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D E C I S I O N
of 16 December 1997

Case Number: T 0722/94 - 3.3.2

Application Number: 88100205.9

Publication Number: 0275054

IPC: A61K 9/06

Language of the proceedings: EN

Title of invention:
Ointment base and ointment

Patentee:
Toko Yakuhin Kogyo Kabushiki Kaisha

Opponent:
The B.F Goodrich Company

Headword:
Gel ointment/TOKYO-YAKUHIN KOGYO KABUSHIKI KAISHA

Relevant legal provisions:
EPC Art. 123(2), (3), 54, 56, 69(1)

Keyword:
"Main request - Inventive step (no)"
"Auxiliary request - change of category (yes) - second
non-medical use"
"Novelty (yes) - Inventive step (yes)"

Decisions cited:
G 0002/88

Catchword:
-



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Boards of Appeal

Chambres de recours

Case Number: T 0722/94 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 16 December 1997

Appellant I:
(Proprietor of the patent) Toko Yakuhin Kogyo Kabushiki Kaisha
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Appellant II:
(Opponent) The B.F. Goodrich Company
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Akron, Ohio 44313 (US)

Representative: Thomas, Roger Tamlyn
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 14 July 1994
concerning maintenance of European patent
No. 0 275 054 in amended form.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: C. Germinario
 J. H. van Moer

Summary of Facts and Submissions

- I. European Patent No. 0 275 054 was granted in response to European patent application No. 88 100 205.9 on the basis of a set of 9 claims for all the contracting states, with the exception of Spain, and of a second set of 8 claims for Spain.
- II. Notice of opposition was filed by appellants II (opponents), requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step.

The following documents, cited during the opposition proceedings, are relevant for the present decision:

- (1) FR-A-2 040 954,
- (4) EP-A-0 162 007,
- (7) Carbopol, Water-Soluble Resins, Service Bulletin GC-36, BFGoodrich, pages 1 to 59 (1957), revised on 1978,
- (8) Carbopol Technical Bulletin, TDS 53, BFGoodrich, pages 1 to 5 (1973),
- (9) T. W. Schwarz and G. Levy, "J. Am. Pharm. Assoc." Vol. 47, pages 442 to 443, June 1958,
- (13) US-A-4 010 254,
- (15) Kirk-Othmer, ed. 78/79, Vol. 3, pages 128 to 130, Vol. 5, pages 351 to 352.

III. In its interlocutory decision, the opposition division held that the patent could be maintained in amended form.

The text of maintained claims 1, 4 and 9 reads as follows:

"1. A gel ointment base which comprises an aqueous carboxyvinyl polymer solution and an amino acid selected from the group consisting of valine, isoleucine, serine, cysteine, proline, threonine and methionine in an amount of 0.1 to 10.0% by weight based on the whole weight of the base for increasing the viscosity of the aqueous carboxyvinyl polymer solution.

4. A gel ointment which comprises as a base an aqueous carboxyvinyl polymer solution, an amino acid selected from the group consisting of valine, isoleucine, serine, cysteine, proline, threonine and methionine in an amount of 0.1 to 10.0% by weight based on the whole weight of the base for increasing the viscosity of the aqueous carboxyvinyl polymer solution, and an effective amount of an active medical substance.

9. Use of an amino acid selected from the group consisting of valine, isoleucine, serine, cysteine, proline, threonine and methionine, for preparing a gel ointment base stabilized against irradiation of a light comprising an aqueous carboxyvinyl polymer solution and one of said amino acids in an amount of 0.1 to 10.0% by weight based on the whole weight of the base for increasing the viscosity of the aqueous carboxyvinyl polymer solution."

The opposition division, having rejected the main request because the subject matter of claim 4 lacked novelty in the light of the compositions described in document (13), recognised the novelty of the subject-

matter claimed in the auxiliary request, which no longer cited the amino acids already cited in different prior art documents, namely alanine, ornithine, lysine, arginine and histidine.

The closest prior art document was identified as document (9), which disclosed that the gel compositions comprising neutralised Carbopol underwent a marked viscosity decrease when exposed to daylight. The viscosity breakdown was minimised when triethanolamine was used as a neutralising agent. The underlying technical problem was to be seen as that of providing an ointment base and an ointment which were stable against irradiation.

