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Datasheet for the decision of 27 September 2012

Case Number: T 1914/11 - 3.3.02

Application Number: 02793665.7

Publication Number: 1458388

IPC: A61K 31/465, A61P 25/34

Language of the proceedings: EN

Title of invention:
A liquid pharmaceutical formulation comprising nicotine for the administration to the oral cavity

Patentee:
McNeil AB

Opponent:
NicoNovum AB

Headword:
Liquid formulation of nicotine/MCNEIL

Relevant legal provisions:
EPC Art. 83

Keyword:
"Sufficiency of disclosure (no): no reliable and reproducible way of measurement of the essential technical effect"

Decisions cited:
-

Catchword:
-

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Case Number: T 1914/11 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 27 September 2012

Appellant: (Patent Proprietor)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 7 July 2011 revoking European patent No. 1458388 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: D. Boulois
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 458 388 based on application No. 02 793 665.7 was granted on the basis of a set of 29 claims. Independent claim 1 read as follows:

"1. A liquid pharmaceutical formulation comprising nicotine, characterized in that the nicotine is present as nicotine base, in that it is for administration to the oral cavity by spraying, dropping or pipetting, preferably by spraying, most preferably by spraying under the tongue, in that it is alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by 0.3 to 4 pH units."

II. An opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for lack of disclosure.

III. The documents cited during the opposition and appeal proceedings included the following:

(2) Experimental Report A by Prof. Jette Jacobsen, 10 and 22 September 2009
(3) Experimental Report B by Prof. Jette Jacobsen, 25 March, 17 April and 13 May 2009
(36) Experimental Report C by Prof. Jette Jacobsen, 16 March, 2011
(51) In House Study, pH measurement, Zonnic Nicotine mouth spray, 25 June, 2009

(52) Study Report - pH measurement, Sublingual Spray 17.5 mg/ml pH 9.0, Mc Neil R&D, 23 August, 2012
(53) Declaration of Dr Siekmann in respect of European patent 1 458 388 B1

IV. In the decision pronounced at the oral proceedings on 9 June 2011, the patent was revoked (Article 101(3)(b) EPC) for extension of the subject-matter beyond the content of the application as filed for the main request filed during oral proceedings, and insufficiency of disclosure for auxiliary request 1 filed during oral proceedings and auxiliary requests 2 to 4 submitted with the letter of 8 April 2011 as auxiliary requests 1 to 3.

As regards auxiliary request 1 filed at the oral proceedings before the opposition division, the opposition division held that it did not meet the requirements of Article 83 EPC since the request failed to disclose a method of measurement of the pH of the oral cavity. In claim 1, the feature "*in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH unit*" was seen as a key feature. The patent specification did not disclose any method of measurement of the pH, which left the skilled person without teaching about how to do it.
The location of measurement, which led to different results as shown by document (36), was not sufficiently disclosed in the description and the claims of the patent in suit. Nor was the timing of measurement and the number of subjects on whom to perform the measurement.

As no guidance was given to the person skilled in the art as how and where to measure the pH, the disclosure of the patent was not sufficient to measure consistent values.

The opposition division considered that auxiliary requests 2-4 did not fulfil the requirements of Article 83 EPC, since they all shared the same feature "*in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH unit*" in claim 1. The reasons given for auxiliary request 1 therefore applied mutatis mutandis.

Furthermore, the opposition division did not admit auxiliary request 5 filed during oral proceedings, since it seemed *prima facie* to raise new problems under Articles 84 and 123(2) EPC.

V. The patentee (appellant) filed an appeal against this decision.

VI. With a letter dated 19 September 2011, the City Court of Stockholm requested accelerated processing before the board of appeal.

VII. With a letter dated 16 November 2011 the appellant filed a new main request and auxiliary requests 1 to 6. Arguments regarding sufficiency of disclosure were also attached.

VIII. The opponent (respondent) filed a letter dated 19 January 2012 as a reply to the appellant's grounds of appeal. The respondent submitted a new document (51)

and arguments regarding admissibility, sufficiency of disclosure, novelty and inventive step of the requests.

