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Datasheet for the decision of 30 September 2014

Case Number: T 0877/11 - 3.3.07

Application Number: 99946722.8

Publication Number: 1107730

IPC: A61K9/00, A61K31/465

Language of the proceedings: EN

Title of invention:
MEDICATED CHEWING GUM DELIVERY SYSTEM FOR NICOTINE

Patent Proprietor:
JSR NTI LLC

Opponent:
Fertin Pharma A/S

Headword:
MEDICATED CHEWING GUM DELIVERY SYSTEM FOR NICOTINE/JSR NTI LLC

Relevant legal provisions:
RPBA Art. 12
EPC Art. 54(2), 111(1), 104

Keyword:
Admissibility of documents (yes)
Novelty - (no)
Remittal to the department of first instance - (yes)
Apportionment of costs - (no)

Decisions cited:
G 0001/92

Catchword:

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Case Number: T 0877/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 30 September 2014

Appellant: (Opponent)	Fertin Pharma A/S Industrivej 8 DK - 7120 Vejle (DK)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Patent Proprietor)	JSR NTI LLC 3 Bethesda Metro Center Suite 1400 Bethesda MD 20814 (US)
Representative:	Paul, Dieter-Alfred Paul & Albrecht Patentanwaltssozietät Hellersbergstrasse 18 41460 Neuss (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 February 2011 concerning maintenance of the European Patent No. 1107730 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Boulois
	D. T. Keeling

Summary of Facts and Submissions

I. European patent No. 1 107 730 B1 based on application No. 99 946 722.8 was granted on the basis of a set of 32 claims.

Independent claim 1 read as follows:
"1. A composition for systemic, oral administration of nicotine, said composition comprising:
a) a chewable base material;
b) nicotine, and
c)a buffer system,
wherein upon oral administration and onset of mastication said buffer and nicotine are released and the nicotine is adsorbed, characterized in that upon oral administration and onset of mastication said nicotine is released in a bi-phasic manner comprising an initial rapid release lasting about three to five minutes or less in which at least 15% of the nicotine is released and a succeeding slower release phase."

II. An opposition was filed against the granted patent. The patent was opposed under Article 100(a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, the patent was not sufficiently disclosed and its subject-matter extended beyond the content of the application.

III. The documents cited during the opposition proceedings included the following:
(9): Nicorette Database entry from www.biam.fr
(10): EP 0 344 267 B1
(11): Nicorette product information (Nov. 1992)
(12): "M.A.H. Russel, M. Raw and M.J. Jarvis, Clinical use of nicotine chewing-gum, British Medical Journal, 1980, 1599-1602"

IV. The present appeal lies from the decision of the opposition division to maintain the patent as amended. The decision was based on two sets of claims filed as main request and auxiliary request 1 during oral proceedings of 1 December 2010.

Independent claim 1 of the main and auxiliary request 1 read as follows, difference(s) compared with claim 1 as granted shown in bold:

(a) Main request

"1. A **chewing gum** composition for systemic, oral administration of nicotine, said composition comprising:
a) a chewable **gum base matrix**;
b) nicotine, and
c)a buffer system,
wherein upon oral administration and onset of mastication said buffer and nicotine are released and the nicotine is adsorbed, characterized in that upon oral administration and onset of mastication said nicotine is released in a bi-phasic manner comprising an initial rapid release lasting about three to five minutes or less in which at least 15% of the nicotine is released and a succeeding slower release phase."

(b) Auxiliary request 1

"1. A **chewing gum** composition for systemic, oral administration of nicotine, said composition comprising:
a) a chewable **gum base matrix**;
b) nicotine, and
c)a buffer system,

wherein upon oral administration and onset of mastication said buffer and nicotine are released and the nicotine is adsorbed, characterized in that **the gum base matrix comprises at least one substantially hydrophilic polymer** and that upon oral administration and onset of mastication said nicotine is released in a bi-phasic manner comprising an initial rapid release lasting about three to five minutes or less in which at least 15% of the nicotine is released and a succeeding slower release phase."

V. According to the decision under appeal, the subject-matter of claim 1 of the main request did not meet the requirements of novelty over document (11), "Nicorette product Information, Nov. 1992". The opposition division came to the conclusion that the release rate of a chewing gum was highly dependent on the conditions of its use and was not suitable to define a composition.

As regards auxiliary request 1, the opposition division noted that the date of the last update of document (9), "Nicorette Database entry from www.biam.fr", dated 6.12.1999, after the priority date of the contested patent, and that it seemed impossible to determine which part of the document had been updated. Thus, document (9) failed to unequivocally disclose the exact composition of Nicorette chewing gum before the priority date of the contested patent, and was not novelty-destroying.

The opposition division defined document (12), "M.A.H. Russel, M. Raw and M.J. Jarvis, Clinical use of nicotine chewing-gum, British Medical Journal, 1980, 1599-1602", as the closest prior art, since it addressed the pH dependency of the absorption rate of nicotine.

The subject-matter of claim 1 of the auxiliary request

differed from the composition of document (12) in that a hydrophilic polymer is used in the gum matrix.
The influence of the gum base on the release rate was seen in the examples of the patent, in comparisons between Nicorette and compositions according to the invention, leading to the presence of an inventive step.

VI. The opponent (appellant) filed an appeal against the decision of the opposition division.
With the statement setting out the grounds of appeal the appellant-opponent submitted the following items of evidence:
(13): Chewing rate - Nicorette. Report 5471-FR-06
(14): Annual report Dandy Holding A/S 1996
(15): Annual report Dandy Holding A/S 1997
(16): Assessment report by British Medicines Control Agency, Nicotinell, May 1996
(17): Danoja
(18): Danoja NOF

VII. With a letter dated 7 December 2011, the proprietor (respondent) filed a main request and 11 auxiliary requests, namely auxiliary requests A1, A2, B1, B2, C1, C2, D1, D2, D3, D4 and D5.
It also requested a different apportionment of costs.

VIII. With a letter dated 12 April 2013, the appellant filed the index page of document (16).

IX. With a letter dated 23 April 2014, the appellant submitted new items of evidence:
(19): Experimental Report C
(20): Study report

X. With a letter dated 29 August 2014, the respondent submitted a new main request, auxiliary requests A1, A2, B1, B2, C1, C2, D1, D2, D3, D4, D5 in replacement of the equivalent requests filed with letter dated 7 December 2011.
The subject-matter of claim 1 of the main request is identical to claim 1 of auxiliary request 1 filed during oral proceedings before the opposition division of 1 December 2010.

XI. In a communication sent in preparation to oral proceedings, the Board gave its preliminary non-binding opinion.
It stated in particular, that documents (14)-(18) should be admitted into the proceedings, as well as the requests filed wit the letter dated 29 August 2014. Moreover, it appeared that these documents showed that the subject-matter of claim 1 of the main request was not novel.

XII. With a letter dated 26 September 2014, the respondent submitted auxiliary requests A1, A2, B1 and B2.
It stated that these auxiliary requests would be the only auxiliary requests.

The subject-matter of the independent claim 1 of auxiliary request A1 read as following, difference(s) compared with claim 1 of the main request or as maintained by the opposition division shown in bold:

"1. A chewing gum composition for systemic, oral administration of nicotine, said composition comprising:
a) a chewable gum base matrix;
b) nicotine, and

c)a buffer system,
wherein upon oral administration and onset of mastication said buffer and nicotine are released and the nicotine is adsorbed, characterized in that the gum base matrix comprises at least one substantially hydrophilic polymer, that upon oral administration and onset of mastication said nicotine is released in a bi-phasic manner comprising an initial rapid release lasting about three to five minutes or less in which at least 15% of the nicotine is released and a succeeding slower release phase, and **that a sufficient amount of the buffer system is present in the chewing gum composition to elevate th pH in a user's mouth to greater than 8.5 after 1 minute from the onset of mastication.**"

