necessarily considered to depend on the dose used (see also D22, page 1001, table 34.10). Moreover, neither the above EC regulations nor the patent in suit diversify various degrees of risk as regards reprotoxicity in relation to amounts of a given compound above the reported threshold, with the patent in suit disclosing by the way only tests on mixtures of NBP with NMP (paragraphs

[0050]-[0052]) regarding the enameling of copper wires, without however any toxicity data.

It is thus not credible that a mixture as claimed and containing e.g. 50 vol.% of NBP and 50 vol.% of NMP, i.e. an amount of NMP well above the threshold defined in D12, would reduce the reprotoxicity of solvents comprising greater amounts of NMP, or would allow the group of persons affected by this toxicity to be exposed longer to the solvent mixture without being negatively affected by the reprotoxicity of NMP.

Conversely, as regards in particular mixtures with less than 3% NMP, it was known that such mixtures were not labeled as reprotoxic, so that they can be considered to be less reprotoxic than one comprising more than 3% NMP.

It follows from the above considerations that the above alleged unexpected effect, if considered, has not been convincingly proven to exist across the entire scope of claim 1 at issue.

3.4 The objective technical problem convincingly solved by means of claim 1 at issue can thus only be formulated as the provision of alternative solvent compositions having at least properties similar to NMP for their normal applications as a solvent.

3.5 Since document D1 (page 2, lines 2-5) teaches to use as alternative to compositions consisting of NMP also mixtures of NMP with NBP as alkyl pyrrolidone solvents for the therein disclosed compositions for topic application, and further discloses (D1: claims 1 and 5) that the solvent mixture may comprise up to 100% by weight of NBP, it was obvious for the skilled person to

modify the composition of example 9, comprising 30 parts by weight of NBP and 69.9 parts by weight of water, by increasing the amount of NBP for example to 50 vol%, reducing the water content, and to use it in combination with minor amounts of NMP.

D1 also does not contain any teaching that would have led the skilled person away from trying solvents comprising more than 50 vol% NBP or to use it in combination with NMP.

3.6 And even if it was known to the skilled person at the priority date of the patent that NMP was classified as a potentially reprotoxic substance, it was also known, as explained above, that a mixture containing less than 3% by weight of NMP, as encompassed by claim 1 at issue, had not to be classified as reprotoxic and could be used without expecting a damage to human health. It was thus obvious for the skilled person to use in a mixture with NBP also amounts of NMP below the threshold set by the authority for a labeling as reprotoxic solvent mixture.

3.7 For all the above reasons it was thus obvious for the skilled person to provide a composition as claimed so that the subject-matter of claim 1 lacks inventive step over D1 and thus does not meet the requirements of Article 56 EPC.

3.8 As none of the sets of claims underlying the respondent's requests complies with the requirements of the EPC, the opponent's appeal succeeds.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe J.-M. Schwaller

Decision electronically authenticated