IX. A board's communication pursuant to Article 15(1) RPBA dated 28 March 2012 was sent to the parties as an annex to the summons to oral proceedings.
In said communication, the board expressed the necessity to discuss during oral proceedings the admissibility of the main request in the light of Article 12(4) RPBA.
The board gave its preliminary opinion regarding the requirements of sufficiency of auxiliary request 1 and concluded that the skilled person lacked guidance as to how to repeat the invention.
The conclusions drawn for auxiliary request 1 applied to all remaining auxiliary requests.

X. The appellant (patentee) filed with the letter dated 24 August 2012 a new main request and auxiliary requests I-III replacing the requests on file.

The independent claims in those requests read as follows:

(a) Main request:
"1. A liquid pharmaceutical formulation comprising nicotine, characterized in that the nicotine is present as nicotine base, in that it is for administration to the oral cavity by spraying, dropping or pipetting, preferably by spraying, most preferably by spraying under the tongue, in that it is alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by

0.3 to 4 pH units, and in that it includes a physiologically acceptable buffering substance for alkalizing the formulation."

(b) Auxiliary request I:

"1. A liquid pharmaceutical formulation comprising nicotine, characterized in that the nicotine is present as nicotine base, in that it is for administration to the oral cavity by spraying, in that it is alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by 0.3 to 4 pH units, and in that it includes a physiologically acceptable buffering substance for alkalizing the formulation,
wherein the amount of nicotine base delivered at each incidence of administration is about 0.25-6 mg."

(c) Auxiliary requests II and III:

"1. A liquid pharmaceutical formulation for treatment of addiction to tobacco comprising nicotine, characterized in that the nicotine is present as nicotine base, in that it is for administration to the oral cavity by spraying, in that it is alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by 0.3 to 4 pH units, and in that it includes a physiologically acceptable buffering substance for alkalizing the formulation,
wherein the amount of nicotine base delivered at each incidence of administration is about 0.25-6 mg."

XI. The respondent (opponent) responded with a letter dated 11 September 2012 enclosing a new document.

XII. Oral proceedings took place on 27 September 2012.

XIII. The appellant-patentee's arguments can be summarised as follows:

As regards the decision of the opposition division, its reasoning shows that the present case is a matter of Article 84 EPC and not of disclosure under Article 83 EPC. The entire evidence submitted indeed concern the scope of the claims, not the disclosure under Article 83 EPC.

As regards sufficiency of disclosure, the description of the specification included a test performed on 50 subjects (see page 26, Fig. 1 ; example 4). Extensive evidence regarding the disclosure had thus been provided, in particular regarding a rapid uptake of nicotine.

Moreover, document (36), which did not relate to an attempt of showing a rapid uptake, showed nevertheless that the compositions of example 1 of the present invention achieved a transient increase of pH of the saliva of 1.1 units (see Experiment 1).

Document (52) had also been filed to show that the examples show a transient pH increase, as demonstrated in example 4.

The skilled person was also in a position to implement the teaching of the description of the specification. There was no undue burden, it was just a matter of trial and testing. His task was a simple routine of trial and error concerning the amount of compounds to be used for the invention. On the other hand,

measurement of the pH was a simple high school chemistry testing measurement. A pH increase of the saliva guaranteed a rapid plasma uptake of nicotine, whatever method of determination of the pH was used. It would only be possible to get a false negative result, which would be to the detriment of the patentee but to the benefit of the public. The opponent had failed to demonstrate that any composition falling under the scope of the claims, would not involve a pH increase and realise a rapid plasma uptake.
As regards a possible variability between individuals, it was clear that some people might be non-responsive, which however did not disqualify the medicament. The skilled person did take a reasonable panel of patients to reproduce the measurements. The functional feature of claim 1 provided a fair balance, and was necessary to the patentee to set a protection. The amount of experimentation remained within reasonable bounds, but the invention works and the disclosure is sufficient. The skilled person is in position to choose the dose of nicotine, the amount of liquid to administer, such as 200 µl as shown in the description of the specification (par. [0036]), and would be able to adapt the formulation for administration to the oral cavity by spraying to get the specific effect.