XIII. Oral proceedings took place on 30 September 2014.

XIV. The arguments of the appellant (opponent), as far as relevant for the present decision, may be summarized as follows:

During he oral proceedings before the opposition division, claim 1 was amended by a feature coming from the description, more particularly claim 1 as filed. The amendment could not find a basis as such in a dependent claim, since it was linked with other technical features, namely the presence of an hydrophobic polymer. The amendment made during oral proceedings constituted therefore a new fact and a shift on the debate, on which the opponent had no opportunity to react. This shift justified the filing of the new documents (14)-(18).

As regards novelty over a prior use shown by documents (14)-(18), it had to be shown when it was available and

what was contained inside, and that it was credible that the product could have been analyzed. Documents (14)-(18) formed a chain of documents published on close dates, which showed that a product called Nicotinell® was marketed in 1996.
Documents (14) and (15) showed thus that the product Nicotinell® was available in 1996, and was a commercial success on 1997.
Document (16) showed the composition of the product and documents (17) and (18) further indicated the composition of the gum bases used in the compositions disclosed in document (16). Said gums were a mixture of polyvinyl acetate and poly isobutylene, thus a mixture of an hydrophilic and a hydrophobic gum. The composition was thus identical to the composition claimed in the main request.
As regards the claimed release profile, it had to be assumed that it was met by the chewing gum Nicotinell®, since it contained the same components as the chewing gum of the contested patent. The bi-phasic release profile is in particular achieved by any nicotine chewing gum, and could not be seen as a meaningful feature. The initial rapid release was dependent on the chewing rate, and it had to be clear which test should be used to measure and at which chew rate.
As to the analysis of the composition of the product Nicotinell®, it was possible for a skilled person to perform it, especially with regards to the main components of the marketed chewing gum.

As regards a remittal to the first instance, it would not be efficient, and would benefit only the patentee.
As to the costs, the documents (14)-(18) were filed in response to the amendments made during the oral proceedings before the opposition division.

XV. The arguments of the respondent (proprietor), as far as relevant for the present decision, may be summarized as follows:

There was an obligation to cite all known documents in the opposition proceedings, and all documents (14)-(18) related to the product Nicotinell® should have been filed earlier in the proceedings. The documents were therefore late-filed and should not be admitted into the appeal proceedings.
The filing of these documents could not be seen as a response to the amendments made during the oral proceedings before the opposition division, since the amendments came from a dependent claim.

It had not been proven that the assembled pages of document (16) constituted one unique document, therefore this document could not constitute the basis for showing the composition of the product Nicotinell®. The document (16) referred in particular to the chewing gums "Nicotinell Original" and "Nicotinell Mint" , a reference which was lacking in documents (14) and (15) and not taken again in the compositions of document (16) on pages 35 and 37. The index of document (16) also showed inconsistencies with the content. Moreover, the chewing gum compositions of pages 35 and 37 of document (16) did not correspond to said "Nicotinell Original" and "Nicotinell Mint", since referring to a "Tutti sweet chewing gum" and a "Mint Chewing Gum". Moreover, a large part of document (16), as well as of documents (17) and (18) was blacked out and the documents were confidential.
As regards the claimed release profile, it was not proven in any cited document that the product Nicotinell® could achieve the same release profile. The combination of the buffer and the specific gum base was

responsible of said release and nothing showed in document (16) that the buffer and gum used therein could have provided the same release profile. Moreover, it was clear from the examples of the contested patent that the chew rate was 10 to 20 chews per minute. Moreover, in 1996, 1997 it was not possible for a skilled person to perform an analysis of a complex product such as Nicotinell® and to determine its composition.

Finally, document (16) did not prove that said product Nicotinell® was on the market, since the cited passages of the documents does not specify if the authorization was given.

Finally, the case should be remitted to the first instance on the basis of auxiliary request A1 and a different apportionment of costs should be decided, in view of the late-filing of documents (14)-(18).