The opposition division held that the skilled person would perhaps have been led by document (8) to replace triethanolamine by amino acids in order to improve the clarity and the moisturising properties of the gel but, in doing so, he would not have sought or expected any improvement in the light stability of the gel, since document (8) did not address the same problem of viscosity.

Neither would the skilled person, aware of the teaching in (1), envisage replacing the amino acids disclosed therein by the amino acids claimed in the auxiliary request in order to improve the light stability of a gel, since no UV-stability was considered in document (1).

In conclusion, the opposition division decided that none of the relevant cited documents rendered the subject-matter of the amended claims obvious.

- IV. Both appellants I (patentees) and appellants II (opponents) lodged an appeal against this decision. Oral proceedings were held on 16 December 1997.

With the statement setting out the grounds of appeal, appellants I filed amended claims and an amended description. A further amended set of 6 claims (and corresponding 5 claims for ES) was filed as main request during the oral proceedings. Additionally, an amended single claim was filed as auxiliary request for all the designated contracting states.

The text of claim 1 of the main request reads as follows:

"1. A gel ointment which comprises as a base an aqueous carboxyvinyl polymer solution, an amino acid selected from the group consisting of valine, isoleucine, serine, cysteine, ornithine, lysine, arginine, histidine, proline, threonine and methionine in an amount of 0.1 to 10.0% by weight based on the whole weight of the base for increasing the viscosity of the aqueous carboxyvinyl polymer solution, and an effective amount of an active medical substance selected from the group consisting of a hypnotic, a sedative, an antipyretic, an analgesic, an anti-inflammatory agent, a local anaesthetic, an agent for ophthalmic use, an agent for nasal use, a cardiogenic, an antiarrhythmic agent, a coronary vasodilator, an agent effective for digestive organs, a corticoid, an antiplasmin, a fungicide, an antitumor agent, an antibiotic and a physiologically active peptide, with the proviso that the active medical substance is different from the amino acids listed above and therein the carboxyvinyl polymer is not a vinyl ether-maleic anhydride copolymer."

The text of the single claim of the auxiliary request reads as follows:

"1. Use of an amino acid to stabilize a gel ointment against irradiation of light and to increase the viscosity of the aqueous carboxyvinyl polymer solution of said gel ointment, said gel ointment comprising as a base an aqueous carboxyvinyl polymer solution and an active medical substance selected from the group consisting of a hypnotic, a sedative, an antipyretic, an analgesic, an anti-inflammatory agent, a local anaesthetic, an agent for ophthalmic use, an agent for nasal use, a cardiogenic, an antiarrhythmic agent, a coronary vasodilator, an agent effective for digestive organs, a corticoid, an antiplasmin, a fungicide, an antitumor agent, an antibiotic and a physiologically active peptide, wherein said amino acid is one of the group consisting of valine, isoleucine, serine, cysteine, ornithine, lysine, arginine, histidine, proline, threonine and methionine and is used in an amount of 0.1 to 10.0% by weight based on the whole weight of the base."

In addition to the statement setting out the grounds of appeal and further submissions, appellants II (opponents) provided the following additional documents:

(16) English translation of: M. Mandak et al., Farm. Obzor (Bratislava) "Study of the stabilisation of the injectable preparations furosemide Spofa", pages 107 to 114 (1981).

V. During the written phase of the proceedings, appellants I argued that none of the documents cited during the opposition proceedings was prejudicial to the novelty

of the gel ointment of claim 1. However, during the oral proceedings they limited the subject-matter claimed in the main request by disclaiming the content of prior documents (1) and (13).

As to the inventive step of the subject-matter claimed in both main and auxiliary requests, appellants I agreed with the board that the closest prior art could not be represented by document (9) as maintained by the opposition division.

Appellants I indicated document (8) as the most relevant. They stressed that this document was not concerned with the problem of gel stabilisation against UV/light irradiation. Therefore, the skilled person would have found in (8) no indication that some selected amino acids, in addition to some known benefits, would also have improved the light stability of the gel.