As regards auxiliary request I, the appellant argued that the restriction to a dosage of nicotine and administration by spraying would imply a further limitation of the volume to be administered, and this reduced the experimentation needed to repeat the invention. Furthermore, in document (36) the opponent did not administer the formulation by spraying but by pipetting.

As regards auxiliary requests II and III, the reformulation of a claim in a product-for-use format according to the medical format imposed a more limited scope. The feature of administration by spraying provided a less localised administration of nicotine, and rather a broad administration into the mouth.

XIV. The respondent-opponent's arguments can be summarised as follows:

The ambiguity in the claims was significant on the key functional feature, and had to be seen as a problem of insufficient disclosure and not of clarity.
A rapid increase of the plasma uptake with alkaline formulations was known at the filing date, and could therefore not constitute a contribution over the art, but was simple common general knowledge.
The patent description was silent on how to make formulations according to the invention, and the claims covered a great number of formulations, but the teaching was thin in comparison.
Moreover, the description did not provide any method of calculation of the transient increase of the pH of the saliva. The pH of the saliva was an unusual variable parameter.
As regards the examples, the transient pH increase was not measured for any of them, and the subsequently filed experimentation would not help the skilled person to carry out the invention at the filing date.
The trial and error approach was bound to fail, since a formulation had to be tested. The ambiguity of the pH measurement was an obstacle. Document (36) showed that

the site at which the pH was measured is decisive and might provide different results.
As regards document (53) (declaration of Dr Siekmann), the respondent disagreed with the statement that the pH of the liquid of the oral cavity could be measured without difficulty. Indeed the result would have been different according to the method of measurement.

As regards auxiliary request I, the respondent could not see any difference related to the dose of nicotine and the administration by spraying, with respect to the transient increase of pH in the oral cavity and the way to measure it. The skilled person still faced the same problems.

As regards auxiliary requests II and III, the respondent argued that that there was no evidence that pippetting would provide another effect than spraying.

XV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained according to the main request or alternatively, to one of auxiliary requests I to III, submitted with letter dated 24 August 2012.

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

Reasons for the decision

1. The appeal is admissible.

2. Main request - Article 83 EPC

Article 83 EPC stipulates that the European patent application must disclose the invention in a manner sufficiently clear and **complete** for it to be carried out by a person skilled in the art.

In particular, the requirements of Article 83 EPC are met if:

(a) at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention, **and**

(b) this disclosure allows the invention to be performed in the **whole area claimed** without undue burden, applying common general knowledge.

2.1 Claim 1 of the main request refers to a product, namely a liquid formulation of nicotine base and a buffering substance, ***"alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units"***.

The feature "*alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units*" is a functional feature defining a technical result achieved on the patient, i.e. *in vivo*. This feature and the technical result involved is a key element of the claimed invention. The increase of the pH of the saliva promotes a rapid trans-mucosal uptake

of nicotine in the oral cavity, in order to satisfy the craving that certain users of tobacco experience (par. [0025], [0028] [0043]- [0045]).

The question to be answered is whether or not the skilled person would have been taught by the patent specification or would have known by applying common general knowledge which alkalised liquid formulations comprising nicotine base and a buffering substance were able to transiently increase the pH of the liquid of the oral cavity of a subject by about 0.3 to about 4 pH units.

Sufficiency of disclosure might be questionable if specific values of a technical effect were formulated in a patent as essential to the invention but **no method of measuring that effect in a reliable and reproducible way was either known in the art or disclosed in the patent.**

When the solution to a technical problem is expressed in the form of an effect on a patient, as in present case, the patentee has the duty not only to give sufficient technical guidance for the preparation of compositions achieving the effect but also to define the said effect in the description in such a way that the skilled person can reproduce and measure it reliably for the whole scope of the claims, without undue burden or experimentation. The method of determining such technical effect on a patient must be described with due care, to avoid uncertainties and guesswork.
Indeed, it would not be satisfactory to say that any composition that does not fulfil the required

properties falls outside the scope of the claims without presenting, at the same time, clear guidance on how to reproduce and measure the effect reliably and to arrive at compositions that comply with the claimed requirements.

