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Datasheet for the decision of 14 September 2010

Case Number: T 1151/07 - 3.3.02

Application Number: 00902958.8

Publication Number: 1153616

IPC: A61K 47/36

Language of the proceedings: EN

Title of invention:
Tablets quickly disintegrated in the oral cavity

Applicant:
Dainippon Sumitomo Pharma Co., Ltd.

Opponent:
ROQUETTE FRERES, S.A.

Headword:
Fast disintegrating tablets/DAINIPPON SUMITOMO PHARMA

Relevant legal provisions:
EPC Art. 123, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: Inventive step (no) obvious solution"
"Auxiliary requests (not allowable): unallowable generalisation from one example"

Decisions cited:
-

Catchword:
-

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Case Number: T 1151/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 14 September 2010

Appellant: (Patent Proprietor)	Dainippon Sumitomo Pharma Co., Ltd. 6-8, Dosho-machi 2-chome Chuo-ku Osaka-shi Osaka 541-8524 (JP)
Representative:	Duckworth, T. J. J.A. Kemp & Co. 14 South Square Gray's Inn London WC1R 5JJ (GB)
Respondents: (Opponent)	ROQUETTE FRERES, S.A. F-62136 Lestrem (FR)
Representative:	Boulingulez, Didier Cabinet Plasseraud 52 rue de la Victoire F-75440 Paris Cedex 09 (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 11 May 2007 revoking European patent No. 1153616 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 1 153 616, which was filed as application number 00902958.8, was granted on the basis of eight claims.

Claim 1 as granted read as follows:

"1. A tablet preparation **characterised by** its comprising a starch, a water-soluble excipient, a lubricant and a medicament and substantially not containing a binder other than starch, wherein the water-soluble excipient is at least one member selected from mannitol and lactose, and the lubricant is at least one member selected from magnesium stearate, calcium stearate, sodium stearyl fumarate and light silicic anhydride".

II. The following documents and exhibits cited during the proceedings are relevant for the present decision:

(1) US 5 679 685
(2) Pharmaceutical Bulletin-Atlas Chemical Bulletin, Inc. 2/63), pp 1-6: "Melt-in-your-mouth" chewable vitamin and antacid tablets, 1963.
(13) Handbook of Pharmaceutical Excipients, Second Edition, 1994, edited by Ainley Wade and Paul J Weller.
(14) N.H. Shah, Drug Development and industrial Pharmacy, 12(8&9), 1329-1346, 1986
(15) Arne W. Hölzer *et al*, Acta Pharm. Suec. 18, 139-148, 1981.
(16) *Pharmacopoea Japonica editio pentadecima* and its English translation.

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC (lack of novelty and inventive step).

IV. The present appeal lies from a decision of the opposition division revoking the patent under Article 102(1) EPC 1973.

The opposition division admitted into the proceedings all the documents "filed after the notice of opposition". Moreover, the opposition division considered that the subject-matter claimed in the main request (set of claims as granted) lacked novelty vis-à-vis documents (1) and (2). The opposition division further considered that the subject-matter of the first auxiliary request lacked an inventive step (Article 56 EPC).

V. The patentee filed an appeal against said decision. Moreover, it filed with its grounds of appeal a main request, an auxiliary request (as first auxiliary request) and an "experimental report" containing comparative tests.

VI. The respondent (opponent) filed with its response to the grounds of appeal counter-arguments to the patent proprietor's appeal and further documents (numbered as documents (13) to (15)).

VII. A communication expressing the board's preliminary opinion was sent to the parties as an annex to the summons for oral proceedings. In said communication the board drew the parties' attention to the fact that the copy of *Pharmacopoeia Japonica edition pentadecima*,

announced on page 4 of the experimental report filed by the patent proprietor with its grounds of appeal, had not been filed.

VIII. The appellant filed a response to the board's communication with its letter dated 12 August 2010. It filed as an annex thereto an extract from *Pharmacopoeia Japonica edition pentadecima* together with an English translation thereof (document (16)) and a further experimental report. It also filed four new auxiliary requests, auxiliary requests 2 to 5.

IX. Oral proceedings took place on 14 September 2010.

At the oral proceedings the appellant withdrew the second auxiliary request filed with the letter of 12 August 2010. Auxiliary requests 3 to 5 filed with said letter were renumbered as auxiliary requests 2 to 4 at the oral proceedings.