VI. Appellants II dropped their objections to the novelty of the claimed gel ointment after the presently valid main and auxiliary requests were filed. They indicated document (8) as the closest prior art.

In relation to the main request, appellants II pointed out that the closest prior art clearly suggested the use of amino acids to neutralise a carboxyvinyl polymer (Carbopol). The emphasis given in the document to four specific amino acids, ie glycine, beta-alanine, 4-amino butyric acid and 6-amino exanoic acid, indicated as the most effective thickening agents, was without prejudice to the use of other amino acids with lower thickening efficiency.

The fact that said amino acids, in addition to their neutralising effect, also exhibited gel stabilising activity against UV-irradiation, was to be considered as a benefit gained automatically by the skilled person following the suggestion in the prior art.

As to the possibility that an inventive merit could be based on the selection of the specific amino acids claimed, appellants II argued, on the basis of table 3 in the patent disclosure, that the stabilisation achieved using said amino acids was not at all different from the stabilisation obtained with non claimed amino acids such as alanine.

In relation to the auxiliary request, appellants II maintained the objection of lack of inventive step in the light of (8). They expressed the opinion that the reformulation of the claim did not substantively change the circumstances which should lead to the rejection of the main request. In fact the UV stabilising effect was inherent in the known use of the amino acids as disclosed in (8) and it would have been achieved concomitantly and inevitably by following the suggestion in (8).

Finally, appellants II raised an objection of clarity in relation to the expressions "viscous membrane" in claim 5 and "..gel ointment stabilized against irradiation.." in claim 6 of the main request, with reference to the results in table 3 in the patent, showing stabilisation levels ranging around 60-62% only.

VII. Appellants I (the patentees) request that the appeal be dismissed and the patent be maintained on the basis of:

Main request: Claims 1 to 6 for AT, BE, CH, DE, FR, GB, IT, LI, NL, SE and Claims 1 to 5 for ES.

Auxiliary request: one single claim for all the designated contracting states,

all received during the oral proceedings on 16 December 1997.

Appellants II (the opponents) request that the decision under appeal be set aside and that European patent No. 0 275 054 be revoked.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 The board is satisfied that the main request complies with the requirements of Articles 123(2) and (3) and 84 EPC.

Appellants II objected to the clarity of claims 5 and 6 of the main request. This objection however turned out to be irrelevant since it was overtaken by the outcome of the proceedings.

2.2 Novelty - Article 54 EPC

2.2.1 Document (4) describes stable gel compositions for the treatment of acne vulgaris comprising insulin, which is a physiologically active peptide according to present claim 1 and within the meaning given on page 6 of the original description of the patent in suit. The composition also comprises a polyacrylic acid as gelling agent, which in all the examples is Carbopol and an inorganic or organic base as neutralising agent. The document contains no explicit example of specific compositions comprising any of the amino acids listed in claim 1 of the opposed patent, as neutralising agents. However, the description of document (4) gives, on page 6, a list of equivalent neutralising agents, which includes arginine and lysine.

2.2.2 The teaching of a cited document is not confined to the detailed information given in the examples, but embraces any information in the claims and description enabling a person skilled in the art to carry out the invention. Since document (4) teaches that the mere substitution of the neutralising agent of the specific compositions by arginine or lysine, offered as alternatives in one single list, would give the same result as the one achieved in the examples, the person skilled in the art is not placed in a selection situation. In opposition to cases where the skilled person has to select in a document two or more components of a composition from two or more lists without knowing with certainty which combination could actually be meant in its teaching, document (4) gives here a clear, direct and enabling teaching which leaves no room for any burden at all in respect of its implementation. Following the direction given in the case law of the Boards of appeal in other circumstances, eg T 12/81, OJ EPO 1982, 296, or T 7/86, OJ EPO 1988, 381, the board concludes that any composition of (4) comprising such neutralising agents is to be considered as disclosed within the meaning of

Article 54(2) EPC. Therefore, document (4) anticipates gel compositions containing all the essential components of the gel ointment of claim 1.