XVI. Requests

The appellant (opponent) requested that the decision under appeal be set aside and that European Patent No. 1107730 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed (Main Request) or, in the alternative, that the decision under appeal be set aside and the patent maintained in accordance with one of the Auxiliary Requests (A1, A2, B1 and B2) filed with letter of 24 September 2014.
Furthermore, the respondent (patent proprietor) requested a decision apportioning the costs pursuant to Article 104 EPC.

Reasons for the Decision

1. Admission of documents (14)-(18) into the proceedings

These documents were filed at the earliest stage of the appeal proceedings, namely with the the statement setting out the grounds of appeal by the appellant.

All the documents (14)-(18) refer to a commercial product, namely the chewing gum Nicotinell®, and to some of its components. The composition of Nicotinell® appears to be *prima facie* relevant for the assessment of novelty in relation to the main request.

Despite the fact that the product Nicotinell® was known to the appellant and that documents (14)-(18) could therefore have been filed earlier in the opposition proceedings, since Nicotinell® is one of its own commercial products, the filing of these documents is a reaction to the filing of the amended set of claims of auxiliary request 1 during the oral proceedings before the opposition division. The term "*the gum matrix comprises at least one substantially hydrophilic polymer*" in claim 1 of auxiliary request 1 was indeed introduced for the first time during oral proceedings before the opposition division and did not have any basis in the granted claims in this isolated form.
The term was introduced to overcome the lack of novelty over the product Nicorette® which was cited by the opponent with the statements of grounds of opposition, and was thus known to the proprietor. The filing of this amended set of claims during oral proceedings constituted a surprise for the opponent.

Consequently, documents (14)-(18) are admitted into the proceedings.

2. Main request -Novelty

Documents (14)-(18) were submitted to demonstrate the existence before the priority date of the contested patent of a product called Nicotinell® which encompasses all characteristics of the claimed product.

2.1 Documents (14) and (15) are extracts of the annual reports of 1996 and 1997 of the holding company to which the appellant belonged at this time. They refer to its commercial product Nicotinell®. Document (14) states in particular that the product Nicotinell® was launched in 1996. These documents thus establish unambiguously the existence of the product Nicotinell® before the priority date of the contested patent. These documents are written in Danish, which is a non-official language of the EPO, but their content has not been contested by the respondent.

2.2 Document (16) is a selection of pages from an assessment report dated May 1996 and prepared by the British Medicines Control Agency on the aforementioned product Nicotinell® for the mutual recognition procedure by several other European countries. The report deals with the products Nicotinell® Original and Nicotinell® Mint as manufactured by the appellant and specifies that said chewing compositions comprise nicotine, calcium carbonate and the gum bases Danoja and Danoja NOF (see pages 35 and 37).
Documents (17) and (18) further indicate that said gum bases Danoja and Danoja NOF comprise polyvinyl acetate and polyisobutylene, namely a blend of an hydrophilic and an hydrophobic polymer.

These documents establish unambiguously a link with the commercial product identified in documents (14) and (15), and that said product Nicotinell® comprised nicotine, a buffer system, and the same gum base matrix with at least one substantially hydrophilic polymer.

The Board could not accept the arguments of the appellant regarding the existence of an inconsistency in document (16) between its content and what is given on the index page.
Its content is indeed totally coherent with the index. In particular, the introduction on page 3 mentions that the "Original" chewing gum comprised the tutti flavour, and the "Mint" chewing gum comprised menthol, peppermint and eucalyptus, which corresponds exactly to the compositions of the tutti sweet chewing gum of page 35 and of the mint chewing gum of page 37.
The presence of further blackened text does not affect the relevance of the document.

2.3 As to the feature characterizing the release of nicotine from the chewing gum in claim 1, namely "*that upon oral administration and onset of mastication said nicotine is released in a bi-phasic manner comprising an initial rapid release lasting about three to five minutes or less in which at least 15% of the nicotine is released and a succeeding slower release phase*", this term represents a functional feature defining the composition. However, the description of the contested patent shows that the release of nicotine depends not only on said composition but is also chewer-responsive, since it is at least partially governed by the chew rate (see par. [0019], lines 29-32, par. [0059], lines 54-57 and par. [0060], lines 19-26).
Given that the subject-matter of claim 1 of the main request relates to a product, this leads to the

conclusion that such a functional feature not only lacks sufficient clarity but also cannot be seen as a distinguishing and restrictive feature over the product Nicotinell® which contains the same components, namely a buffer and of a gum base matrix comprising at least one substantially hydrophilic polymer.
In any case, since it was the choice of the respondent to define its invention by reference to an unclear functional feature, the onus is on the respondent to demonstrate in a credible and exhaustive manner that the prior art formulations are unable to fulfill this release requirement.

2.4 As to the composition of the product Nicotinell®, the chemical composition of a product belongs to the state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition (see G 01/92).
As to the feasibility of the analysis of a product such as Nicotinell Mint or Original in 1996, it is not credible to call it in question, given the technical means available at that date. A detailed and precise analysis regarding the composition of the chewing gum Nicotinell® could indeed be carried out without difficulty in order to determine at least the main components of the chewing gum.

2.5 Since the product Nicotinell® on the market in 1996 comprised all feature of claim 1 of the main request, this request does not meet the requirements of novelty.

3. Auxiliary request A1 - Remittal to first instance

3.1 The subject-matter of claim 1 of auxiliary request A1 has been amended by the addition of the feature **"that a sufficient amount of the buffer system is present in the chewing gum composition to elevate th pH in a user's mouth to greater than 8.5 after 1 minute from the onset of mastication".**
This feature has been added to restore novelty over the product Nicotinell®, featured in documents (14)-(18) (see point 2.1 above), which was presented for the first time during the appeal proceedings, though being a product marketed by the appellant.
The discussion on this unexamined feature constitutes a shift to a fresh case and presents a particular complexity with regard to the requirements of novelty, inventive step, clarity and sufficiency of disclosure of the subject-matter of claim 1 of auxiliary request A1.

3.2 Although Article 111(1) EPC does not guarantee an absolute right to have all the issues of the case considered by two instances, it is well recognised that any party should, whenever possible, be given the opportunity to have the important elements of the case considered by two instances. The essential function of an appeal in inter partes proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and

leaves other essential issues outstanding. In this situation, the case should normally be remitted to the first instance department for consideration of the undecided or fresh issues.

In view of the submission of new facts, namely regarding the product Nicotinell® and the consequent reversal of the decision of the opposition division as regards novelty, the subject-matter of claim 1 of auxiliary request A1 constitutes a fresh case. Moreover, the subject-matter of claim 1 comprises an unexamined feature, namely **"that a sufficient amount of the buffer system is present in the chewing gum composition to elevate th pH in a user's mouth to greater than 8.5 after 1 minute from the onset of mastication"**.
These issues must be considered as essential substantive issues in the present case.

4. Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, the case is to be remitted to the Opposition Division for further prosecution on the basis of auxiliary request A1.

4.1 Apportionment of the costs

The respondents requested a decision regarding the apportionment of costs.

It is true that the evidence regarding the product Nicotinell® was filed for the first time by the appellant in the appeal proceedings, even though that product has been marketed and therefore known to the appellant since 1996. It is thus true that the Board's

decision to remit the case to the first instance is due in part to the filing of this new evidence.
This evidence was, however, itself filed in response to an amendment of the claims submitted for the first time during the oral proceedings before the opposition division by the respondent.
Consequently, the responsibility as regards the Board's decision to remit the case to the first instance is shared by the appellant and the respondent.

Therefore, the Board does not consider an apportionment of costs in favour of the respondent to be justified in this case.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.
3. The request for apportionment of the costs is refused.

The Registrar: The Chairman:

N. Schneider J. Riolo

Decision electronically authenticated