Additionally, in the absence of a standard method of measurement either known in the art or disclosed in the patent, if it turns out that, for a given formulation, the specific values of a technical effect show unpredictable variations or fluctuations depending on factors independent of the formulation, the skilled person would not be in a position to carry out the invention over the whole range claimed. A given formulation is not sufficiently characterised and disclosed if it is defined by an effect the realisation of which within the claimed range depends on variable factors which are external to the formulations, and fall sometimes within, sometimes outside the claimed range depending on the methodology chosen by the skilled person. The skilled person would not be able to ascertain that this given formulation has achieved or not the technical effect.

2.2 In the present case, the description gives 8 examples, namely examples 1 and 4-10, examples 2 and 3 being comparative examples and example 11 dealing with the determination of buffer capacities.

While an effect on the pH of the oral cavity has not been measured for any of the examples, the data provided by Figure 2 of the specification indicate that the compositions of example 1 show a rapid plasma uptake of nicotine. A relationship between a transient

increase of the pH of saliva and a rapid plasma uptake has however not been demonstrated for example 1, or for any other example of the description as originally filed.

The description does not give any further teaching than the claimed effect as such, except that "*the amount of buffering agent or agents in the liquid pharmaceutical formulation is sufficient in the specific embodiments to raise the pH of the saliva to above 7*" (par. [0051]).

In particular, the description is silent on the amount of buffering agent needed to achieve a liquid formulation "*alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units*".

Apart from the specific embodiments of the description, the skilled person is not taught any alternative way of preparing liquid formulations according to the invention, or given any instructions on the quantities of the compounds to use to achieve the claimed effect.

2.3 The skilled person wishing to repeat the invention therefore has no other choice than to prepare a composition and test the corresponding pH variation of the liquid of the oral cavity in a patient.

The disclosure of the patent is however silent on the procedure for measuring the pH of the liquid of the oral cavity. There is also no standardised or unique

test known from common general knowledge for such measurement. All the tests used by the parties were post-filed:
- in document (52), cited by the appellant, the subjects were instructed to expectorate all saliva, and the pH was measured immediately after expectoration by means of a pH electrode,
- in document (36), cited by the respondent, the pH of the saliva was measured at different locations, i.e. on the dorsal middle tongue, on the floor of the mouth and in whole expectorated saliva, by a pH electrode,
- in document (51), cited by the respondent, but used by the appellant in national infringement proceedings, the pH was measured by a pH indicator strip on the tongue of the subjects,
- in documents (2) and (3), cited by the respondent, and discussed by the parties in the written proceedings, the pH was measured *in vivo* by pH strips and pH paper, or on whole saliva by electrode.

In all the post-filed tests, the method of measurement is different. The skilled person therefore faces a choice among multiple possible methods and tests to measure the pH of saliva and lacks standardised technical guidance for reproducing and measuring reliably the claimed effect for the whole scope of the claims.

2.4 The question remains whether the claimed technical effect is a variable depending mainly on the formulation or if external variables influence the reproducibility of the results.
A technical effect must be measured using a standardised and reproducible method, and must provide

results presenting an acceptable and computable variability. There is bound to be some variability in the technical effect, but it should not compromise the reproducibility and reliability of the measurements.

It appears however that the values of the initial and the transient pH increase vary significantly depending on the patient and the location and method of measurement.
Indeed, the initial pH value of the saliva is variable depending on the patient, as shown for instance by document (52). In the patient sample chosen in document (52), the individual initial pH value of the saliva varies between 6.38 an 7.36 (see Table 1).
Furthermore, document (36) shows in its Experiment 2 (see Table 5 or Figure 2) that a given formulation, namely the formulation of example 1 of the patent specification, provides a transient pH variation falling outside or inside the claimed effect, depending on where the pH is measured in the oral cavity.
Document (36) shows that the mean transient pH increase caused by the formulation of example 1 of the patent in suit may be 0.22 in one experiment and 0.59 in another, depending on the location of measurement.
The transient pH increase may also be dependent on the dose the patient delivers to his mouth, and not only on the concentration of the buffering agent or of any compound acting on the pH of the saliva in the composition. Nothing hinders the skilled person from administering a greater dose of the liquid formulation to the mouth. The delivery of a greater amount of the formulation to the mouth will obviously give rise to a greater variation in the pH of the saliva.

Consequently, the claimed effect depends on the patient, the method of measurement and the quantities delivered, all these variables being independent of the formulation. Given this inter- and intra-variability, the measurement of the pH of saliva does not appear to be a reliable and reproducible parameter for defining the formulation of the invention.

2.5 Thus, the disclosure does not allow the claimed technical effect to be performed in the **whole area claimed** without undue burden, applying common general knowledge. The description and common general knowledge do not teach the skilled person any reliable and reproducible method for measuring the claimed transient increase of the pH of the liquid of oral cavity and consequently for preparing formulations according to the invention. Nor does this technical effect appear to be reliable enough to define a product.
Consequently, the main request does not meet the requirements of Article 83 EPC.

2.6 Additional arguments of the appellant

2.6.1 The appellant argued that the promise of the invention is a rapid uptake of nicotine, rather than a transient increase of the pH of the liquid of the oral cavity. This rapid uptake is illustrated by figure 2 of the specification in respect of the formulation of example 1. Moreover, document (52) shows a transient pH increase after sublingual administration of the liquid formulation of example 4 of the specification. As a consequence, it is clear that the requirements of sufficiency of disclosure are met.

This argument cannot succeed because both effects, namely a rapid uptake of nicotine and a transient increase of the pH of the liquid of the oral cavity, are closely inter-connected. It is not sufficient to show a rapid uptake of nicotine, it is also necessary to show the transient increase of the pH of saliva.

The board agrees with the appellant that the essence of the invention is the provision of means and methods to satisfy the craving that certain users of tobacco experience (see specification, par. [0025] and [0028]). This effect is achieved through the rapid absorption of nicotine from the oral cavity into the systemic circulation. In order to promote absorption of nicotine the pH of the saliva must be increased (see specification par. [0043]-[0045]). Thus, a liquid formulation is alkalised in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units (see par. [0050] and [0051]).

It is therefore not sufficient to show a rapid plasma uptake of nicotine; it is also necessary to demonstrate that this uptake is linked with a trans-mucosal absorption of nicotine, i.e. a transient increase of the pH of the liquid of the oral cavity. This is indeed the necessary preliminary step to the rapid nicotine uptake of the present invention. The transient pH increase cannot be dissociated from a rapid trans-mucosal uptake in the buccal cavity.

The board notes also that the description does not provide any other method for providing a rapid uptake

of nicotine than the manufacture of alkalised liquid formulations able to provide a transient pH increase of the saliva. Taking as the promise of the invention a rapid uptake of nicotine independently from a transient pH increase of the saliva would involve other mechanisms of absorption that are not taught by the description of the patent in suit.

As regards the teaching of document (52), the provision of this post-filed evidence (52) may be taken into account, but not to establish sufficiency of disclosure on its own. Under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application as such must disclose a complete teaching showing the suitability of the product to be manufactured for the claimed essential technical effect on the patient.
Document (52) uses a specific protocol and methodology which represented one choice among multiple possible protocols and methodologies. There is nothing in document (52) which shows the existence of a standardised method or that the skilled person would inevitably have chosen this particular protocol and methodology of measurement.

2.6.2 The appellant also argued that the decision of the opposition division and the facts and evidence submitted by the respondent concern the scope of the claims, and not the disclosure, and should be a matter of clarity under Article 84 EPC. The feature *"alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units"* is a key

technical feature, serving to delimit any other liquid formulation from the patent in suit. Any element of ambiguity in this technical feature would be a matter of clarity under Article 84 EPC and not of disclosure under Article 83 EPC.

The board could not follow this line of argumentation either. It is not contested that the feature present in claim 1 and defining a technical result, namely *"alkalized by buffering and/or pH regulation in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units"*, presents an ambiguity contrary to the requirements of Article 84 EPC. However, the skilled person must be in a position to reproduce the invention and to prepare a formulation according to the invention in a clear and complete manner for the whole scope of the claims.

Moreover, the board cannot follow the argumentation that the lack of sufficiency only affects the edges of the invention. In the light of the teaching of the description, it is not possible for the skilled person to know whether or not a given alkalised liquid formulation comprising a nicotine base and a buffering substance would inherently provide a transient pH increase "*in such a way that upon administration to a subject the pH of the liquid of the oral cavity of the subject is transiently increased by about 0.3 to about 4 pH units*".

Accordingly, the question at stake in the present case is not the question of the boundaries of the claimed subject-matter, but whether the lack of indications in the description and in claim 1 in respect to the core

of the claimed invention does not amount to an undue burden for the skilled person trying to reproduce the invention. In the absence of any test method and further teaching regarding the formulation, the problem the skilled person faces is not only a lack of mathematical precision but also a real burden to realise and reproduce an invention in the meaning of Article 83 EPC.

2.6.3 According to the appellant, any composition which increases the pH as claimed will work, whatever method of pH determination is used.

The board could not follow this argument, as it was contradicted by the experimental results shown in document (36), which demonstrated the dependency of the results on the method and location of measurement of the pH of the saliva. A given composition may alternatively increase the pH as claimed or not, independently of the formulation. Such a formulation may be seen alternatively as a false positive or a false negative.

3. Auxiliary request I

3.1 Auxiliary request I differs from the main request mainly in that claim 1 has been amended by the introduction of the feature "*wherein the amount of nicotine base delivered at each incidence of administration is about 0.25-6 mg*" and by a restriction regarding the way of administration, namely "*in that it is for administration to the oral cavity by spraying*".

None of the amendments made to the subject-matter of claim 1 affects the above argumentation regarding insufficiency.
Indeed, the amount of nicotine delivered per incidence or administration of the formulation by spraying does not provide any further teaching regarding the amount of buffering agent delivered, nor does it affect the buffering capacity of the liquid formulation, since the nicotine base has too weak a buffering capacity on its own, as shown by example 11 of the specification.

As a consequence, the reasoning set out in point 2 above applies mutatis mutandis to the invention defined in auxiliary request I. The requirements of Article 83 EPC are therefore not met.

3.2 The appellant held that the features regarding the amount of nicotine to be delivered would reduce the experimentation required and the feature regarding the specific way of administration limits the volume to be administered. Moreover, the teaching of document (36) related to administration by pipetting and should therefore no longer be taken in consideration.

This argumentation cannot be followed, since both features were present in the description of the specification and their incorporation into the claims does not remedy the lack of disclosure discussed above. These features do not give further information regarding the method of measurement of the pH of the oral cavity and the quantity of buffering agent to be delivered.

Administration by spraying the oral cavity instead of pipetting does not disqualify the teaching of document (36) because whatever method of administration is chosen the measurement gives variable results according to the location of measurement.

4. Auxiliary request II

Auxiliary request II differs from the main request mainly in that claim 1 is in the form of a product-for-use as defined by Article 54(5) EPC, i.e. restricted to a medical use, namely "*for treatment of addiction to tobacco*", and has been further amended by the introduction of the feature "*wherein the amount of nicotine base delivered at each incidence of administration is about 0.25-6 mg*" and by a restriction regarding the way of administration, namely "*in that it is for administration to the oral cavity by spraying*".

As discussed above for auxiliary request I, none of the amendments made to the subject-matter of claim 1 affects the above argumentation regarding insufficiency.

The requirements of Article 83 EPC are therefore not met.

5. Auxiliary request III

Auxiliary request III differs from auxiliary request II in that all dependent claims have been deleted. Since claim 1 of auxiliary request III is identical to claim 1 of auxiliary request II, the conclusions reached previously apply *mutatis mutandis*.

Consequently, the requirements of Article 83 EPC are not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald