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Datasheet for the decision of 13 November 2015

Case Number: T 2369/10 - 3.4.01

Application Number: 06736911.6

Publication Number: 1853345

IPC: A61N1/36

Language of the proceedings: EN

Title of invention:
CRANIAL NERVE STIMULATION FOR TREATMENT OF SUBSTANCE ADDICTION

Applicant:
Cyberonics, Inc.

Headword:

Relevant legal provisions:
EPC Art. 53(c), 54(4), 54(5), 112(1)
EPC 1973 Art. 52(4), 54(5)
Vienna Convention on the Law of Treaties (1969) Articles 31, 32

Keyword:
Second (or further) medical use of a device - novelty (no)
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:
G 0005/83, G 0001/04, G 0001/07, G 0002/08, G 0001/12, J 0005/81, T 0773/10, T 1314/05, T 1099/09, T 1069/11

Catchword:

Europäisches Patentamt
European Patent Office
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Case Number: T 2369/10 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 13 November 2015

Appellant: (Applicant)	Cyberonics, Inc. 100 Cyberonics Boulevard Houston TX 77058-9798 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 July 2010 refusing European patent application No. 06736911.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	G. Assi
Members:	F. Neumann
	D. Rogers

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application number 06 736 911.6.

II. The examining division refused the application because claim 1 defined a method for treatment of the human or animal body by therapy and therefore fell under the exception to patentability identified in Article 53(c) EPC.

III. With the statement setting out the grounds of appeal, the appellant filed two new sets of claims as "*Alternative A*" and "*Alternative B*". It was requested that the decision under appeal be set aside and that "*it be decided that the subject-matter of claim 1 according to the attached claim set "Alternative A" is novel over the prior art cited by the examining division*" or that "*it be decided that the subject-matter of claim 1 according to the attached claim set "Alternative B" is novel over the prior art cited by the examining division*".

In the case that the above requests could not be granted, the appellant further requested that the following two questions relating to novelty of a claim having the form "*Medical device Y for the treatment of a disease Z*" (question (1)) and novelty of a claim having the form "*Use of a device X for producing a medical device Y for the treatment of a disease Z*" (question (2)) be referred to the Enlarged Board of Appeal:

Question 1:

"*Does Article 54(4) and (5) apply mutatis mutandis to medical devices with the effect that the subject-matter of a claim having the form "Medical device Y for the treatment of a disease Z" is novel over prior art according to which the medical device Y are (sic) known in the art, but the treatment of the disease Z with the medical device Y is novel?*"

Question 2:
"*Is the subject-matter of a claim having the form "Use of device X for producing a medical device Y for the treatment of a disease Z" novel over prior art according to which the device X, the medical device Y, and the method for producing the medical device Y are known in the art, but the treatment of the disease Z with the medical device Y is novel?*"

The appellant also requested that the case be remitted to the examining division for further prosecution.

Oral proceedings before the Board took place on 30 July 2015.
The appellant maintained the requests mentioned above.
After the closure of the debate, the Chairman announced that the Board had not reached a decision and that therefore a decision would be issued in writing.

IV. The following documents were referred to during the appeal proceedings:
D1: US-A-5 154 172;
D2: US-A-4 702 254.

V. Claim 1 of Alternative A reads as follows:

"*Neurostimulator system for treating a patient having a substance addiction to alleviate a symptom of the*

substance addiction, the neurostimulator system comprising an electrode configured for directly coupling to a cranial nerve of the patient and applying an electrical signal to said cranial nerve."

Claim 1 of Alternative B reads as follows:

"*Use of an electrode configured for directly coupling to a cranial nerve of a patient and applying an electrical signal to said cranial nerve for the manufacture of a neurostimulator system for treating a patient having a substance addiction to alleviate a symptom of the substance addiction.*"

VI. In brief, the appellant argued as follows:

In decision G 5/83 (OJ EPO 1985, 64), the Enlarged Board of Appeal did not take a literal view of Article 54(5) EPC 1973. Although this provision related only to the novelty of substances and compositions for use in a first medical indication, the Enlarged Board considered that "*it seemed justifiable by analogy*" to extend this principle to second and further medical indications (Reasons, point 21).

Using the same principle, the appellant submitted that the Board should not take a literal view of Articles 54(4),(5) EPC in the present case. Although these provisions related only to "*any substance or composition*", it would seem justifiable by analogy to extend this principle to products, in particular to devices.

The novelty of a device could therefore be derived from a new therapeutic use of the device. Although a neurostimulator having the same structural features as

that of claim 1 was known from D1, it was neither known nor obvious to employ the known neurostimulator in the treatment of substance addiction.

The claimed subject-matter was therefore new and inventive.

Reasons for the Decision

1. The appeal is admissible.

2. Citation practice

In the present decision, Articles and Rules of the EPC 1973 shall be referred to using the notation "*EPC 1973*" and Articles and Rules of the EPC 2000 shall be referred to using the notation "*EPC*".

3. Preliminary comments

The independent claim of Alternative A is formulated as a use-related product claim, in particular a device for use in a method of treatment of the human or animal body by therapy.

The independent claim of Alternative B is directed to essentially the same subject matter, but is drafted as a Swiss-type claim.

The appellant indicated that neither form of claim wording was preferred over the other. In essence, the main issue to be resolved by the current appeal was whether a second (or further) medical use could confer novelty on a known device. The alternative wordings simply represented an attempt to adhere as closely as possible to the wording which has been held allowable

for substances or compositions claimed in terms of their second (or further) medical use.

4. Decision G 5/83

In G 5/83 the Enlarged Board observed that the intention of Article 52(4) EPC 1973 was "*only to free from restraint non-commercial and non-industrial medical and veterinary activities*" (Reasons, point 22). Subsequent decisions and opinions of the Enlarged Board have endorsed this finding (see G 1/04, Reasons 4; G 1/07, Reasons 3.3.6 and G 2/08, Reasons 5.3).

In particular, the Enlarged Board held in G 5/83 (Reasons, point 22) that, to prevent the exclusion of Article 52(4) EPC 1973 from going beyond its proper limits, it seemed appropriate to take "a *special view of the concept of the "state of the art" defined in Article 54(2) EPC [1973]*". Article 54(5) EPC 1973 defines a special provision with regard to the first medical use of substances or compositions and provides "a *partial compensation for the restriction of patent rights in the industrial and commercial field resulting from Article 52(4) EPC [1973], first sentence*". Remarking that "*the rule of interpretation that if one thing is expressed the alternative is excluded (expressio unius (est) exclusio alterius), is* a *rule to be applied with very great caution as it can lead to injustice*", the Enlarged Board could not deduce from Article 54(5) EPC 1973 *"that there was any intention to exclude second (and further) medical indications from patent protection other than by* a *purpose-limited product claim.*" Similarly, no intention to exclude second (and further) medical indications generally from patent protection could be deduced from either the terms of the EPC or from the legislative history

thereof. It was therefore held that it was *"legitimate in principle to allow claims directed to the use of* a *substance or composition for the manufacture of* a *medicament for* a *specified new and inventive therapeutic application"* (Reasons, point 23).

5. Revision of the EPC

During the revision of the EPC, new Article 54(5) EPC was introduced with the intention of "*unambiguously permit*[ting] *purpose-related product protection for each new medical use of* a *substance or composition already known as* a *medicine*" (see the Travaux Préparatoires, MR/18/00, point 4). This new provision formally codified that protection may be granted to known substances and compositions for a specific use in second (and further) medical indications.

6. The appellant's arguments

6.1 The appellant submitted that the mode of reasoning of the Enlarged Board in decision G 5/83 could be applied to the current case.

Applying the reasoning of point 22 of G 5/83 to the present case, and, where necessary, using the equivalent provisions of the EPC 2000, the appellant made the following analysis:

The intention of Article 53(c) EPC was only to free from restraint non-commercial and non-industrial medical and veterinary activities. In order to prevent the exclusion of Article 53(c) EPC from going beyond its proper limits, it was appropriate to take a special view of the concept of the state of the art defined in Article 54(2) EPC. Article 54(4) EPC only provided a

partial compensation for the restriction of patent rights resulting from Article 53(c) EPC, allowing a special view of novelty for substances and compositions for use in a first medical indication. Article 54(5) EPC extended this principle to a second medical indication but still only went part way in remedying the severity of Article 53(c) EPC, since products other than substances and compositions were not explicitly covered by this provision. The appellant emphasized the importance of interpreting Article 54(5) EPC using the same principles as the Enlarged Board in G 5/83. In particular, in order to ensure that only medical and veterinary activities were excluded from patentability, the interpretative maxim "*expressio unius (est) exclusio alterius*" should not be applied in the present case. This had the consequence that the explicit mention of "*any substance or composition*" in Article 54(4),(5) EPC did not necessarily mean that products other than substances and compositions (specifically, devices) were not covered by these articles. Hence, it might not be deduced from the special provisions of Article 54(4),(5) EPC that there was any intention to exclude protection for devices for use in a medical method. Moreover, no intention to exclude devices for use in a medical method generally from patent protection might be deduced from the terms of the EPC or from the legislative history thereof. Therefore, it had to be concluded that it was legitimate to allow claims directed to a device for use in a specified new and inventive therapeutic application.

6.2 The appellant also made reference to decision G 2/08 (OJ EPO 2010, 456) which contained some discussion of Article 54(4),(5) EPC. In this decision it was pointed out that the EPC 1973 contained no provision on second medical indications. Under the new law, Article 54(5)

EPC filled the gap in the former provisions. Until the EPC 2000 came into force, the gap in the law had been filled by the Enlarged Board's decision G 5/83.

The appellant argued that in the same way that a gap had existed with respect to a second medical indication, the absence of any provision concerning devices for use in medical methods was also to be seen as a gap in the law. This gap could be filled either in the praetorian way of decision G 5/83, or by applying the provisions of Article 54(5) EPC not only to substances and compositions, but also to devices. The appellant noted that the Enlarged Board in G 2/08 used the term "*product*" in point 5.8 when referring to Article 54(4) EPC as follows:
"*either* a *product for use in* a *method under Article 53(c) EPC is new per se and can constitute the subject matter of a product claim under Article 53(c), second sentence, EPC, or a* ***product*** *(substance or composition) is already known per se but can nevertheless be granted patent protection provided, under Article 54(4) EPC, said* ***product*** *has not yet been used in a method under Article 53(3), first sentence, EPC*" (emphasis added). The appellant held that the usage of the term "*product*", as highlighted above in bold, implied that the Enlarged Board tacitly understood that not just substances and compositions were intended to be included under the terminology of Article 54(4) EPC.

The appellant considered that this opinion was supported by paragraph 5.10.1 of G 2/08 which states: "*That decision* [G 5/83] *of the Enlarged Board of Appeal had filled a gap in the legal provisions and allowed claims concerning* a *second therapeutic indication of* a *known* ***product****, although not specifying whether such* a

second use could be something else than the treatment of another disease" (emphasis added).
This again implied a tacit understanding of the Enlarged Board that the product protection afforded by Article 54(5) EPC applied not only to substances and compositions but also to products in general and therefore also to devices.

6.3 The appellant also outlined the historical development of the legislation in an attempt to explain why devices had not been included in the provision of Article 54(5) EPC 1973. The Travaux Préparatoires clearly showed that Article 54(5) EPC 1973 was introduced as a result of lobbying by the pharmaceutical industry. "*Interested circles*" had indicated that it would be valuable to humanity to encourage research involving new therapeutic uses of known substances (BR/135/e/71 ms, point 92). The appellant postulated that, in contrast to this, the failure to refer to "*products*" in Article 54(5) EPC 1973 was because, when the EPC 1973 was being drafted, medical devices would have been designed with a specific purpose in mind.

In this respect, the question of a use-related protection would not have arisen since the use would be implied by the specific structural features of the device itself. As Article 52(4), second sentence, EPC 1973 guaranteed that products to be used in medical methods would not be excluded from patentability, product claims would be the most appropriate form, particularly since this form also provided the most general protection. Moreover, at that time, devices and instruments were used mainly for surgery (e.g. scalpels) or diagnostics (e.g. X-ray devices). Devices to be used for therapy (e.g. pacemakers) were only just starting to emerge. At that point in time, any

therapeutic treatment of the human or animal body would have been performed almost exclusively with medication.

As medical device technology has developed (the 2014 Annual Report of the EPO shows that Medical Technology is now the field with the highest number of applications, with more than twice the number of applications as the field of Pharmaceuticals), it has become increasingly the case that certain devices may be used in therapeutic applications other than that for which the device was originally developed. This was evidenced not only by the present application, in which a neurostimulator which was initially developed for the treatment of epilepsy had been found to be also suitable for the treatment for substance addiction and subsequently also for the treatment of bulimia, but also by numerous decisions of the Boards of Appeal which dealt with exactly this issue (see, e.g., T 0773/10 (not published), T 1314/05 (not published), T 1099/09 (not published), T 1069/11 (not published)). Thus, it was now plainly obvious that it would be of benefit to humanity to encourage research into new therapeutic uses of known devices. The appellant noted that the necessary clinical trials and approval procedures for such methods were just as intensive as the testing of new uses of known drugs and should therefore be rewarded in the same manner. In the same way that Article 54(5) EPC allowed purpose-related product protection for a substance or composition which could be used in alternative medical methods, so too should purpose-related product protection be available for a device which could be used in alternative medical methods.

6.4 The appellant emphasized that the line of argument adopted in the present case based on the approach

developed in G 5/83 had not been considered by the boards of appeal in previous cases. There was no case law which discussed this approach. The appellant underlined that it was not being argued that a "*device*" could be equated with a "*substance or composition*" in the Swiss-type form of claim, as was often argued in previous decisions. Instead, it was being argued that the Board should apply the same mode of reasoning as the Enlarged Board used in G 5/83 to the present case. In this manner, the Board would arrive at an analogous conclusion to that of G 5/83 and find that devices for use in second medical indications were allowable.

7. The Board's position

7.1 Vienna Convention on the Law of Treaties, concluded at Vienna on 23 May 1969

In points 1 to 6 of the Reasons of G 5/83, the Enlarged Board sets out some preliminary observations concerning the interpretation of the EPC. In point 4 of the Reasons, the Enlarged Board concluded that the European Patent Office should apply the rules of interpretation of treaties incorporated in the Vienna Convention on the Law of Treaties (hereinafter "*Vienna Convention*") when determining how to interpret the EPC.

Article 31 of the Vienna Convention sets out the general rule of interpretation. Paragraph 1 states that, "*A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.*"

Applying this general rule of interpretation, the EPC shall be interpreted in good faith. Unless it is

established that the contracting states intended that a special meaning should be given to a term, the terms of the EPC shall be given their ordinary meaning in their context and in the light of the object and purpose of the EPC.

Article 32 of the Vienna Convention concerns supplementary means of interpretation and states that, "*Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:*
(a) leaves the meaning ambiguous or obscure; or
(b) leads to a result which is manifestly absurd or unreasonable."

Applying this provision to the EPC, recourse may be had to the Travaux Préparatoires in order to confirm the meaning of terms as resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31 either leaves the meaning ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable.

Therefore, the ordinary meaning shall first be given to the terms of the EPC in their context. Thereafter, the Travaux Préparatoires may be consulted to confirm this meaning or, if necessary, to determine the intended meaning.

7.2 Article 54(4), (5) EPC

7.2.1 Article 54(4) EPC reads "*Paragraphs 2 and 3 shall not exclude the patentability of any substance or*

composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art."

Article 54(5) EPC reads "*Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.*"

Giving the terms of Article 54(4),(5) EPC their ordinary meaning results in the interpretation that any known substance or composition may be patented for use in a new method referred to in Article 53(c) EPC. The application of the maxim "*expressio unius (est) exclusio alterius*" leads to the conclusion that the explicit recitation of "*any substance or composition*" excludes any products other than the explicitly mentioned substances and compositions.

The appellant indicated that the Enlarged Board stated in G 5/83 that the maxim mentioned above should be applied with caution, since it could lead to injustice. In the present case, the injustice would be that known pharmaceuticals might be patented for use in new medical treatments but not known devices.

Whilst the Board acknowledges that a difference exists between the protection for pharmaceuticals and the protection for devices, "*it is neither the Board's duty nor its competence to evaluate the arguments about how desirable or equitable patent protection for any medical product may or may not be*", as the board held in T 0773/10 (not published, Reasons, point 3.4.1). As

a matter of principle, the Board does not question the motives of the legislator for employing the specific wording of Article 54(4),(5) EPC. Rather, the Board assumes that the restriction to substances and compositions is deliberate.

With regard to G 5/83, it may be inferred that the Enlarged Board did not rely on the maxim "*expressio unius (est) exclusio alterius*" because it could not deduce from Article 54(5) EPC 1973 "*that there was any intention to exclude second (and further) medical indications from patent protection other than by* a *purpose-limited product claim*" (Reasons, point 22).

In the present case, however, the Board comes to a different conclusion with respect to the intention to exclude devices from patent protection when defined in terms of their second (and further) medical indication. In particular, the terminology employed in Article 54(4),(5) EPC betrays a deliberate intention to restrict the special provisions on novelty to first and further medical uses of substances and compositions only.

7.2.2 Article 54(4),(5) EPC governs novelty of a known substance or composition for a first medical use and a second or further medical use, respectively.

Article 53(c) EPC, to which both paragraphs 4 and 5 of Article 54 EPC refer, sets out that European patents shall not be granted in respect of methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body, but emphasizes that "*this provision shall not apply to* ***products, in particular substances or***

compositions, *for use in any of these methods*" (emphasis added).

In T 1069/11 (not published, Reasons, point 3.3.2), it was held that "*It can thus be seen from the text of those articles that there is an explicit difference between the wording chosen by the legislator for Article 53(c) EPC and the wording of Article 54(4) and (5) EPC. First of all, as a consequence of the use of "in particular", Article 53(c) EPC in itself indicates that products are not limited to substances and compositions. Moreover, whereas Article 53(c) mentions products, in particular substances or compositions, Article 54(4) and Article 54(5) only mention substances and compositions.*
The legislator has thus made a distinction between products that can qualify as substances or compositions, and which are patentable within the framework of Article 54(4) and (5) EPC, and other products, which do not fall under the exceptions provided by those provisions ..."

The Board sees no reason to deviate from this analysis. In the present case, the Board considers that there is no reason why the application of the maxim "*expressio unius (est) exclusio alterius*" should be considered inappropriate. In the absence of any clear reasons for taking a different view, the Board holds it appropriate to adhere to the "*ordinary meaning*" interpretation governed by Article 31 of the Vienna Convention.

Thus, with this understanding, the novelty conferred by these provisions is restricted to substances and compositions only.

7.3 Travaux Préparatoires of the EPC 1973
Travaux Préparatoires of the EPC 2000

Since the ordinary meaning of the provisions according to Article 54(4) and (5) EPC is *per se* clear, there is no need to turn to the Travaux Préparatoires to aid the understanding of these provisions. Nevertheless, for the purposes of a review of the conclusions drawn above, the Board holds it expedient to refer to the Travaux Préparatoires (Article 32 of the Vienna Convention).

Whilst very little appears in the Travaux Préparatoires of the EPC 1973 concerning medical instruments and devices, when discussing what finally turned out to be Articles 52(4) and 54(5) EPC 1973, the Dutch delegation made the following proposal (MR/32, point 8):
"*In order to avoid the possibility that this paragraph is interpreted to exclude a contrario the patentability of any product other than* a *substance or composition for use in therapeutical treatment (like* a *medical instrument), we propose to draft Article 50, par. 3, as follows:*
"The provisions of paragraph 2(d) does not exclude the patentability of any product, in particular any substance or composition, for use in a *method referred to in that provision".*"

In the very next paragraph of their submissions the Dutch delegation then proposed an amendment to Article 54(5) EPC 1973 where the wording "*substance or composition*" was retained unamended with no reference to "*product*" (MR/32, point 9).

This appears to be the only reference to "*medical instruments*" in the Travaux Préparatoires of the EPC 1973.

The Board has found no reference to "*medical instruments*" or the like in the Travaux Préparatoires of the EPC 2000.

In the absence of any further documentation, the reasons for making a distinction in the wordings of Article 52(4) EPC 1973 and Article 54(5) EPC 1973 can only be speculated upon. The fact remains, however, that despite being fully aware of the fact that "*substance or composition*" did not cover medical instruments, the Dutch delegation did not propose to carry the wording of Article 52(4) EPC 1973 through to Article 54(5) EPC 1973 to include reference to "*any product, in particular any substance or composition*" in order to specify that novelty could also be conferred on, e.g., a known device for use in a first medical indication. It thus appears that a deliberate distinction has been made between the wording of Article 52(4) EPC 1973 and that of Article 54(5) EPC 1973, resulting in the exclusion of products other than substances or compositions from the novelty provided by Article 54(5) EPC 1973.

This therefore confirms the "*ordinary meaning*" interpretation which the Board arrived at above.

7.4 G 2/08

Having regard to the appellant's reference to the gap in the law highlighted by G 2/08, the Board observes that the legal situation prevailing before G 5/83 was such that a provision existed which conferred novelty

on a substance or composition for use in a first medical indication. The current legal situation is that no provision exists which confers novelty on a device for use in any medical indication. Devices are simply not afforded the benefit of novelty provided by Article 54(4),(5) EPC, even if they are defined in terms of a new medical use.

A gap in the law was identified as resulting from the provision of only a partial compensation (the first medical indication) to the restriction imposed by Article 52(4) EPC 1973. This gap was filled firstly by G 5/83 and then by Article 54(5) EPC. Specifically, Article 54(5) EPC permits a purpose-related substance or composition protection for a second or further medical indication. The EPC does not foresee such novelty for a device for use in a first medical indication, hence a different situation exists, which means that the approach mentioned above cannot be analogously applied.

Moreover, the Board can see no suggestion in G 2/08 that the use-related claims permitted by Article 54(4), (5) EPC could be used to protect products other than substances or compositions. The term "*product*" appears to be used merely as shorthand in G 2/08.

In this respect, attention is drawn to the expression "*a product (substance or composition)*" (Reasons, point 5.8, second paragraph), in which the term "*product*" is to be understood as being a "*substance*" or a "*composition*". Attention is also drawn to the sentence "*Article 54(5) EPC now provides for patent protection of a known substance or composition for "any specific use" of the said product in a method of therapy provided this use is not comprised in the state of the*

art and is inventive" (Reasons, point 5.10.2, second sentence). Here, the Enlarged Board refers to ”a *known substance or composition*” and then to "*said product*", clearly meaning the substance or composition previously mentioned.

In other passages where Article 54(4),(5) is discussed, the Enlarged Board consistently refers to "*substances or compositions*" (Reasons, point 5.9.2.1, last paragraph; point 5.9.2.2, first and second paragraphs).

Thus, it may not be inferred from the usage of the general term "*product*" that the Enlarged Board intended, in G 2/08, to imply that Article 54(4),(5) EPC was not limited to substances and compositions but also implicitly referred to other products.

7.5 Public policy considerations

Having regard to the appellant's analysis of the historical development of Article 54(5) EPC 1973, the Board agrees that it results from the Travaux Préparatoires that it was due to the concerns of "*interested circles*" that Article 54(5) EPC 1973 was included in EPC 1973. These concerns were, namely, that "*whereas new drugs were well protected by patents either in their processes or in respect of the products themselves, there was no economic incentive to invest in research involving new therapeutic uses of known substances as these were not patentable. The pharmaceutical industry considered that as this might be of equal value to humanity, it would be desirable to include such applications as being patentable*" (BR/135/e/71 ms, point 92). The Working Party dismissed this proposal in the early stages of the drafting process, arguing that "*the reasons advanced were not sufficient*

to justify a *provision which would be in fact contrary to common practice in the countries concerned*" (BR/135/e/71 ms, point 92). Nevertheless, it is clear from the final version of Article 54(5) EPC 1973 that the lobbying of the "*interested circles*" resulted in a certain concession to the pharmaceutical industry, at least insofar as the first medical indication of a substance or composition is concerned.

The reasons why this thinking was not extended to new medical uses of devices is not apparent. The appellant suggests that, as explained above, the development of medical devices was not, at that time, advanced enough to establish further therapeutic uses thereof. It was inconceivable at that time that a device could be used for a treatment other than that for which the device had been designed. However, the Board considers that whilst that may have been true when the drafting work for the EPC 1973 was being performed, it was no longer the case when the EPC 2000 was being drafted. The Board has failed to find any mention of medical uses of devices in the Travaux Préparatoires of the EPC 2000, even although Article 54 was subject to a major revision in which the practice of G 5/83 was formally codified in Article 54(5) EPC.

The Board sees the failure to mention devices in Article 54(4),(5) of the EPC as a further indicator that products other than substances or compositions were not intended to be covered by the novelty afforded by those Articles.

8. Conclusions

8.1 Meaning of Article 54(4),(5) EPC

In the present case, the Board holds that, having regard to the wording of Article 54(4),(5) EPC, the ordinary meaning of this Article shall not be extended so as to include something which is not explicitly provided for.

Consequently the Board considers that there is no basis to contemplate that novelty may be conferred on products, other than substances and compositions, by virtue of the provisions of Article 54(4),(5) EPC.

8.2 Alternative A

The neurostimulator system of claim 1 is defined in both structural as well as functional terms. In terms of structural features, the neurostimulator system comprises an electrode configured for directly coupling to a cranial nerve of a patient and applying an electrical signal to said cranial nerve. In terms of functional features, the neurostimulator system is for treating a patient having a substance addiction to alleviate a symptom of the substance addiction.

As indicated in the application itself (page 7, lines 16-21), a neurostimulator suitable for use in the treatment of a patient having a substance addiction is known from D1. The neurostimulator system of D1 comprises an electrode configured for coupling to a cranial nerve of the patient in the manner set out in D2 and applying an electrical signal to said cranial nerve (column 1, lines 48-50; column 3, lines 24-30). D2, to which D1 explicitly refers in this respect, shows that the electrode is indeed directly coupled to the vagus nerve (column 2, lines 21-24).

A functional reference cannot normally impart novelty to an otherwise known product unless the function implies a structural difference to the known product. The only exception to this finding is based on Article 54(4),(5) EPC. As shown above, the Board holds that these provisions are restricted to substances and compositions. The appellant has not even attempted to argue that the new use implies that the structure of the claimed neurostimulator is in any way different to that of the known neurostimulator. On the contrary, the application itself makes clear that the neurostimulator of D1 is suitable for use in the new treatment (page 7, lines 16-21).

The subject-matter of claim 1 of the Alternative A therefore lacks novelty over the disclosure of D1 (Article 54(1),(2) EPC 1973).

8.3 Alternative B

Claim 1 of Alternative B is directed to the manufacture of the known neurostimulator system already defined in claim 1 of Alternative A. The indication of purpose, i.e. for treating a patient having a substance addiction to alleviate a symptom of the substance addiction, does not affect the structure of the neurostimulator itself.

Since an assembled neurostimulator comprising an electrode configured for directly coupling to a cranial nerve of the patient and applying an electrical signal to said cranial nerve is known from D1 (column 1, lines 48-50; column 3, lines 24-30 in combination with D2, column 2, lines 21-24), the Board comes to the same conclusion as with Alternative A.

The subject matter of claim 1 of Alternative B therefore lacks novelty over the disclosure of D1 (Article 54(1),(2) EPC 1973).

8.4 Referral to the Enlarged Board

Under Article 112(1) EPC, in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, a board shall refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes.

The appellant has argued that its questions concern a point of law of fundamental importance.

The Board does not contest this finding. As set out in decision G 1/12 (Reasons, 10), a point of law is to be regarded as of fundamental importance "*if its impact extends beyond the specific case at hand. Such importance is established if it could be relevant to a large number of similar cases.*" Notwithstanding the fact that it is impossible to ascertain the number of cases in which the question of second (or further) medical use of a device was, is or might become relevant, it is apparent from the appellant's submissions that the impact of this point of law is not isolated to the present case but is clearly relevant to a number of similar cases.

However, the case law of the boards of appeal consistently provides that when deciding whether to refer such questions a board should consider whether the board itself can answer the questions by reference to the EPC in such a way as to leave the board in no doubt as to the correctness of its answer. If this is

the case, then the board should not refer the questions (J 5/81, OJ EPO 1982, 153). This approach was confirmed in decision G 1/12 (Reasons, 10) in which the Enlarged Board held that the ground "*point of law of fundamental importance*" for referring a question requires that a board considers that the question cannot be answered directly and unambiguously by reference to the EPC.

In the present case, the questions can be answered directly and unambiguously by reference to the EPC in such a way as to leave the Board in no doubt as to the correctness of its answer.

The Board, therefore, holds that the referral of the appellant's questions to the Enlarged Board of Appeal is not necessary.

Order

For these reasons it is decided that:

The request for referral of questions to the Enlarged Board of Appeal is refused.

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Assi

Decision electronically authenticated