- 2.2.3 The additional feature of claim 1 represented by the amount of amino acid of 0.1 to 10.0% deserves further consideration.

Carbopol, which is the most preferred carboxyvinyl polymer of both present invention and prior art invention, was, since years back, a well known and worldwide employed gelling agent. As divulgated in any product-description released by the producer (BFGoodrich), the typical viscosity-properties of Carbopol are achieved upon neutralisation of the otherwise acid solution or dispersion of this carboxylic polymer. See document (7), page 7 to 9, specifically the first paragraph of page 7 or document (8), page 1, first and second paragraphs. Therefore the neutralisation and the thickening of a carbopol solution are concomitant and inextricably connected steps of the preparing process of any gel ointment comprising Carbopol as gelling agent. For this reason, the amino acid of the present invention "*for increasing the viscosity of the aqueous carboxyvinyl polymer solution*" and the organic or inorganic bases of (4), including arginine and lysine, are actually intended for the same purpose, namely **neutralising** the polymer thereby thickening the solution.

On the basis of these considerations, the amount of amino acid given in claim 1, namely 0.1 to 10.0%, does not provide the skilled reader with any additional technical information beyond that already inherent in the intended purpose of the amino acid, that is that of neutralising the polymer solution. Hence, the amount of amino acid suitable for *increasing the viscosity* will,

first of all, be indicated to the skilled person by the achievement of a nearly neutral pH (ie neutralisation). This amount is not an absolute value, but depends on the neutralising properties of each amino acid, therefore it must be found experimentally by the skilled person in the attempt to reduce the invention to practice, regardless of the range of amounts given in the claim.

Under these circumstances, the range of percent values of amino acid defined in present claim 1 does not involve any new feature or discriminating technical effect with regard to the teaching in (4), which simply defines the amount of neutralising agent as "*quod sufficit ad pH 7.3*" (see examples 5 to 8). In other words, the alleged difference implied by the indicated amino acid amounts lies only in a different wording.

Summing up, document (4) discloses compositions comprising all the essential components of the gel ointment of claim 1 in the same amounts.

- 2.2.4 Accordingly, no previously unknown technical property allegedly characterising the compositions of the invention, such as the viscosity-stabilisation against light irradiation, can be invoked to justify the novelty of the subject-matter of product-claim 1. In fact, the same property is also present, though unknown, in any prior compositions in which Carbopol is neutralised with one of the claimed amino acids.

In conclusion, the board's judgement is that document (4) is prejudicial to the novelty of the subject matter of claim 1 of the main request.

3. *Auxiliary request*

3.1 Article 123(2) EPC

The use of the amino acids at issue to stabilise a gel ointment against irradiation of light and to increase its viscosity is unambiguously disclosed in the filed application on page 2, line 15, to page 3, line 4, experiment 1, tables 1 to 5 and figures 1 to 4.

3.2 Article 123(3) EPC

3.2.1 Claim 4 of the granted patent protected a gel ointment comprising the three essential components: the carboxyvinyl polymer solution, the amino acid for increasing the viscosity of the polymer solution and the medical substance.

Granted claim 4 for contracting state ES protected the method for preparing said gel ointment.

The single claim of the auxiliary request seeks protection for the use of an amino acid, as claimed, to stabilize a gel ointment against irradiation of light and to increase the viscosity of the aqueous carboxyvinyl polymer solution.

In both granted claims, the use of the claimed amino acids to increase the viscosity is cited *expressis verbis*.

The extent of the protection has to be determined in accordance with Article 69(1) EPC and its Protocol, which provides a guide to the manner in which the technical features of the claims are to be interpreted. The description and drawings are to be used for this interpretation in order to avoid too much emphasis on

the literal wording of the claims when considered in isolation from the remainder of the text of the patent in which they appear.

From the description and drawings it is immediately evident that the use of the claimed amino acids "for increasing the viscosity of the aqueous carboxyvinyl polymer", as cited in the granted claims, is not limited to the simple and precise action of gelling the aqueous solution of the polymer to produce the gel composition, but also to the action of maintaining the viscosity under circumstances in which it would otherwise decrease: namely upon daylight irradiation. As shown in tables 1 to 5 and in figures 1 to 4, the viscosity of compositions comprising an amino acid as neutralising agent, after light irradiation, remains significantly higher (ie increased) as compared to the viscosity of compositions comprising other neutralising agents. Therefore, the technical effect resulting from the addition of the amino acid also comprised, as a matter of fact, the stabilisation of the gel viscosity against irradiation.

In such circumstances, the board's view is that the "use", which is the subject-matter of the single claim in the auxiliary request, was already within the scope of the granted claims. Therefore, the new claim does not extend the protection conferred by the granted claims, and is admissible according to decision G 2/88 (OJ EPO, 1990, 93).

3.2.2 Appellants II objected to the admissibility of the auxiliary request under Article 123(3) EPC. They pointed out that the situation considered in decision G 2/88 related to a patent with claims to a "compound" and to a "composition including such compound" which were amended so that the claims were directed to the "use of that compound in a composition" for a

particular purpose disclosed in the patent. Unlike the case to which G 2/88 relates, the opposed patent, as granted, did not include any claim to the "compound", ie the amino acid, but only to the composition comprising the compound.

The board recognises this difference. However, this difference cannot be regarded as prejudicial to the admissibility of the auxiliary request, but it makes the admissibility still more evident. In fact, as explained above, the specific purpose of the compound (here amino acids) underlying the new use-claim was already in the scope of the granted product-claims when interpreted in the light of the description and drawings.

For these reasons the appellants' arguments are rejected.

3.3 Novelty

None of the cited prior documents discloses the use of an amino acid as cited to stabilise a gel ointment against irradiation of light and to increase the viscosity of an aqueous carboxyvinyl polymer solution. The novelty of the claim is therefore recognised. Appellants II did not contest this point.

3.4 Inventive step

3.4.1 Closest prior art

Although the gel of claim 1 comprises a medicament, the claimed use is not intended to achieve a therapeutic effect but rather to stabilise a base excipient. The original invention was in fact directed both to the gel ointment as base excipient and to the gel ointment comprising a medicament. For this reason, the board is

of the opinion that the closest prior art is not necessarily represented by a prior pharmaceutical composition as in the case of the product-claims according to the main request. Instead it should be a document specifically dealing with the problem of the viscosity breakdown of gel upon UV or light irradiation and with possible solutions to this problem, regardless of whether they are in the therapeutic or cosmetic domain. It is considered that the person skilled in one of the two fields would also be sufficiently aware of the problems typical of the second.

Accordingly, the board's view is that document (8) represents such closest prior art. This opinion was also shared by both appellants.

This document describes the use of amino acids as neutralising agents for Carbopol resins. Basic amino acids such as glycine, beta-alanine, 4-amino butyric acid and 6-amino hexanoic acid are said to be the most effective, while amino acids lacking a terminal amino group yielded salts of Carbopol with lower thickening efficiency. The document discloses, under the heading "Clarity and Stability" on page 5, that "the ultraviolet radiation of strong sunlight may reduce the viscosity of clear gels by attacking the Carbopol resins and the amino acids". For this reason the addition of UV absorbing agents is recommended. More detailed information concerning these agents is given by way of reference to the previous Carbopol Bulletin GC-36, page 12, document (7). This document teaches that a combination of sodium salt of EDTA with a water-soluble UV adsorber, or thiourea alone, are effective stabilisers.

- 3.4.2 Starting from this prior art, the underlying technical problem to be solved is that of providing alternative methods for thickening a gel ointment comprising a

neutralised carboxyvinyl polymer (ie Carbopol) and at the same time stabilising its viscosity against decrease due to light irradiation.

- 3.4.3 The solution proposed by the patent is the use of an amino acid as listed in the claim to achieve the dual technical effect.

The results illustrated in tables 1 to 5 and in figures 1 to 4 in the patent prove indisputably that the use of the claimed amino acids results in the desired increase in viscosity of the aqueous polymer solution, accompanied by a remarkable viscosity stabilisation upon light irradiation. Although this stabilising effect is not absolute, as stressed by appellants II, the stability achieved proved higher than or at least comparable with that of gels comprising known neutralising agents. The board is therefore satisfied that the technical problem has been solved.

- 3.4.4 The skilled person, aware of the existence of the problem of light sensitivity of carbopol gels, would have found no information in document (8) or (7) to suggest that some selected amino acids could be suitable at the same time as neutralising agents for the carboxyvinyl polymer and as viscosity stabilizers against light irradiation. In fact, the only measure suggested by (8) is the addition of UV absorbing agents. Also, the passage in document (7) referred to in (8) (page 12, right-hand column) suggests the concomitant use of a chelating agent (EDTA) with a UV absorber or the use of thiourea alone. It is worth noting that (7) teaches that the light sensitivity of Carbopol is reduced when the pH is raised to 10.0 or above and that for UV stability the inorganic bases are slightly more effective than the organic bases. Thus it would suggest just the opposite direction to that

disclosed by the opposed patent. Assisted by these teachings and faced with the underlying technical problem, the skilled person would have investigated the best-known chelating agents or UV absorbers rather than trying new classes of potential stabilisers such as the amino acids.

Nor would the skilled person have been better assisted by the teaching in other prior documents. The only further piece of prior art dealing with the viscosity decrease of carbopol neutralised with the commonly used inorganic or organic bases is document (9). Like the previous one, this document suggests the use of a number of antioxidants, polyhydroxy compounds and chelating agents to inhibit the degradation of the gel. Amino acids are not contemplated as possible stabilisers. All the other cited documents suggest, at best, the use of some of the amino acids at issue as neutralising agents for a carboxyvinyl polymer, but they are totally silent on the drawback of light-sensitivity of such gels and on any possible measure to avoid such a problem.

- 3.4.5 Relying on documents (15) and (16), appellants II argued that some amino acids are indeed metal-chelating agents or anti-oxidants. Therefore, the skilled person confronting the suggestions in documents (8), (7) or (9) would have envisaged the use of amino acids for the intended purpose.

Document (15) actually cites, on page 351, the amino acid series referred to in table 3 (page 352) as possible chelating agents. However, table 3 lists only glycine and secondary or tertiary amine derivatives of glycine, none of which are cited as suitable stabilisers in the patent claim. It should moreover be stressed that, among all the chelating agents cited in table 3, glycine results to be one of the least

efficient. The board is therefore of the opinion that a skilled person seeking an efficient chelating agent would not have been led by this document to select any amino acid at all.

The board also recognises that DL-methionine and L-cysteine may exhibit some stabilising effect on furosemide compositions due to their anti-oxidant activity as disclosed in (16). However, beyond some speculation on the involvement of UV-catalysed oxidation reactions, no evidence has been submitted by the parties to explain the mechanism of viscosity decrease in carboxyvinyl polymer gels and to make the conclusion plausible that the viscosity breakdown of a gel and the decomposition of furosemide follow the same mechanism which could be inhibited by the same agent, namely cysteine or methionine.

Finally, appellants II argued that the claimed use according to the auxiliary request could not be recognised as involving an inventive step since the technical effect of the viscosity stabilisation was already inherent in the use, known from documents (1) or (8), as neutralising agents of the cited amino acids.

Decision G 2/88 (supra) sets out (Reason 10.3) that a new use of a known compound may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim. If that technical feature has not previously been made available to the public, then the claimed invention is novel, even though such a technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public. Furthermore, the board holds that if that technical feature is not obviously derivable from what

was previously made available to the public, then the invention involves an inventive step. Document (1) does not even acknowledge the existence of the problem of viscosity breakdown which partially occurs also in the presence of amino acids as neutralising agents. Document (8), while acknowledging the problem, fails to recognise the gel-protecting activity of any of the amino acids cited therein which, on the other hand, are not the same as claimed in the auxiliary request. For all these reasons the arguments put forward by appellants II are rejected.

It results from the above that the subject-matter of the single claim of the auxiliary request involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain a patent with the following claim and a description to be adapted:

Claim 1 received during oral proceedings (Auxiliary request).

The Registrar:

The Chairman:

P. Martorana

P. Lançon