X. Claim 1 of the main request filed with the grounds of appeal read as follows:

"1. A tablet preparation characterized by its comprising a starch, mannitol, sodium stearyl fumarate and a medicament and substantially not containing a binder other than starch, which preparation disintegrates within one minute in the mouth".

Claim 1 of the first auxiliary request filed with the grounds of appeal read as follows:

"1. A tablet preparation characterized by its comprising a starch, mannitol, sodium stearyl fumarate

and a medicament and substantially not containing a binder other than starch, which preparation disintegrates in the mouth, wherein the preparation is obtained by a process comprising dispersing a portion of the starch in water, gelatinizing the dispersion obtained by warming, adding the gelatinized starch to a mixture comprising the remainder of the starch, the medicament and mannitol, drying the resultant mixture, mixing the sodium stearyl fumarate with the dried mixture and compressing with a rotary tablet machine".

Claim 1 of auxiliary request 2 (filed as auxiliary request 3 with the letter of 12 August 2010) read as follows:

"1. A tablet preparation characterized by its consisting of a medicament and additives consisting of (1) to (7):

(1) a starch,
(2) a D-mannitol,
(3) a disintegrator,
(4) a sodium stearyl fumarate,
(5) a high-sweetness artificial sweetener,
(6) a flavouring agent, and
(7) a light silicic anhydride,

which preparation disintegrates within one minute in the mouth".

Claim 1 of auxiliary request 3 (filed as auxiliary request 4 with the letter of 12 August 2010) read as follows:

"1. A tablet preparation characterized by its consisting of a medicament and additives consisting of (1) to (7):

(1) a starch,
(2) a D-mannitol,
(3) a low-substitution-degree hydroxypropylcellulose,
(4) a sodium stearyl fumarate,
(5) an aspartame,
(6) a flavouring agent, and
(7) a light silicic anhydride,

which preparation disintegrates within one minute in the mouth".

Claim 1 of auxiliary request 4 (filed as auxiliary request 5 with the letter of 12 August 2010) read as follows:

"1. A tablet preparation characterized by its consisting of a medicament and additives consisting of (1) to (7):

(1) a corn starch,
(2) a D-mannitol,
(3) a low-substitution-degree hydroxypropylcellulose,
(4) a sodium stearyl fumarate,
(5) an aspartame,
(6) a flavouring agent, and
(7) a light silicic anhydride,

which preparation disintegrates within one minute in the mouth and wherein the preparation is obtainable by a process comprising dispersing a portion of the corn

starch in water, gelatinizing the dispersion obtained by warming, adding the gelatinized starch to a mixture comprising the remainder of the corn starch, the medicament, D-mannitol, low-substitution-degree hydroxypropylcellulose, aspartame and light silicic anhydride drying the resultant mixture, mixing the flavouring agent and sodium stearyl fumarate with the dried mixture and compressing with a rotary tablet machine".

XI. The appellant's arguments can be summarised as follows:

The auxiliary requests 2 to 5 (they later became auxiliary requests 2 to 4, since the second auxiliary request filed with the letter of 12 August 2010 was withdrawn during the oral proceedings) were filed as a direct response to the board's communication sent as an annex to the summons for oral proceedings. Said board's communication did not tend to support the patentee's position, so further auxiliary requests were submitted. It was also the appellant's intention to respond therewith to the objections concerning inventive step. Furthermore, the test report filed with the letter of 12 August 2010 was a second test report with slightly modified method conditions. Its filing was made as a fair attempt to address the observations in the board's communication, as well as the objections the opponent had raised against the experimental report filed with the grounds of appeal.

The appellant stressed that it was familiar with the Rules of Procedure of the Boards of Appeal (RPBA) but that it had taken a certain amount of time after the receipt of the board's communication for its client to

perform the experiments. The filing had been made as soon as possible.

As regards the main request, the appellant submitted the following: It was reasonable to take document (2) as the closest prior art and the tablets on page 2, right-hand column, as the starting point for the analysis of inventive step. The definition of the problem to be solved was to provide a tablet which disintegrates more quickly in the mouth and which shows sufficient hardness. The appellant stressed the expression "tablet disintegration" as having a particular meaning which was not equivalent to "tablet dissolution". Moreover, it submitted that the allegation made by the respondent that the problem was not solved across the scope of the claim was unsupported. In its opinion, the respondent was "misconstructing" the claim, since the condition "which preparation disintegrates within one minute in the mouth" was a functional feature which delimited the claim. Although no specific amounts were listed in the claim, the skilled person was able to adjust them to achieve the goal by following the guidance given in the description. Moreover, it would have been very difficult to give amounts which would fit every definition for the individual ingredients. Additionally, the appellant submitted that it had provided comparative tests with the tablets of document (2) which showed a substantial improvement in the disintegration tests. The appellant disagreed that documents (13) to (15) showed that the proposed solution was obvious. In particular, document (15) related to the evaluation of the effects of eight lubricants in a sodium chloride test tablet. The

experimental results reported on page 143 in relation to disintegration time related among other things to Mg-St (5.6 to 7.9 minutes) and SSF (3.6-5.2 minutes). The appellant further submitted that the system tested in document (15) was very different from that claimed in the patent in suit. In particular, the tablets of document (15) did not contain mannitol and starch. Moreover, the disintegration times of the tablets tested in document (15) were not near to one minute, but close to five minutes. The appellant also stated that document (14) related to the evaluation of lubricants, but on pages 1344-1345 they were speaking about "dissolution rates" (i.e. dissolving of active ingredient in a solution) which was not the same as "disintegration time". The appellant further submitted that document (13) (paragraph 19 for SSF) only referred to improvement in tablet dissolution. The tests which were required to measure disintegration were different from those required to measure dissolution. The appellant referred to the Pharmacopoeia document (16).

In the appellant's opinion, the claimed tablet preparation was inventive since the improvement in the disintegration properties could not have been expected from the prior art.

The appellant strongly disagreed that the preparation in example 8 was not one according to the claimed invention. It further submitted that reading the patent with a fair mind showed low-substitution-degree hydroxypropylcellulose as a disintegrant and not as a binder. In particular, **low-substitution-degree** hydroxypropylcellulose was disclosed in paragraph [0006] among other conventional disintegrators, whereas

hydroxypropylcellulose was cited as a binder substantially not contained in the preparations in paragraph [0010].

The appellant also stated that the skilled person was in a position to adjust the amounts of the ingredients by routine experimentation in order to achieve one minute disintegration in the mouth. The appellant also stated that the onus of proof was on the opponent.

As regards the first auxiliary request, the appellant stated the following: claim 1 contained all features of claim 1 of the main request with the exception of the condition of disintegration in one minute in the mouth. However, that condition was not in granted claim 1, so claim 1 of the first auxiliary request did not contravene the requirements of Article 123(3) EPC. Additionally, the claim contained product-by-process-like features which were based on the preparation process in example 8. The method steps in example 8 were essentially the same as those listed in the amended claim. The skilled person would recognise that the process features in example 8 could be generalised to the preparation of the tablets according to the invention and that they were not restricted to one single experiment.

As regards the second auxiliary request, the appellant submitted that the components recited were the only components in the tablet owing to the use of the expression "consisting of". Hence, the characteristic "substantially not containing a binder other than starch" had become superfluous and had been deleted from the claim. The components listed were derived from

example 8 with the exception that the active ingredient remained defined in a generic form as "medicament". There had never been any suggestion on the other party's side that the invention had to be restricted to a particular active ingredient. The generically disclosed tablet preparations were restricted in the light of the preparation of example 8. Low-substitution-degree hydroxypropylcellulose was used as a "disintegrator".

The appellant further submitted that the term "disintegrator" was clear to the skilled person and that there was a known class of disintegrators to which the low-substitution-degree hydroxypropylcellulose belonged. Hydroxypropylcellulose listed in paragraph [0010] of the patent in suit as a binder had approximately a substitution degree of 50-70%, whereas low-substitution-degree hydroxypropylcellulose, listed in paragraph [0006] as a disintegrator had a substitution degree of 5-16%. There was a clear distinction between the two substances. All the components (1) to (7) listed in claim 1 appeared in example 8.

As regards the third auxiliary request, the appellant added that the basis for claim 1 was example 8. The amendments introduced in that claim were intended to be as close as possible to the ingredients in the preparation in example 8. It was clear from the content of the application as filed that example 8 was not to be restricted to corn starch but that it applied to any other starch.

As regards the fourth auxiliary request, the appellant submitted that the starch had been specified as corn starch and that the preparation method had also been introduced according to example 8, as a "product-by-process" feature. The expression "obtainable by" had now been used.

XII. The respondent's arguments as far as relevant for the present decision can be summarised as follows:

The respondent withdrew its objection against the admissibility of the first auxiliary request.

However, the respondent objected to the admissibility of the auxiliary requests filed with the letter of 12 August 2010 as late-filed. It also objected to the admissibility of the experimental report filed as an annex to said letter. As regards the auxiliary requests and the experimental report filed with the letter of 12 August 2010, the respondent contended that their lateness (one month before the date for the oral proceedings) was unjustified. Moreover, it referred to the RPBA (OJ EPO 2007, 536), in particular Article 12(2).

As regards the main request, the respondent submitted the following: The subject-matter claimed in claim 1 lacked an inventive step (Article 56 EPC). There was a lack of inventive step based on document (2), taken alone, or in combination with one of the documents (13), (14) or (15). Document (2) represented the closest prior art since it disclosed tablets which quickly disintegrate in the mouth. In particular, the "melt-in-your-mouth" multi-vitamin tablet (prepared by dry

granulation) disclosed on page 2 of document (2), right-hand column, was the specific starting point. Said multi-vitamin tablet contained mannitol, corn starch and magnesium stearate. Moreover, according to document (2), said multi-vitamin tablet disintegrates in the mouth in 30 seconds. The difference with the tablets claimed in claim 1 was the lubricant, namely magnesium stearate (Mg-St) instead of sodium stearyl fumarate (SSF). The problem to be solved lies in the provision of tablets which disintegrate in the mouth more quickly and at the same time have an acceptable hardness. This problem was not solved within the whole scope of the claim. Claim 1 does not contain either the absolute or relative amounts of the constituents of the tablets. Thus, the claim requires that, independently of the amounts of the components and the preparation process, the goal of disintegration in the mouth within one minute has to be achieved. The respondent stated that this way of arguing was not an attempt to introduce an objection within the meaning of Article 83 EPC, but was meant to follow the jurisprudence of the boards of appeal, and cited the decision in the "Agrevo" case (*this is in fact decision T 939/92, EPO OJ 1996, 309*).

The respondent further stated that the characteristic "which disintegrates within one minute in the mouth" in claim 1 was merely a wishful result-to-be-achieved. It was not plausible that, independently of the actual composition in relation to the relative and absolute amounts of the components, the preparation disintegrated within one minute in the mouth. Since the problem had not been solved within the whole scope claimed, there was a lack of inventive step.

Alternatively, the respondent submitted that the problem may be defined as the provision of tablets which disintegrate within one minute in the mouth and showed at the same time sufficient hardness. The proposed solution was to exchange Mg-St by SSF as lubricant. However, it was known to the skilled person from the prior art knowledge that it had to exchange Mg-St by SSF in order to shorten disintegration time.

To support its position, the respondent cited documents (15), in particular page 146, 1st paragraph under the heading "Tablet disintegration"; document (14) as a whole, the paragraph bridging pages 1344 and 1345, and the last paragraph on page 1346; and the Handbook document (13), paragraph 19, for the entry "Sodium Stearyl Fumarate". The respondent submitted that these three documents reflected the general knowledge of the skilled person and that there was a clear incentive to replace Mg-St by SSF. Thus, the solution was obvious for the skilled person.

The respondent further submitted that in the patent in suit there was no single example showing that the intended goal, i.e. disintegration in the mouth within one minute, was indeed achieved by the preparations containing SSF. The preparations for which a disintegration time of less than one minute was shown (see tests results in Table 1 on page 6 of the patent in suit) were those of examples 1, 2, 5 and 6. However, all these preparations contained Mg-St as a lubricant. The only preparation containing SSF which had been tested in the patent in suit was that of example 8. However, example 8 was not an example according to the

invention claimed, since it contained low-substitution-degree hydroxypropylcellulose in an amount of 32.4 g. Thus, in the respondent's opinion the low-substitution-degree hydroxypropylcellulose fulfilled the function of a binder in the preparation of example 8. Thus, the requirement in claim 1 "substantially not containing a binder other than starch" was not met by said preparation. No test results had been shown in the patent in suit for the preparations of the examples 4 and 7, both containing SSF as a lubricant. Thus, the alleged effect had not been shown for the scope claimed.

Moreover, the respondent also argued that if the problem to be solved was defined as the provision of tablets with a sufficient hardness and with quicker disintegration times than those containing Mg-St as a lubricant, then document (15) showed that the proposed solution was obvious.

As regards the first auxiliary request, the respondent submitted the following: The amendments introduced in claim 1 related to an unallowable generalisation of example 8 (Article 123(2) EPC). Example 8 related to a very specific tablet preparation (characterised by the presence of specific ingredients in specific amounts and proportions) and the preparation process was very specific. Some of the specific features of the process in example 8 were lacking in the amended claim. In particular, it was essential for the granulation method that the starch dispersion previously prepared and gelatinised was 1%. The fact that the granulation was made by spray-drying was also omitted in the claim.

As regards the second auxiliary request, the respondent stated that claim 1 related to an unallowable generalisation of the preparation in example 8 (Article 123(2) EPC), since there was no basis for generalising some of the ingredients in example 8 and at the same time specifying others. Example 8 was specific as to the nature of starch and as to the presence of low-substitution-degree hydroxypropylcellulose. Such specific compositions were prepared by a specific process, there was no basis for the generalisation undertaken. Only the specific preparation in example 8 was capable of being directly compressed.

Additionally, the respondent raised an objection re Article 84 EPC against claim 1 of the second auxiliary request since there was a confusion between the function "disintegrator" and "binder" for the ingredient low-substitution-degree hydroxypropylcellulose. In the respondent's opinion said ingredient in example 8 fulfilled a double function: as disintegrant and as binder. Moreover, in view of this lack of clarity about the function performed by the "disintegrator", the boundaries of the amended claim were ambiguous. Thus, the claim contravened Article 123(3) EPC in view of the deletion of the feature "substantially not containing a binder other than starch".

The respondent also stated that the description on page 6 of the application as filed referred to magnesium stearate and sodium stearyl fumarate as advantageous lubricants, but no basis could be found in the application as filed for the selection of the

combination of SSF together with light silicic anhydride as now defined in claim 1. The generalisation of this particular combination from specific example 8 into a generic claim was unallowable.

As regards the third and fourth auxiliary requests the respondent maintained *mutatis mutandis* the objections it had raised for the higher ranking auxiliary requests. Additionally, it pointed to the fact that the granulation was not mentioned in the process in claim 1 of the fourth auxiliary request (Article 123(2) EPC).

XIII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, or of the first auxiliary request both filed with the grounds of appeal, or on the basis of one of the auxiliary requests 2 to 4, filed as auxiliary requests 3 to 5 with the letter of 12 August 2010.

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

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of the auxiliary requests and the experimental report filed with the letter of 12 August 2010*

1.2.1 Article 12(2) RPBA set outs the general principle that the statement of the grounds of appeal and (in the case of *inter partes* proceedings) the reply to the other's party submissions must contain a party's complete case.

However, Article 12(1)(c) RPBA clearly states that the appeal proceedings must also be based on "any communication sent by the Board and any answer thereto filed pursuant to the directions of the Board".

The auxiliary requests filed with the letter of 12 August 2010 and the further experimental report were filed as a direct response to the board's communication sent as an annex to the summons for oral proceedings. The board has therefore decided to exercise its discretionary power to admit the auxiliary requests filed with the letter of 12 August 2010, since they represent a fair attempt to overcome the board's objections raised with the communication sent as an annex to the summons for oral proceedings.

As regards the admissibility of the further experimental report, it has to be considered that it was filed in an attempt to reply to the board's observations in relation to the method steps of the preparation process in the experimental report filed with the grounds of appeal. Since the experiments are simple (without any major variations in relation to the previous experimental report), the experimental conditions are easy to reproduce and the ingredients used are commonly available, the further experimental report filed with the letter of 12 August 2010 has also been admitted into the proceedings.

1.2.2 The respondent did not take into consideration, when it took the position that Article 12(2) RPBA precludes the appellant from filing further auxiliary requests after the reply to the respondent's submissions, that the board's communication with substantive observations was sent prior to the appellant's filing of those requests. The RPBA clearly reflect that the assessment of the admissibility of late-filed submissions lies within the board's discretionary power, after the circumstances of the case have been examined.

The respondent never argued that it had intended to reproduce the experiments filed by the appellant with the letter of 12 August 2010, and that it was hindered in doing so due to lack of time.

Additionally, the respondent did not contend that the time after the late-filing of the further auxiliary requests and the second experimental report had been too short for preparing its counter-arguments for the oral proceedings.

1.2.3 Accordingly, the auxiliary requests and experimental report filed with the letter of 12 August 2010 are admissible.

1.2.4 As regards the submission of the copy of document (16) and its English translation, this was made in accordance with the conditions set out in Article 12(2)(b) RPBA. Moreover, this document merely served to explain the disintegration test performed in the experimental reports. Thus document (16) is admissible.

2. *Main request*

2.1 The amendments introduced in claim 1 of the main request are allowable (Articles 123 and 84 EPC). The respondent did not contest the main request in this respect.

2.2 The novelty of the subject-matter claimed in the main request was not objected to by the respondent and the board sees no reason to do so either.

2.3 As regards the assessment of inventive step the board agrees with the parties and the opposition division that document (2) represents the closest prior art. In particular, document (2) discloses "melt-in-your mouth" vitamin tablets obtained by dry granulation, and containing mannitol and corn starch (right-hand column on page 2). Magnesium stearate is used as a lubricant in the specifically disclosed tablets in document (2).

The "melt-in-your-mouth" tablets in document (2) "dissolve" or "melt" in the mouth within 30 seconds by sucking (i.e. without the addition of water).

2.3.1 Furthermore, as becomes apparent from paragraph [0001] of the patent in suit, the expressions "rapid disintegrability in the mouth" and "rapid solubility in the mouth" (with little water or even without water) are used indistinctly for defining the "quick-disintegration tablet preparation" according to the "invention" in the contested patent.

2.3.2 Thus, the problem to be solved lies in the provision of tablets that have sufficient hardness and disintegrate more quickly in the mouth.

The solution defined in claim 1 of the main request lies in the choice of lubricant, namely sodium stearyl fumarate (SSF) instead of magnesium stearate (Mg-St).

2.3.3 The appellant has filed two experimental reports (the first with the grounds of appeal and the second with the letter of 12 August 2010) in order to compare the effect of the exchange of lubricant (SSF *versus* Mg-St) in the vitamin tablets of document (2).

The experimental test reports filed with the grounds of appeal and with the letter of 12 August 2010 appear to show that the improvement in the disintegration time (i.e. shorter disintegration time measured by the disintegration test disclosed in the Pharmacopoeia document (16)) achieved in the comparisons is attributable to the exchange of lubricant (SSF instead of Mg-St).

However, it has to be assessed whether the tests provided by the appellant do in fact demonstrate that the tablets according to the patent in suit disintegrate more quickly than the tablets disclosed in document (2).

The second experimental report (filed with letter of 12 August 2010) was filed by the appellant as a response to the respondent's objections to the first experimental report. The respondent had objected that the experimental report was not a valid comparison with

the tablets disclosed in document (2). The correctness of this objection was confirmed by the board in the communication sent as an annex to the summons for oral proceedings. The reasons are that the preparation method employed for the comparison did not correspond identically to the preparation method disclosed in document (2), in particular in relation to a different addition of corn starch and lubricant.

In fact, the corn starch is added in the preparation process disclosed in document (2), together with the lubricant Mg-St and talc, to the premix of the other components. Thus, a certain amount of lubricant relative to the amount of corn starch is required for an adequate mix since corn starch, talc and magnesium stearate are mixed and then added together to the rest of the granulate. This information is inferred from the disclosure in document (2) and has to do with the lubricating activity the lubricant (Mg-St, talc) is used for when preparing tablets by dry granulation and compression. Thus, document (2) teaches: "Add the corn starch, magnesium stearate and talc, mix well, and compress" (page 2, right-hand column), wherein the ingredients are in specific amounts and proportions.

The lubricant is added in a last step to the dry granulate in the method of the first experimental report (filed with the grounds of appeal) and the relative proportion of lubricant to the "dry granulated particles" (total) is comparable to that disclosed in document (2). However, the absolute amounts of the ingredients (in particular corn starch and mannitol) and the relative amount of corn starch to lubricant are not the same as those in the example in document (2).

This is not essential for an adequate mixing of all components in the preparation method of the first experimental report in view of the working steps which imply dry mixing of all components and then addition of the lubricant before compressing the tablet. However, although the appellant changed the sequential steps in the preparation method of its second experimental report (i.e. it added the corn starch together with the lubricant), it maintained the relative amount of lubricant to corn starch as that used for the dry granulate in its first experimental report. In doing so, it disregarded the fact that the relative amount of lubricant to corn starch now played an essential role for an adequate mix. Thus, the amount of lubricant (Mg-St) in the second experimental report was lower than that used in the example of document (2) in respect of the amount of corn starch employed. This is a difference which influences the mixing before the compression of the tablets and, hence, it has a bearing on the test results.

Thus, even assuming in the appellant's favour that the experimental reports have shown that the exchange of lubricant (SSF instead of Mg-St) shortens the disintegration time of the tablets, the actual magnitude of the improvement vis-à-vis the tablets disclosed in document (2) remains undetermined.

Therefore, the experimental tests submitted by the appellant serve to support the assertion that at least the technical problem defined above has been plausibly solved, but they do not prove that a "**substantive**" improvement has been achieved vis-à-vis the closest prior art tablets.

2.3.4 It now remains to be assessed whether the proposed solution is obvious to the skilled person.

Magnesium stearate (Mg-St) and sodium stearyl fumarate (SSF) are both well known lubricants, commonly used in pharmaceutical technology at the effective date of filing of the patent in suit (the patent in suit was filed in the year 2000 and claims the priority date of 15 February 1999). Therefore, the physical behaviour of these two substances as lubricants belongs to the general knowledge of the skilled person in the field. This is shown, in particular, by document (15) which concerns an evaluation of lubricants (already performed in 1981) by comparison of friction coefficients and tablet properties. It can be read in the abstract of document (15): "Eight lubricants were compared with magnesium stearate and stearic acid by, firstly, the determination of friction coefficients during tabletting and, secondly, the effects on the **strength** and **disintegration** of sodium chloride tablets" (emphasis added). SSF is among the tested lubricants. Therefore, document (15) reflects a study tailored in standard sodium chloride tablets, i.e. in tablets devoid of other ingredients (such as pharmaceutical excipients) in order to determine without interference the actual physical behaviour of specific lubricants regarding tablet strength and disintegration. The measurement of the parameter friction coefficient, stress ratio, tensile strength and disintegration time is made with the **purpose of comparing** the different lubricants under the same tablet conditions. Thus, it is irrelevant whether or not the sodium chloride tablets are "melt-in-your-mouth" tablets such as the

mannitol/corn starch tablets in document (2). The tests results in table 2 on page 143 of document (5) show that SSF shortens the disintegration time of the tablets when compared with Mg-St. These results are further confirmed on page 146 of document (15), under the heading "Tablet disintegration".

Therefore, the skilled person looking for a solution to the technical problem defined in point 2.3.2 above would have made use of its general knowledge in the field as shown by document (15) and have tried SSF as a lubricant (instead of Mg-St) with a genuine expectation of success.

Accordingly, the subject-matter in claim 1 of the main request lacks an inventive step (Article 56 EPC).

2.3.5 The appellant did not contest the vitamin tablets disclosed in document (2) as an appropriate starting point for the problem-solution approach.

However, it submitted that the skilled person would not have been able to predict that, by exchanging the lubricant (SSF instead of Mg-St), substantially shorter disintegration times would be attained in mannitol/corn starch tablets than those in document (2).

As already explained in paragraph 2.3.3 above, the exact magnitude of the improvement attained by the exchange of lubricant in tablets according to document (2) has not been disclosed by the experimental reports provided by the appellant. Thus, it cannot be argued that the improvement is "substantive".

Moreover, the skilled person, when looking for a solution to the technical problem, finds a clear indication in document (15) for replacing the lubricant Mg-St by SSF with the expectation of attaining shorter disintegration times for the tablets. Additionally, the teaching in document (15) relates to a comparison between surfactants for which standard sodium chloride tablets were used. The absolute values for the disintegration time of the sodium chloride tablets are irrelevant since they are dependent on the constitution of the compressed tablet, namely sodium chloride. What counts in document (15) is the teaching which can be extracted from the comparative behaviour of the lubricants about their influence on the strength and disintegration of tablets.

Additionally, the teaching in document (2) is not confined to the use of Mg-St as a lubricant (in the last paragraph on page 6 other lubricants are also mentioned). In fact, the appellant never asserted that there exists a general technical prejudice in the prior art against the use of SSF in mannitol/corn starch tablets. Hence, the teaching in document (15) is applicable to the "melt-in-your-mouth" tablets disclosed in document (2) and renders the proposed solution obvious to the skilled person.

2.3.6 Consequently, the main request fails since it does not meet the requirements of inventive step (Article 56 EPC).

2.4 *First auxiliary request*

Claim 1 of the first auxiliary request relates to a tablet preparation comprising a starch, mannitol, sodium stearyl fumarate and a medicament and substantially not containing a binder other than starch, which preparation disintegrates in the mouth. Moreover, claim 1 of the first auxiliary request incorporates "product-by-process" like features.

The appellant stated that the basis in the application as filed for the process features incorporated into claim 1 was to be found in example 8. In fact, there is no generic disclosure in the application as filed for the process now appearing in the generic claim. The disclosure on page 7 is very general and refers to the following: "Tablets can be obtained by blending the starch, water-soluble excipient and medicament and compressing the resulting composition". Milling, before or after blending, and granulation of the ingredients are also mentioned as possible options, without giving any further details.

Thus, there is no generic disclosure of a preparation process including all the particular method steps introduced in claim 1. Therefore, it has to be investigated whether or not the specific example can serve as an allowable basis for the amended claim.

The tablet preparation in example 8 is very specific in respect of its constitution (specific choice of ingredients in specific absolute and relative amounts). In particular, corn starch (9%), D-mannitol (80.5%) and low-substitution-degree hydroxypropylcellulose (3%) are

present. Moreover, two lubricants are employed, namely SSF (2%) and light silicic anhydride (0.5%) (*the percentages are expressed as approximate weight-by-weight calculated values in relation to the total composition*). This particular choice of elements has a direct bearing on the preparation process in said example, which specifically relates to a spray drying of a previously prepared gelatinised dispersion of "**1%** starch size". Therefore, claim 1 of the first auxiliary request relates to an unallowable generalisation of example 8 in relation to both, the process conditions and the particular constituents of the composition.

Consequently, the first auxiliary request fails since it does not meet the requirements of Article 123(2) EPC.

2.5 *Second auxiliary request*

Claim 1 of the second auxiliary request relates to a tablet preparation characterised by the presence of the ingredients: starch, D-mannitol, disintegrator, SSF, high-sweetness artificial sweetener, flavouring agent and light silicic anhydride, which preparation disintegrates within one minute in the mouth.

Claim 1 of the application as filed read as follows: "a tablet preparation characterised by its comprising a starch, a water-soluble excipient and a medicament and substantially not containing a binder other than starch".

Although mannitol is mentioned on page 4 of the application as filed as the preferred water-soluble excipient, the generic disclosure in the application as

filed offers several options in relation to the presence and nature of further possible ingredients.

There is no basis in the description of the application as filed for the specific combination of seven ingredients listed in the amended claim. Example 8 was cited by the appellant as the basis for the amended claim, but as already said in the analysis made in point 2.6 above for the first auxiliary request, this particular example illustrates a very specific tablet preparation in which specific ingredients are present in specific absolute and relative amounts. These amounts have a direct bearing on the tablet characteristics, in particular its strength and disintegration time. Thus, claim 1 of the second auxiliary request amounts to an unallowable generalisation of the tablet in example 8.

Consequently, the second auxiliary request fails since it does not meet the requirements of Article 123(2) EPC.

2.6 *Third auxiliary request*

The assessment made in point 2.5 above for the second auxiliary request applies *mutatis mutandis* to the third auxiliary request. Claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request in that the nature of the disintegrator has been specified, according to example 8, as "low-substitution-degree hydroxypropylcellulose". However, the relative amounts of the ingredients in the claimed composition are lacking. Thus, claim 1 of the third auxiliary request amounts to an unallowable generalisation of example 8.

Consequently, the third auxiliary request also fails since it does not meet the requirements of Article 123(2) EPC.

2.7 *Fourth auxiliary request*

The findings in point 2.6 above directly apply to claim 1 of the fourth auxiliary request in which the starch has been defined as corn starch but the relative amounts for the ingredients are not given. Moreover, not all the process features (the spray-drying using a gelatinised dispersion of 1% starch size is lacking) of the preparation process in example 8 have been introduced as "product-by-process" features for the tablet preparation claimed.

Therefore, claim 1 of the fourth auxiliary request amounts to an unallowable generalisation of example 8.

Consequently, the fourth auxiliary request also fails since it does not meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald