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Datasheet for the decision of 8 December 2023

Case Number: T 0910/21 - 3.3.07

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Language of the proceedings: EN

Title of invention:
METHOD FOR IMPROVING EXECUTIVE FUNCTION

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Executive function / NUTRICIA

Relevant legal provisions:

EPC Art. 54(5), 56, 83
RPBA 2020 Art. 13(1)

Keyword:

Novelty - novelty of use - second (or further) medical use
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendment to appeal case - justification by party (no)

Decisions cited:

T 1491/14, T 0233/96, T 0836/01

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Case Number: T 0910/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 8 December 2023

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 May 2021 revoking European patent No. 2773361 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	L. Basterreix

Summary of Facts and Submissions

I. European patent 2 773 361 ("the patent") was granted on the basis of nine claims.

Claim 1 as granted defined:

"A composition for use in improving executive function of a subject in need thereof, wherein said composition comprises:

i) one or more of uridine and cytidine, or salts, phosphates, acyl derivatives or esters thereof; and

ii) a lipid fraction comprising at least one of docosahexaenoic acid (22:6; DHA), eicosapentaenoic acid (20:5; EPA) and docosapentaenoic acid (22:5; DPA), or esters thereof,

wherein said subject suffers from a memory or cognitive disorder, memory decline or cognitive dysfunction, such as Age Associated Memory Impairment (AAMI), Alzheimer's Disease, multiple sclerosis, vascular dementia, frontotemporal dementia, semantic dementia or dementia with Lewy bodies, and/or psychiatric and developmental disorders, including obsessive-compulsive disorder, Tourette's syndrome, depression, schizophrenia , attention-deficit/hyperactivity disorder, and autism (asperger)."

II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step and that the claimed invention was not sufficiently disclosed.

The patent proprietor filed the appeal against the decision of the opposition division to revoke the patent.

The decision was based on the main request relating to the patent as granted and auxiliary requests 1-12 and 7A-12A filed on 23 April 2020 and 12 February 2021.

In its decision the opposition division cited *inter alia* the following documents:

D1: Wikipedia - Exekutive Funktionen (September 2019)
D2: Wikipedia -Arbeitsgedachtnis (September 2019)
D3: Handbook of Psychological Assessment, 4th Ed., p. 208-209, p. 549 -555 (2003)
D5: Alzheimer's & Dementia, 2008, 4, S153-S168
D6: WO 2009/002146 A1
D7: WO 2009/002148 A1
D8: Alzheimer's & Dementia, 2010, 6, 1-10
D10: US 2008/0292649 A1
D11: WO 03/041701
D12: US 2005/0129710 A1
D13: WO 2009/002165 A1
D14: WO 2006/127620 A2
D15: US 2007/0004670 A1
D22: Cold Spring Harb Perspect Med 2012;2:a006171.
D26: Clin. Neuropsychol., 2009, 23(3), 446-461
D27: Am. J. Geriatr. Psychiatry, 2003, 11(6), 683-686
D28: WO 2009/002163 A1

The opposition division arrived at the following conclusions:

(a) Claim 1 of the patent as granted (main request) lacked novelty in view of document D6 as well as document D28, which already disclosed the utility

of the defined composition for supporting daily activities wherein the executive brain functions play an important role.

(b) The amendments according to auxiliary requests 1-6, 7 and 8 also lacked novelty in view of documents D6 and D28.

(c) Auxiliary requests 7A, 8A, 9, 9A, 10, 10A, 11, 11A, 12 and 12A did not involve an inventive step starting from document D6 or D28 as closest prior art.

III. With the statement of grounds of appeal of 29 September 2021 the patent proprietor upheld the requests filed during the first instance proceedings, arguing *inter alia* that according to document D26 instrumental activities of daily living (IADL) can be affected by memory (MEM), executive function (EXEC) or both and that therefore the improvements in IADL described in documents D6 and D28 do not directly and unambiguously reveal an improvement in EXEC.

IV. In the reply to the appeal of 9 February 2022 the opponent maintained the objections as raised during the first instance proceedings, arguing *inter alia* that the defined treatment did not involve any new group of patients.

In its letter of 15 September 2022 the opponent cited criteria for identifying a new subgroup of patients as mentioned in T 1491/14.

With the letter of 15 September 2022 the opponent also filed the following document:

D29: BMC Geriatrics (2020) 20:513 (https://doi.org/10.1186/s12877-020-01926-9)

V. In its communication pursuant to Article 15(1) RPBA the Board expressed *inter alia* the preliminary opinion that

- the opponent's argument based on T 1491/14 was to be admitted and document D29 was not to be admitted

- the patent as granted fulfilled the requirements of novelty, inventive step and sufficiency of disclosure.

VI. Oral proceedings were held on 8 December 2023.

VII. The arguments of the patent proprietor relevant to the present decision are summarized as follows:

(a) Admittance reference to T 1491/14 and document D29

The opponent's additional line of argument relying on decision T 1491/14 lacked pertinence.

Document D29 was filed without valid justification and lacked relevance in view of its publication date as well as its content.

(b) Novelty

As explained in paragraphs [0029] and [0030] of the patent and in documents D1, D3, D22 and D26 EXEC concerned a brain function associated with problem solving which is distinct from other brain functions such as MEM. EXEC deficits could be specifically identified by an appropriate test, such as the trail making test TMT-B, and could be independently targeted

by the treatment as defined in the patent. In line with the established jurisprudence, in particular T 836/01, the improvement of EXEC therefore qualified in as a characterizing feature of therapeutic treatment.

Documents D6 and D28 referred to improvement in IADL. From document D26 it was evident that IADL could be affected by MEM, EXEC or a combination thereof. Any improvement in IADL from treatment as described in documents D6 and D28 could result from improved MEM and would therefore not imply an improvement of EXEC as defined in claim 1 as granted.

Documents D5, D7, D8 and D10-D15 did not mention treatment aimed at improving EXEC and could therefore also not anticipate the claimed subject-matter.

(c) Inventive step

The difference between the claimed subject-matter and the teaching in documents D28 or D6 as well as document D8 concerned the definition of the therapeutic indication.

The experimental data from a clinical study reported in the patent demonstrated that an improvement in EXEC from treatment with the defined composition may only become evident after a prolonged period of more than twelve weeks.

The problem to be solved in view of the cited prior art could be formulated as the provision of a further therapeutic use for the defined compositions.

The prior art provided no suggestion towards the utility of the defined compositions for improving EXEC.

The improvement in IADL after twelve weeks of treatment as reported in document D28 correlated with the improvement in MEM after twelve weeks as reported in document D8, which suggested that the effects reported in document D28 resulted from an improvement of MEM rather than any improvement of EXEC.

(d) Sufficiency

The patent demonstrated with the results from the mentioned clinical study the suitability of an exemplified composition for improving EXEC in patients as defined in the claims. The opponent had not substantiated any serious doubts with verifiable facts regarding the sufficiency of disclosure.

VIII. The arguments of the opponent relevant to the present decision are summarized as follows:

(a) Admittance reference to T 1491/14 and document D29

The citation of T 1491/14 merely sustained the maintained objection that the claimed subject-matter does not involve a new patient group.

Document D29 confirmed that IADL are strongly linked to EXEC. The document was filed in response to the proprietor's allegation in the letter of 16 June 2022 that the improvement in IADL as reported in document D28 could be related to an improvement in MEM instead of EXEC.

(b) Novelty

Documents D6 and D28 described the use of the defined compositions for improving IADL and for supporting and

enabling complex activities involving initiation, planning and effective operation performances in patients with Alzheimer's disease (AD). Such utility was necessarily associated with an improvement in EXEC. Documents D6 and D28 actually explicitly referred to the important role that EXEC plays in these activities.

Moreover, EXEC was generally affected in patients with AD for whom the prior art already described treatment with the defined composition. In these patients EXEC could not be improved in isolation, because EXEC was strongly related to MEM and evidently linked to IADL. Having regard to the considerations in T 233/96, T 836/01, T 1491/14 the purpose of improving EXEC was not associated with a new therapeutic indication involving a new sub-group of patients. The defined treatment was therefore anyway anticipated by documents D6 and D28 as well as documents D5, D7, D8 and D10-D15, which already described the defined compositions for the same treatment of the same group of patients.

(c) Inventive step

In as far as the treatment defined in claim 1 as granted was not anticipated by the teaching concerning the improvement of IADL in patients with AD as described in document D28 (or D6), the difference only concerned the criterion for treatment of the same group of patients.

Similarly, the difference with respect to the teaching concerning the improvement of memory in patients with AD as described in document D8 could only involve the reason for providing the treatment of the same group of patients.

The objective technical problem could only be seen in the provision of a further criterion or reason for providing treatment to the defined group of patients.

The significance of a decline in EXEC in the defined group of patients was, however, well known in the prior art as evidenced in the first place by documents D28 and D6 as well as by documents D1-D3, D26 and D27.

The claimed solution was therefore obvious to the skilled person.

(d) Sufficiency

The patent provided no plausible disclosure that an improvement in EXEC could be achieved with the defined composition in the diverse groups of patients as defined in claim 1 as granted who were not mild AD patients. In this respect document D21 indicated that no improvement in EXEC from treatment with a relevant composition was observed in prodromal AD patients.

It was also not credible that any combination of compounds in any amount as defined in claim 1 as granted would allow for an improvement of EXEC in mild AD patients, let alone in the other types of patients defined in claim 1 as granted. In this respect documents D21 and D25 underlined the relevance of all components of the multinutrient composition "Fortasyn Connect", which essentially corresponded to the tested composition in the patent. Moreover, document D4 indicated that cytidine was far less efficient than uridine in crossing the blood-brain barrier.

The patent itself further indicated that even with the exemplified composition used in the reported clinical

study any beneficial effect on EXEC is only achieved after twelve weeks of treatment of patients with mild AD.

IX. The patent proprietor (appellant) requested that the decision under appeal be set aside and that the patent be maintained as granted or as amended according to one of the auxiliary requests 1-12 or 7A-12A on which the decision under appeal was based.

The proprietor further requested that document D29 and an additional line of argument from the respondent relying on decision T 1491/14 not be admitted into the appeal proceedings.

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

The opponent further requested that document D29 be admitted into the appeal proceedings.

Reasons for the Decision

Patent as granted (main request)

1. Admittance reference to T 1491/14 and document D29

1.1 The objection that the claimed subject-matter does not involve a new patient group had been maintained in the opponent's reply to the appeal (see section 4.1). The additional reference to T 1491/14 in the opponent's letter of 15 September 2022 merely further developed this argument and is therefore not disregarded as an amendment to the respondent's case under Article 13(1) RPBA.

1.2 Document D29 represents new evidence, which was filed by the opponent after its reply to the appeal. The filing of document D29 thus corresponds to an amendment to the opponent's appeal case under Article 13(1) RPBA.

The opponent argued that document D29 confirmed that IADL are strongly correlated to EXEC and that MEM does not have such effect on IADL. According to the opponent document D29 was filed in response to the allegation in the proprietor's letter of 16 June 2022 that a change in IADL did not necessarily reflect a change in EXEC.

The Board observes that the proprietor already relied in its statement of grounds of appeal (see for instance pages 6-7) on the argument that IADL can be affected by MEM, EXEC or both. Moreover, whilst document D29 reports that IADL are associated with cognitive functions and mentions that EXEC may be more important than MEM for performing ADL functions (see D29, abstract under "Conclusions"; see also page 2, right column), the document does not exclude that a change in IADL may be linked to a change in MEM.

Accordingly, the Board has not admitted document D29 into the appeal proceedings under Article 13(1) RPBA, because the reason for filing of document D29 at the late stage of the appeal proceedings is not convincing and because the filing of document D29 is not suitable to resolve the issue raised by the proprietor.

2. Novelty

2.1 Documents D6 and D28 describe compositions comprising uridine or an equivalent thereof, EPA and/or DHA for improving activities in which the operational and the

executive brain functions play an important role, i.e. the instrumental and/or basic activities of daily living (IADL/BADL), and for supporting and enabling those complex activities where initiation, planning and effective operation performances play a role (see D6, page 1, line 30 to page 2, line 16 and page 3, lines 6-12; see D28, pages 2-3; pages 4-5). The compositions are described to be in particular useful for patients with early or mild Alzheimer's disease, preferably with a MMSE score of 20-26 (see D6, page 12, lines 5-13; see D28, page 13). Document D28, which refers to document D6 as priority document, additionally reports in example 5 the results from a clinical study. An improved ADCS-ADL score was observed in AD patients following treatment with a relevant composition for the duration of twelve weeks. These improvements resulted mainly from an improvement in instrumental activities (see D28, pages 20-21).

2.2 The Board observes that documents D6 and D28 describe the beneficial effect of a formulation with the same components as defined in claim 1 as granted on activities which are influenced by EXEC, in particular the IADL, but do thereby not explicitly disclose the beneficial effect on EXEC itself as defined in claim 1 as granted.

The opponent argued in line with the findings in the decision under appeal that any improvement in the activities as described in documents D6 and D28 is nevertheless inevitably associated with a positive effect on EXEC.

However, document D26 explains that changes in MEM and EXEC are independently associated with the rate of change in IADL (see D26, abstract and page 5, lines

13-17). The benefit of treatment with respect to IADL as described in documents D6 and D28 does therefore not necessarily imply an improvement in EXEC, because the reported benefit may well have resulted from an improvement in MEM.

2.3 The opponent further argued that EXEC was generally affected in patients with AD and could not be improved in isolation. The purpose of improving EXEC as defined in claim 1 as granted did therefore anyway not qualify as a new therapeutic indication with respect to the teaching in documents D6 and D28, which already described the same compositions for treatment of the same patients.

However, document D22 indicates that in patients with dementia there is no parallel decline in EXEC and MEM. In particular, document D22 shows in the column charts of Figure 2 (see D22, page 11), that in different forms of dementia , namely Alzheimer type, primary progressive aphasia and frontotemporal dementia (FTD), different levels in the decline in EXEC and MEM are observed. The presented column charts furthermore demonstrate that in each different form of dementia the decline in EXEC and MEM develops differently over time. The presented data indicate for the initial stages of dementia in primary progressive aphasia and FTD a more prominent impairment of EXEC over MEM, whereas for the initial stage of Alzheimer type dementia a strikingly more prominent decline in MEM over EXEC is reported.

It is evident from document D22 that a decline in EXEC, and thus also the need for treatment intended to improve EXEC, can be specifically diagnosed in patients who develop dementia and that the change in EXEC over time, and thus also the response to treatment, can be

specifically monitored. As confirmed in for instance document D3 (see page 555) the Trail Making Test B (TMT-B) described in the patent (see paragraphs [0033]-[0035] and [0105]) is commonly known as suitable for this purpose. The Board therefore considers that the purpose of improving EXEC defines a specific clinical situation which characterizes the therapeutic use as defined in claim 1 as granted.

In this context the Board is not convinced by the opponent's argument that in view of the considerations in decisions T 233/96 (see Headnote) and T 1491/14 (see section 2.2) the treatment defined in claim 1 lacked novelty, because it does not define the treatment of a new group of patients. The purpose of improving EXEC as defined in claim 1 as granted relates to a specific clinical situation requiring treatment, namely the situation in which it is desired to target a decline in EXEC. As explained above, this decline can be specifically diagnosed and an improvement of the cognitive funtion EXEC following a therapeuitc treatment can be specifically monitored. Thus, in line with the considerations in T 836/01 (see section 10) the purpose of improving EXEC distinguishes the treatment defined in claim 1 as granted from the treatment of patients with AD as described in documents D6 and D28 even without the explicit definition of a new patient group.

2.4 Documents D5, D7, D8 and D10-D15 were cited by the opponent as further evidence that compositions with the same components as defined in claim 1 as granted were known to have a beneficial effect on the brain function in patients with AD.

These documents do not specifically address the effect of such composition on EXEC.

In this context the Board observes that document D8 reports a beneficial effect of a corresponding composition on the verbal recall scores of patients following twelve weeks of administration (see D8, page 6, Figure 2 and page 7, Table 3; see also Abstract). However, document D8 describes the delayed verbal recall test as a measure of episodic memory (see D8, page 2, right column, lines 3-5) and presents the verbal recall scores as indicators of memory performance, not of EXEC (see D8, page 7, the subscript under Table 3).

Documents D5, D7, D8 and D10-D15 do therefore not provide any more pertinent disclosure than documents D6 and D28 regarding the utility of the compositions for improving EXEC as defined in claim 1 as granted.

2.5 Accordingly, the Board concludes that the patent as granted meets the requirement of novelty.

3. Inventive step

3.1 As explained in section 2.1, documents D6 and D28 describe the utility of a composition as defined in claim 1 of the patent for improving IADL, in particular in patients with early or mild Alzheimer's disease. Document D28 represents more pertinent prior art than document D6 in view of the additional information regarding a clinical study in which an improved ADCS-ADL score was observed in AD patients following twelve weeks of treatment, which resulted mainly from an improvement in instrumental activities.

As further explained in section 2.4, document D8 describes improvements in the verbal recall score of mild AD patients who were treated with a composition as defined in claim 1 of the patent during a period of twelve weeks.

Following the conclusion in section 2.5, the difference between the claimed subject-matter and the teaching in document D28 as well as the teaching in document D8 concerns the definition of the therapeutic indication, namely the utility for improving EXEC.

3.2 The patent demonstrates that the administration of an exemplified composition according to claim 1 as granted to patients with mild AD during a period of twenty-four weeks provided a beneficial effect on EXEC (see the patent, paragraphs [0097]-[0105], "Example 2. Clinical study" and Figure 2).

As explained above in section 2.3, the purpose of improving EXEC relates to a specific clinical situation which distinguishes the defined treatment from the treatment of patients with AD as described in documents D6 and D28. Contrary to the opponent's argument the purpose of improving EXEC does therefore not merely concern a further criterion or reason for providing the otherwise known treatment of this group of patients.

The problem to be solved in view of document D28 or document D8 may therefore be formulated as the provision of a further therapeutic use for the defined compositions.

The question to be answered is whether on the basis of the prior art the skilled person had a reasonable expectation that the defined composition would be

useful for improving EXEC in the defined group of patients.

3.3 It was not in dispute that EXEC is compromised in patients with AD and that EXEC plays an important role in IADL. However, as pointed out in section 2.2 above, changes in MEM and EXEC are according to document D26 independently associated with the rate of change in IADL. Without any further specific indication from the prior art the improvement in IADL reported in document D28 does not provide a reasonable expectation of a beneficial effect on EXEC, because the improvement in IADL could well have resulted from an improvement in MEM.

Moreover, the results reported in the patent (see Figure 2) indicate that the effect of administration of the defined composition on EXEC may only become clearly recognizable after twelve weeks from the start of the administration. The skilled person who further investigates the effects on IADL from the twelve week treatment as reported in document D28 may thus not recognize the improvement in EXEC as disclosed in the patent. On the contrary, when investigating the effect on IADL from twelve week administration of the composition as described in document D28 the skilled person would on the basis of the results from the administration of such a composition for the duration of twelve weeks as described in document D8, which concerned improved verbal recall scores (see D8, page 6, Figure 2 and page 7, Table 3; see also Abstract), likely conclude that the reported improvement in IADL was due to an improvement of MEM.

The prior art did therefore not provide the skilled person with reasonable expectation that the defined

composition would be useful for improving EXEC in the defined group of patients.

3.4 Accordingly, the Board concludes that the patent as granted meets the requirement of inventive step.

4. Sufficiency

4.1 As mentioned above in section 3.2, the patent demonstrates in Example 2 that the administration of an exemplified composition according to claim 1 as granted during a period of twenty-four weeks allows for an improvement of EXEC in patients with mild AD. According to the Board the patent credibly discloses with this example the suitability of the composition for the therapeutic indication as defined in the claims as granted.

4.2 The Board considers that the opponent's objection that the patent does not sufficiently disclose the suitability of the claimed composition for improving EXEC in other patients than those suffering from mild AD remained without substantiation.

The opponent referred to diverse groups of patients as defined in claim 1 and pointed to the results from the study of the effects of the multinutrient combination "Fortasyn Connect" in patients with prodromal AD reported in the post-published document D21. This study did not reveal a significant effect on primary and secondary end points regarding the neuropsychological test battery (NTB) scores, including the scores for the NTB executive domain (see D21, page 970, Table 3 and right column, lines 5-9).

However, the mere fact that no statistically significant effect on EXEC was observed in the study reported in document D21 does in the Board view not raise serious doubts as to the utility of the composition defined in the claims of the patent. In fact, document D21 explicitly recognizes that the study was inadequately powered and recommends further investigation with larger sample sizes (see D21, summary under "Interpretation").

The Board considers that the mere reference to the diverse nature of the disorders defined in claim 1 as granted does not further substantiate the opponent's objection. The claim is specifically directed to the improvement of EXEC, which may be compromised in patients afflicted by the defined disorders and for which the patent exemplarily demonstrates efficacy in patients with mild AD.

4.3 The opponent further objected that the clinical study reported in the patent had only been carried out with a formulation comprising specific amounts of the uridine derivative UMP and the lipids EPA and DHA in combination with a variety of further nutritional components (see the patent, paragraph [0097], Table 1). Taking account of the evidence in documents D21 and D25 the effect on EXEC reported in the patent for this complex composition could not be plausibly extrapolated to the simple combination defined in claim 1 as granted.

Document D21 states that the nutrients in the multinutrient combination "Fortasyn Connect", which includes the components listed in Table 1 of the patent, were selected on the basis of their established neuroprotective properties and combined to enhance

their efficacy (see D21, bridging paragraph pages 965-966). Document D25 reports that the effects of the multinutrient combination "Fortasyn Connect" on pheochromocytoma cells in terms of their response to muscarinic receptor agonists could not be attributed to single nutrients (see D25, page 631, Abstract). Document D4 discloses that the administration of uridine or uridine precursors leads to increased levels of cytidine in the human brain and that the potential benefit of an uridine source administration overwhelmingly exceeds the benefit of cytidine administration due to lesser crossing of the blood-brain barrier by cytidine (see D4, page 1, lines 17-26).

The Board observes, however, that document D4 actually confirms that uridine and equivalents thereof, including cytidine, have a beneficial effect on brain function (see D4, page 1, lines 19-21). Moreover, document D5 indicates that the beneficial effects of the omega-3 fatty acid DHA on brain function are enhanced by uridine and can be reproduced with EPA (see D5, abstract). The above discussed documents D6/D28 and D8 further indicate the beneficial effect of the combination of the components defined in claim 1 as granted on the cognitive function in relevant patients. Taking account of the thus already known potential of the defined combination of ingredients to improve compromised brain function, the effects demonstrated in the clinical study reported in the patent may reasonably be attributed to the components defined in claim 1 as granted. In this context the patent provides in paragraphs [0055] and [0069] specific guidance as to the suitable dosages for these active ingredients. The Board therefore considers that the relevance of the additional nutritional components mentioned in

documents D21 and D25 does not raise any serious doubts concerning the efficacy of the combination as defined in claim 1 as granted and the skilled person's ability to carry out the claimed invention without undue burden.

4.4 In the clinical study reported in the patent (see Figure 2) the beneficial effect of the administration of the defined composition on EXEC only became clearly recognizable after twelve weeks from the start of the administration. However, this delay for the defined effect to develop does not imply that the initial administration is without consequence. In fact, the clinical study provides the skilled person with guidance towards effective treatment notwithstanding any initial delay before the effect can be observed.

4.5 Accordingly, the Board concludes that the patent as granted sufficiently discloses the claimed invention.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated