BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 22 July 2008

Case Number: T 0671/05 - 3.3.02

Application Number: 99907592.2

Publication Number: 1058538

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Fast disintegrating tablets

Patentee:
EURAND INTERNATIONAL S.P.A.

Opponent:
ETHYPHARM

Headword:
Fast disintegrating tablets/EURAND

Relevant legal provisions:
EPC Art. 83, 52, 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"The requirements of sufficiency of disclosure are met by all requests"
"Main request and first auxiliary request lack inventive step"
"Remittal based on the second auxiliary request"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0671/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 July 2008

Appellant: (Opponent)
ETHYPHARM
21, rue Saint-Matthieu
B.P. 45
F-78550 Houdan (FR)

Representative:
Touati, Catherine
Cabinet Plasseraud
52 rue de la Victoire
F-75440 Paris Cedex 09 (FR)

Respondent: (Patent Proprietor)
EURAND INTERNATIONAL S.P.A.
Piazzale Marengo, 8
I-20121 Milano (IT)

Representative:
Gervasi, Gemma
Notarbartolo & Gervasi S.p.A.
Corso di Porta Vittoria, 9
I-20122 Milano (IT)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 16 March 2005 concerning maintenance of European patent No. 1058538 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent No. 1 058 538, which was filed as application number 99 907 592.2, based on international application WO 99/44580, was granted on the basis of fourteen claims.

Claim 1 as granted read as follows:

"1. A fast disintegrating tablet comprising a drug in a multiparticulate form, characterised in that it contains:
(i) substantially water insoluble components in an amount of 50-99.5% by weight, preferably 65-98%, or most preferably 70-95%
(ii) one or more water insoluble inorganic excipients, in an amount of 2-40%, preferably 4-25%, or most preferably 6-18% by weight;
(iii) one or more disintegrants, in an amount of 0.5-30%, preferably 1-20%, or most preferably 2-15% by weight;
(iv) optionally, one or more substantially water soluble excipients, in amounts of 0-25%, preferably 0-20%, or most preferably 4-16% by weight".

II. The following documents were cited *inter alia* during the proceedings:

(1) FR-A-2 679 451

(4) Handbook of Pharmaceutical Excipients, 2nd ed., American Pharmaceutical Association 1994, 56-62, 84-87, 252-261; same Handbook, pages 424-427, and 519-521 was also cited during the proceedings as document (2)

(8) EP-A-0 679 400

(10) US 5 506 248

(12) Ferrari et al., Pharmaceutical Development and Technology, 1(2), 159-164 (1996)

(13) P. C. Schmidt, R. Herzog, Pharmacy World and Science, 116-122 (1993)

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

IV. The appeal lies from the interlocutory decision of the opposition division to maintain the patent in amended form based on the request (main and sole request) filed during the oral proceedings before the opposition division (Articles 102(3) and 106(3) EPC 1973).

Claim 1 of the request serving as the basis for the opposition division's decision differed from claim 1 as granted in that the following was added at the end of the definition of component (ii): "wherein said water insoluble inorganic excipient is a calcium salt" and in that the word "disintegrants" appearing in the definition of component (iv) was replaced by the word "superdisintegrants".

V. The opposition division considered that the requirements of Article 83 EPC were met. In particular, in the opposition division's view the terms "tensile strength" and "insoluble" were meaningful for the skilled person, especially in the light of the illustrative examples. Furthermore, the skilled person would know how to measure tensile strength by standard

means. The opposition division also mentioned that the opponents had not provided any experimental evidence in order to cast doubts on sufficiency of disclosure.

The opposition division considered that the subject-matter claimed was novel over the prior art. In particular, the pharmaceutical composition of the amended set of claims was a novel selection of components which was not disclosed in document (10).

The opposition division considered that the subject-matter claimed involved an inventive step (Article 56 EPC). In the opposition division's view document (1) represented the closest prior art.

The opposition division defined the problem to be solved as "to further improve the disintegration time of such fast disintegrating tablets by likewise maintaining or improving friability".

The opposition division considered that the problem was indeed solved as proven by comparative data results in the patent in suit and that the claimed solution was not obvious in the light of the cited prior art.

VI. The opponent (appellant) lodged an appeal against said decision and filed grounds thereto. The opponent filed with its grounds of appeal additional technical data and an "Annex 1" about friability of tablets.

VII. The respondent (patentee) filed as an annex to its response to the grounds of appeal (letter dated 20 February 2006) additional technical data.

VIII. With a letter dated 20 June 2008 the appellant filed document (12) and an expert declaration.

IX. With a letter sent by fax on 18 July 2008 the respondent filed document (13).

X. Oral proceedings took place on 22 July 2008.

XI. At the beginning of the oral proceedings the parties confirmed their written requests, namely the appellant requested that the decision under appeal be set aside and that the patent be revoked, and the respondent requested that the appeal be dismissed.

Following the substantive discussion on the basis of the set of claims of the main request, and (at that stage of the proceedings) sole set of claims on file, in relation to the grounds pursuant to Article 100(b) (sufficiency of disclosure) and 100(a) EPC (novelty and inventive step), the chairman asked the parties whether or not they maintained their requests. This question was answered affirmatively by both parties, and the chairman then closed the debate.

After the announcement of the closure of the debate, the respondent's representative requested that the debate be reopened since it wished to file auxiliary requests as a precautionary defensive measure.

After deliberation, the board decided to reopen the debate. Then the respondent filed two auxiliary sets of claims, and the discussion about the admissibility of the late-filed requests took place.

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the definition of component (ii) reads as follows: "one or more water insoluble inorganic excipients, in amount of **6-40%** by weight; wherein said water insoluble inorganic excipient is a calcium salt" (emphasis added).

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the amount of "6-40% by weight" of component (ii) is restricted to "**25-40%** by weight" (emphasis added).

XII. The appellant's arguments may be summarised as follows:

As mentioned in its letter of 20 June 2008, the filing of document (12), published in 1996, was a response to the respondent's argument that a pro-disintegration effect could not have been expected for dicalcium phosphate at the effective filing date of the patent in suit.

The two auxiliary requests filed by the respondent at the oral proceedings before the board should not be admitted into the proceedings since their late filing was not sufficiently justified by the discussion of inventive step.

In relation to the definitions of the amended ranges in the first auxiliary request filed at the oral proceedings, the appellant stressed that the expression "from ... to ..." had to be avoided because it generated a new specific sub-range and thus contravened Article 123(2) EPC.

In view of the redrafted wording for the ranges, the appellant did not object to the second auxiliary request.

As regards the issue of sufficiency of disclosure the appellant submitted that whereas the granted claims required an insoluble inorganic excipient to be present, the amended claims (it cited in particular claim 1 of the main request) were directed to any calcium salt. With this in mind, the appellant put forward that not every calcium salt was insoluble, pointed in particular to calcium sulphate as being water soluble, and quoted paragraph [0036] of the patent in suit in which "calcium sulfate" was one option among the list of water insoluble salts. Thus, the alleged "invention" was not reproducible in the whole scope claimed.

Moreover, the appellant submitted that, following the claim's wording, the water insoluble inorganic excipients listed in point (ii) of claim 1 were included in the "substantially water insoluble components" comprised in point (i) of claim 1. Additionally, the appellant also stressed that an analogous argument also applied, for instance, to some of the "superdisintegrants" listed in point (iii) of claim 1, which corresponded to the definitions given in paragraphs [0031] and [0032] of the patent in suit.

Thus, the appellant submitted that the formulation of the fast disintegrating tablet was defined in claim 1 only up to 50% of its total composition and that the skilled person had to complete with his knowledge this lack of information. In the appellant's opinion, even if considering the optional water soluble excipient

listed in point (iv) the total amount for the formulation defined in claim 1 was 75%.

Additionally, the appellant also pointed out that there was a lack of disclosure in the case of water soluble drugs. In particular, in the appellant's opinion, it was unclear under which category listed in claim 1 the drug (active component) was to be classified.

The appellant replied as follows to the respondent's assertion that there was no problem for the skilled person to reproduce the "invention" when fast disintegrating tablets containing water soluble drugs were targeted: in the case of encapsulated soluble drugs there was in principle no problem, but the claim's wording only required that the drug was in a multiparticulate form and thus both soluble and insoluble drugs were included by claim 1.

In relation to the issue of novelty of the subject-matter of claim 1 of the main request, the appellant pointed to document (10), as it had already done in its written submissions with the grounds of appeal. In particular, the appellant argued that it disagreed with the opposition division's findings that a selection of several components was sufficient for establishing the novelty of the claim. Moreover, the pharmaceutical composition as defined in claim 14 of document (10) concerned only one mode for carrying out the "invention". Thus, the combination of one element from each of the different categories of ingredients (appearing in claim 14), in the relative amounts given for each of them, was also specifically disclosed in the appellant's view. In particular, the appellant

submitted that the formulation constituting the tablet of claim 14 of document (10) may also comprise 50 to approximately 99% of water insoluble ingredients. Additionally, croscarmellose sodium or crospovidone were listed as disintegrant in the pharmaceutical composition. Therefore, in the appellant's view, there was a novelty destroying overlap of ranges, if considering both the optional ingredients and the mandatory ingredients listed in claim 14 of document (10).

The appellant put forward for the first time during the oral proceedings before the board a further attack of lack of novelty against the subject-matter of claim 1 of the main request, based on the content of document (8). The appellant alleged that this procedural step was admissible since document (8) had already been cited against inventive step during the appeal proceedings previous to the oral proceedings. The appellant merely referred to example 9 of document (8) and stated that the formulation was encompassed by claim 1 of the main request with the additional comment that the tablet of document (8) may also contain 0.5% of additional water soluble ingredients.

As regards the issue of inventive step (Article 56 EPC) for the main request, the appellant's arguments may be summarised as follows: document (1) represented the closest prior art, the difference lay in the presence of an (insoluble) calcium salt, the definition of the problem to be solved by the opposition division could be overtaken and thus it merely remained to be assessed whether or not the problem had been solved in the whole scope claimed.

In this context, the appellant referred to the functions relating to the disintegration time and the friability of the tablets and pointed to paragraphs [0057] and [0058] of the patent in suit. In the appellant's view, in order to achieve a satisfactory disintegration time, the friability values attained were inacceptable (4.4% by a compression force of 20kN).

The appellant put also forward that friability values were to be in the range of 0.5-1% in order to be acceptable. Thus, if the skilled person was looking either for an increase or maintenance of the friability, the values attained in example 1 were unsatisfactory. Hence, according to the appellant, the problem had not been solved in the whole scope claimed.

The appellant also made some comments in relation to the additional examples and technical data filed with the respondent's letter dated 20 February 2006 (reply to the grounds of appeal). In particular, it pointed to the data shown in table II for a compression force of 20kN and stressed that in the case of a disintegration time of 16 seconds, the friability value was inacceptable, namely 3.2(%).

Additionally, the appellant submitted that the respondent had not provided any data which demonstrated a causal link between the addition of a water insoluble calcium salt and the presence of an additional technical effect.

The appellant provided further arguments and submitted that if the problem to be solved were to be seen in the

provision of a simple alternative to the tablets of document (1), then the mere exchange of the filler would have been considered by the skilled person without him having to make use of his inventive skills.

In this context the appellant referred to documents (4) and (12), or, alternatively to documents (4) and (8).

In the appellant's view, the mere exchange of the filler (lactose *versus* calcium phosphate) did not involve an inventive step. In particular, it referred to document (12), in which a fast disintegrating tablet formulation was described which contained croscarmellose sodium (superdisintegrant) and two filler-binders with different water solubility (i.e. dicalcium phosphate dihydrate and anhydrous β-lactose). In this respect, the appellant referred to Figure 3, page 162 of document (12). The appellant explained for the first time at the oral proceedings before the board the possible relevance of the three-phase diagram showing in the contour plot of disintegration time X1, X2 and X3 for croscarmellose sodium, dicalcium phosphate dihydrate and anhydrous β-lactose respectively. Basically, the appellant underlined the surface area in Figure 3 contouring the value seventy seconds as relating to a good disintegration time. Therefore, in the appellant's view, document (12) would incite the skilled person to employ this particular calcium salt in fast disintegrating tablets.

The appellant also cited document (4), page 56, as further proof that the skilled person was able to successfully use at the effective date of the patent in suit a water insoluble calcium salt (namely, dibasic

calcium phosphate) together with a superdisintegrant such as croscarmellose sodium.

As regards the dispute in relation to the relevance of the content of document (4) for the skilled person when looking for a solution to the technical problem, the appellant put forward that document (4) would not have deterred the skilled person from using a water insoluble calcium salt in fast disintegrating tablets, and that said document did not preclude the use of a disintegrant such as a superdisintegrant (e.g. croscarmellose sodium), if necessary.

The appellant also stressed that it had to be considered that the compression force had a direct influence on the friability of the tablets.

The appellant submitted that the amendments introduced into the auxiliary requests, which merely concerned the modification of ranges of the amounts of the calcium salt, did not change anything with respect to the discussed issues of sufficiency of disclosure, novelty and inventive step. Hence, the arguments provided for the main request applied *mutatis mutandis* to the auxiliary requests.

The appellant also asserted that it was known in the art that friability and disintegration time were contradictory parameters and that to achieve little friability was only possible at the cost of high disintegration times.

As regards document (13), the appellant mentioned that said document concerned a general study of tableting

properties of calcium phosphates. Thus, the compressed tablets merely contain a calcium phosphate. Moreover, the friability of 1% was attainable. Such value was an acceptable value for the tablets of the patent in suit.

The appellant stressed that neither document (13) nor document (4) demonstrated the presence of a general prejudice against the use of a calcium salt for fast disintegrating tablets.

XIII. The respondent's arguments may be summarised as follows:

As is apparent from point XI above, the respondent submitted two auxiliary requests at the oral proceedings before the board arguing that, although it was confident in the patentability of the subject-matter of the main request, it wished to file auxiliary requests as a defensive precautionary measure.

As regards the admissibility of the two auxiliary requests filed at the oral proceedings before the board, the respondent argued that their filing was a response to the attack of lack of inventive step supplemented by document (12). The respondent further submitted that document (12) had been filed by the appellant one month before the oral proceedings, but its possible relevance had been discussed for the first time at the oral proceedings. The respondent added that the auxiliary requests were a clear response to the new argumentation since the range defining the amount of the water insoluble calcium salt had been narrowed in the auxiliary requests.

The appellant's objection in relation to a certain wording of the ranges for the amounts of insoluble calcium salt was answered by the respondent by providing a more appropriate wording, namely "of 6-40%" and "of 25-40%" for the first and second auxiliary requests respectively.

Additionally, the respondent mentioned that the specified ranges were covered by the values defined in the application as filed, including the examples.

In relation to the requirements of sufficiency of disclosure the respondent mentioned that Article 83 EPC only required at least one mode of realisation. Furthermore, the patent in suit comprised twenty-three examples which clearly allowed the skilled person to reproduce the "invention". Additionally, the examples referred to different kinds of drugs with different levels of solubility and the methods of preparation were clear and complete. Hence, the claimed formulations were fully disclosed.

Moreover, the examples also illustrated that different standard parameters were measured such as disintegration time and tensile strength.

In this context, the respondent mentioned that the procedure had taken almost three years, and that during this time the opponent had not been in a position to demonstrate that the fast disintegrating tablets disclosed in the patent in suit could not be obtained. On the contrary, in the respondent's view, the further technical data submitted by the opponent demonstrated that they could indeed be obtained.

Additionally, the respondent submitted that the concept of reproducibility over the whole scope claimed put forward by the appellant appeared to be over-valued.

Furthermore, the respondent submitted that all the ingredients employed in the formulation of the fast disintegrating tablet were commonly known to the skilled person from the pharmaceutical technology.

In the respondent's view, the claim's wording set a clear technical condition with regard to the composition of the tablet, namely that the total amount of insoluble components was in the range 50-99.5%. Indeed, the respondent also put forward that there were also two essential technical features required by the claim -the minimum amount of superdisintegrant and a certain dissolution profile of the tablet- in order for it to be a fast disintegrating tablet.

As regards the issue relating to calcium sulphate's relative solubility in water, the respondent submitted that the claim required the calcium salt to be insoluble and pointed to the wording in point (ii) of claim 1.

Furthermore, the respondent mentioned that the appellant had not shown that there were any indications on file that calcium sulphate should be soluble. In the respondent's view, calcium sulphate was mainly an insoluble salt. The respondent also added that, even in the negative case, the wording of the claim was prevalent over the list of options given in the description.

As regards the issue of lack of sufficiency of disclosure for fast disintegrating tablets containing water soluble drugs, the respondent argued that the appellant had not provided any proof that a water soluble drug could not be used in the formulations according to claim 1, if the defined ranges were respected.

The respondent's position in respect of the issue of sufficiency of disclosure may be summarised as follows: the appellant's objection pursuant to the requirements of Article 83 EPC had only a theoretical basis; there was no body of objection re Article 83 EPC for the patent in suit, since the "invention" was very well detailed. Thus, in the respondent's view, the opposition division's decision was fully justified in this respect.

Finally, the respondent submitted that there was no contradiction in subcategorizing the superdisintegrants as ingredients according to categories (i) and (iii) of claim 1. Thus, the appellant's submission that there was a lack of definition for 50% of the composition of the claimed fast disintegrating tablet was not accurate.

The respondent asserted that the skilled person was in a position to reproduce the claimed "invention" by following the teaching of the description.

Regarding the novelty issue, the respondent mentioned that document (10) had already been discussed in some detail during the proceedings before the opposition division. Basically, the respondent's arguments were as

follows: it was an undisputed fact that document (10) did not disclose any specific tablets falling within the scope of claim 1 of the main request. Moreover, claim 14 of said document required the presence of a filler in amounts ranging from (about) 10 to (about) 90% by weight. Thus, the filler of the pharmaceutical composition according to claim 14 of document (10) covered either (almost) the entire body of the tablet, or a very tiny part of it. Moreover, this class of components (filler) included simultaneously, in the respondent's view, water soluble and water insoluble ingredients which made up, in exclusion or inclusion, altogether 10-90%. Therefore, the profile required by the fast disintegrating tablets claimed in the patent in suit was not directly derivable from the multiplicity of options encompassed by claim 14 of document (10).

(NOTE: *In this context the respondent made reference to a hand-written sheet it submitted during the oral proceedings before the board, showing possible combinations of the "optional" components according to document (10). The respondent had shown this sheet as a way of illustrating the verbal analysis it had made. Hence, this extra hand-written sheet does not provide any additional information and it is insubstantial to consider it in the present decision*).

Moreover, the respondent submitted that claim 14 of document (10) was dependent on claim 1, which required the pharmaceutical composition to have good dissolution properties, even after aging.

The respondent also referred to column 3, lines 15-25 of document (10), in order to show that the filler might include the most common pharmaceutical ingredients put together, and to demonstrate that there was no hint in document (10) to derive a profile of a tablet like the fast disintegrating tablet claimed in the contested patent.

The respondent submitted that for an objection of lack of novelty to be successful, the intended subject-matter had to be inevitably derivable from the prior art document, and had to be more specific than the claim under assessment. According to the respondent, the situation was reversed in the present case. In this context, the respondent cited the illustrative modes of realisation disclosed in document (10), wherein dicalcium phosphate dihydrate was seldom used. Furthermore, the amounts of dicalcium phosphate illustrated by the examples of document (10) were always ranging in the upper limit. In particular, the respondent referred to example 3, in which the amount present by weight of dicalcium phosphate dihydrate was 85.95%.

After a 15-minute break, the respondent declared that it was able to provide a reply to the novelty attack based on the content of document (8), which had been advanced for the first time by the appellant at the oral proceedings before the board.

Basically, the respondent submitted that document (8) was not cited either in the statement of grounds of opposition or later in the appeal proceedings and added

that the appellant's attack amounted to an inadmissible fresh case.

Apart from that, the respondent argued that there were significant differences between the fast disintegrating tablets of the patent in suit, which disintegrate in seconds to about one minute (in this context the respondent referred to the definitions given in the description), and the tablets disclosed in document (8). Thus, according to the respondent's opinion, the tablets disclosed in document (8) were not fast disintegrating tablets since they were provided to disintegrate in the stomach following ingestion, even with food. In the respondent's view, this prerequisite required all ingredients to be insoluble in order not to disintegrate in the mouth and to allow easy swallowing.

The respondent put forward that the subject-matter claimed in claim 1 of the main request was at least formally novel over the content of document (8), since the fast disintegrating tablet claimed required at least 0.5% of water soluble ingredients.

In relation to the requirements for inventive step (Article 56 EPC), the respondent submitted that the patent in suit concerned tablets with a high disintegration rate and little friability, and that these parameters were known in the art to be contradictory parameters in respect of which the skilled person had to compromise. The fast disintegrating tablets of the patent in suit were satisfactory since they showed very fast disintegrating

times, namely 15 to 20 seconds, by keeping a good friability 0.5% to 1.4% (compression force 25.2kN).

The respondent agreed with the choice of document (1) as the closest prior art and defined the problem to be solved as to provide a fast disintegrating tablet having very good disintegration rate together with an industrial acceptable friability. In this context the respondent cited paragraph [0015] of the patent in suit.

Moreover, the respondent pointed to the data of the examples contained in the patent in suit, as well as to the experimental data it had submitted during the appeal proceedings. Although the respondent submitted that in the light of these data a better profile for the formulations according to the contested patent was shown, it also stressed that the presence of a surprising effect was not a pre-condition for the acknowledgment of an inventive step.

Additionally, the respondent put forward as an indication for the presence of an inventive step within the meaning of Article 56 EPC, that there was a prejudice in the prior art to employ calcium phosphate as an ingredient of fast disintegrating tablets.

As regards document (4), the respondent submitted that there was no suggestion for using a calcium salt to assist disintegration. On the contrary, the skilled person will keep away in order to avoid problems in fast disintegrating tablets.

As regards document (12), the respondent argued that Figure 3 was a model derived from only a few punctual

values obtained experimentally. The respondent contended that Figure 3 related to a theoretical extrapolation in which the estimation areas could not be taken as if they all concerned specific experimental values. Furthermore, the disintegration times actually shown in document (12) were inacceptable for a disintegration tablet. Additionally, the tablets of document (12) were treated as if they concerned three components showed in the vertices of the triangle, but this required small portions of the drug (5%). Hence, in the respondent's view the models could not be extrapolated for tablets containing higher amounts of the drug.

Additionally, the respondent cited document (13), which was published before the effective date of the patent in suit, in which it was taught that calcium phosphates in general caused high friability problems in the tablets and that a tolerable friability value of 1% could only be reached with high compression pressures. Hence, the respondent stated that the skilled person did not have any information as how to provide a good balance of disintegration rate to friability.

Moreover, the respondent pointed out that the appellant had not provided any experimental data in which calcium phosphate was added to the tablet formulation described in document (1), which in the respondent's opinion was more heavy and compacted inside.

Additionally, the respondent explained that the reason why it had modified the formula of the compositions disclosed in document (1) was to have an adequate comparison when taking into consideration the weight of

the tablets and the percentages of insoluble ingredients. In this respect it pointed to the exchange lactose/microcrystalline cellulose (Avicel^{R}). The respondent submitted that this additional technical information demonstrated that the addition of calcium phosphate improved the disintegration rate by maintaining an acceptable friability.

Furthermore, the respondent contended that the patent in suit included twenty-three illustrative examples, which in its opinion was a fairly appropriate generalisation for the alleged "invention".

In relation to the first auxiliary request, the respondent submitted that all the arguments in favour of the main request also applied *mutatis mutandis* to the first auxiliary request.

XIV. Following a question of the board to both parties in relation to their understanding of the expression "fast disintegrating tablet", employed in claim 1 of all the requests, the respondent briefly commented that it referred to a "functional profile requirement" of the "invention" and stressed that, generally, such a term referred to tablets dissolving in no longer than 60 seconds, whereas the appellant put forward that a fast disintegration without mention of the time required for completion might be very short or not. It mentioned 30 seconds, 5 minutes, and even much longer times, for instance, several hours.

XV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of the first or second auxiliary requests filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters*

It becomes evident from the reading of point XI above that during the oral proceedings held before the board the debate was declared to be closed, and then it was reopened.

The reasons for the reopening of the debate are the following: The complex discussion which took place for the first time during the oral proceedings before the board in relation to the newly filed documents (12) and (13) justified that the respondent had an opportunity to modify the claims. The board decided to reopen the debate in order to allow the respondent such an opportunity (Article 15(5) RPBA, OJ 2007, 536).

2.1 *Admissibility of late-filed documents and requests*

The admissibility of late-filed documents and requests is at the board's discretion and depends upon the overall circumstances of the case under consideration, a general principle being that the later requests and

documents are filed, the less likely they are to be held admissible.

Document (12) (published before the effective filing date of the patent in suit) relates to a research article dedicated to the "Dissolution Enhancement of an Insoluble Drug by Physical Mixture with a Superdisintegrant: Optimization with a Simplex Lattice Design". Document (12) was filed by the appellant one month before the date of the oral proceedings.

This document, which forms part of the prior art within the meaning of Article 54(2) EPC, is admitted into the proceedings since it represents a relevant technical contribution to the discussion concerning the presence (or absence) of an unexpected effect over the prior art. Since a certain amount of material (technical data and documents) which were filed in the present case are post-published, it is essential to have relevant pre-published documents, known to the skilled person at the (effective) filing date of the patent.

However, the late-filing of document (12) (more than two years after the last respondent's submissions) caused at least the following procedural effects: firstly, the very late filing of document (13) by the respondent, secondly, the technically complex discussion in relation to the inventive step issue undertaken for the first time at the oral proceedings before the board, and finally, the late filing of two auxiliary requests by the respondent.

Document (13), which deals with "Calcium phosphate in pharmaceutical tableting", is admitted in the present

inter parte proceedings, since its filing by the respondent represents a direct response to the filing of document (12) by the appellant. The technical complexity of document (12) required some time on the respondent's side for finding an appropriate response.

As regards the two late-filed auxiliary requests, their filing during the oral proceedings was a direct consequence of the late filing of document (12) and the technically complex discussion about inventive step during the oral proceedings, which included arguments based on new facts.

Although for reasons of procedural efficiency and procedural economy it would have been more appropriate to have the auxiliary requests at the beginning of the oral proceedings, their filing was motivated by the discussion of documents (12) and (13) which took place for the first time at the oral proceedings before the board. The said filing clearly relates to a procedurally allowable precautionary defensive measure. Moreover, the amendments introduced are *prima facie* formally allowable. Hence, the two auxiliary requests filed at the oral proceedings are admitted into the proceedings.

3. *Article 123(2) and (3) EPC*

3.1 *Main request*

The main request relates to the amended set of claims filed during the oral proceedings before the opposition division. Although the opposition division did not explicitly express in its written decision the reasons

in favour of the introduced amendments in relation to the requirements of Article 123(2) and (3) EPC, the amendments introduced are clearly derivable from the application as filed and the amended claims clearly relate to restrictions in the scope claimed. Hence, the requirements of Article 123(2) and (3) EPC have been met by the set of claims of the main request.

This was not disputed by the appellant.

3.2 *First auxiliary request*

The amendment introduced in claim 1 of auxiliary request 1 relates to the specification of the amount of component (ii) as "of 6-40% by weight". The generic range covered this sub-range since it was defined in the application as originally filed as "2-40%" by weight. Moreover, a preferred sub-range is defined in the application as filed as (about) "6-18% by weight" (see last paragraph on page 8 of application as filed).

According to consistent case law of the boards of appeal, the lower and upper value defining a range are considered as specifically disclosed.

Therefore, the amount of 6% by weight for component (ii) is specifically disclosed in the application as filed.

Additionally, an inspection of the examples of the application as filed shows that the sub-range defined in the first auxiliary request is covered and exemplified.

Hence, the said amendment concerns a restriction of the claimed subject-matter which does not introduce new subject-matter. Hence, the first auxiliary request is considered to be allowable (Article 123(2) and (3) EPC).

The only remaining objection raised by the appellant in relation to the amendment introduced into the first auxiliary request concerns the suppression of the word "about", in view of the fact that it was used in the application as filed together with the range "6-18%" by weight (page 8, line 29). However, this suppression of the term "about" represents an allowable common practice. Therefore, the appellant's objection has no merit in the absence of a substantiation applicable to the present case.

3.3 *Second auxiliary request*

The amendment introduced in claim 1 of auxiliary request 1 relates to the specification of the amount of component (ii) as "of 25-40% by weight". The amount of 25% by weight is specifically disclosed in the application as filed for analogous reasons to those given above in connection with the value 6% of the first auxiliary request (see last paragraph on page 8 of the application as filed). Moreover, the specification of the range "of 25-40%" by weight does not introduce any information which was not directly and unambiguously derivable from the application as filed, since the amended range is covered by the initial broader range of 2-40% by weight and there are several examples exemplifying such sub-range for the amount of insoluble calcium salt. Therefore, the

requirements of Article 123(2) have also been met by the second auxiliary request.

Additionally, the amendments introduced in the second auxiliary request represent a clear restriction in relation to the granted claims. Hence, the requirements of Article 123(3) EPC have also been met.

The appellant did not contest the second auxiliary request in respect of Article 123(2) and (3) EPC.

4. *Sufficiency of disclosure*

4.1 The ground of opposition pursuant to Article 100(b) EPC concerns sufficiency of disclosure. A European patent, in order to be maintained, must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

The content of the whole patent, i.e. the claims and the description (including the examples), has to be investigated by the skilled person in the light of the knowledge of the technical field involved, without making use of inventive skills. On this point it must to be remembered that, for the requirements of sufficiency of disclosure, the relevant date to be considered is that of the effective filing date of the application.

Additionally, it is the claimed "invention" reflected by the subject-matter of the different sets of claims which has to be investigated. The general legal principle is that the claims define the matter for

which protection is sought and the examples illustrate specific ways of performing the invention.

As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on an assessment of the facts of each particular case, such as the character of the technical field, and the actual technical detail disclosed.

4.2 The subject-matter of claim 1 of the main request concerns a tablet which has been defined by including in the claim several functional definitions such as "fast disintegrating", "substantially water insoluble", "substantially water soluble", "water soluble", "water insoluble" and "superdisintegrants". Functional features are commonly used for defining subject-matter in claims in order not to deprive inventions of due protection. Functional terms provide for a generalisation of specific aspects of an invention which would otherwise be protected too restrictively. However, it is a fact that functional definitions are broad and relative in their nature, with boundaries which are not sharp or specific. The subject-matter defined by means of functional features in a claim has to be read in its broadest technically meaningful sense. For this purpose the general common knowledge of the skilled person of the particular technical field can be invoked.

However, a line has to be drawn to distinguish the assessment of the requirements of sufficiency of disclosure according to Article 83 EPC from the assessment of the requirements of clarity of the claims and support in the description set out in Article 84

EPC. To make a clear distinction is of particular relevance in opposition and opposition appeal proceedings, since Article 84 EPC is not a ground for opposition.

In the present case the appellant has not provided any substantiation for casting reasonable doubts on sufficiency of disclosure. The technical data submitted by the appellant with its grounds of appeal do not point to a lack of reproducibility or feasibility of the claimed "invention". On the contrary, the data show that the skilled person would be able to prepare further tablets according to the patent in suit. In fact, the appellant employed the technical data submitted with the grounds of appeal only in support of its argument against the presence of an inventive step (i.e. in order to demonstrate that an improvement in the disintegration time with simultaneously maintenance of a good friability was not achieved).

The patent in suit states that the "invention" deals with a fast disintegrating tablet, i.e. relates to tablets which disintegrate rapidly but also have good friability characteristics (paragraph [0001] of the patent in suit).

Furthermore, the patent in suit teaches in a clear and complete manner, following the description and the twenty-three illustrative examples, how to prepare the fast disintegrating tablets according to the claims.

Therefore, the fact that the functional definitions in the claims are relative in their nature (and that some of them include intrinsically relative terms such as

"fast" or "substantially") is insufficient for a successful attack of lack of sufficiency of disclosure within the meaning of Article 83 EPC.

In fact, the appellant has not contested the reproducibility of the examples of the patent in suit. It has only disputed that the claimed "invention" was reproducible in the whole scope claimed. To this effect the appellant submitted that the claim encompasses water soluble and water insoluble drugs, whereas none of the specific examples uses a water soluble drug.

This appellant's argument overlooks however the fact that the claim's wording requires the drug to be in a multiparticulate form and that the formulations illustrated by the examples employ the drug in the form of microcapsules, or in the form of coated microcapsules. Therefore, the skilled person following the description and the examples would use a microencapsulated or coated microencapsulated form in the case of a water soluble drug. The appellant itself has acknowledged that it would be feasible to use soluble drugs with a water insoluble coating. This statement demonstrates that the skilled person does not face an insoluble technical problem when providing fast disintegrating tablets in which the active drug is a water soluble drug. Hence, the board sees no reason to doubt the reproducibility of the "invention" when the active drug is water soluble.

Moreover, it has to be stressed that the claims represent a generalisation of the examples and that it is not a prerequisite for fulfilling the requirements of sufficiency of disclosure to provide an illustrative

example for every possible specific combination encompassed by the claims. The claims represent generalisations of the examples and have to be read in a broad, technically meaningful way, but the functional terms should not be read in open contradiction with the whole content of the description.

Hence, the board is convinced of the completeness of the description and that the skilled person in the field of pharmaceutical technology is able to carry out the claimed invention.

4.3 The board does not share the appellant's view that the claims also encompass formulations in which component (ii) is a water soluble calcium salt, since it is clearly required by the claim's wording that the calcium salt is a water insoluble inorganic excipient. Furthermore, calcium sulphate is generally known as an inorganic calcium salt with a low water solubility, and can thus be considered a substantially water insoluble calcium salt. Moreover, it has not been demonstrated by the appellant that the (reduced) water solubility of calcium sulphate negatively interferes in the formulation of the tablet, making it inadequate as component (ii).

Furthermore, the appellant's objection that claim 1 does not exhaustively define all the components of the disintegrating tablet in their absolute and relative amounts relates in fact to an objection within the meaning of Article 84 EPC. However, the said objection addresses a claim's wording, which is already present in claim 1 as granted and therefore cannot be attacked under Article 84 EPC.

Thus, for the purpose of the assessment within the meaning of Article 83 EPC the claim cannot be taken isolated from the description. The description of the patent in suit displays sufficient general information as well as a reasonable number of specific examples for the production of fast disintegrating tablets that contain amounts of water insoluble components within the range of 50-99% by weight (item (i)), with a water insoluble calcium salt in amounts within the range of 2-40% and a superdisintegrant in amounts within the range of 0.5-30%, and optionally containing water soluble components.

The appellant has dropped in the appeal proceedings other objections it had raised in the first instance against the use in the examples of parameters such as "tensile strength", and the board sees neither a reason to further pursue them nor a need to further comment thereupon.

4.4 Therefore the main request meets the requirements of Article 83 EPC and this conclusion directly applies to the two sets of claims of the auxiliary requests, since the analysis made for the main request above applies mutatis mutandis to the auxiliary requests. Moreover, the parties did not submit any additional or supplementary argument in relation to the auxiliary requests.

5. *Novelty*

5.1 *Main request*

5.1.1 Document (10) discloses pharmaceutical compositions (in particular ifetroban compositions), preferably in the form of a tablet or a capsule, which have good dissolution properties when dispersed in water at a certain pH (see claim 1 and column 1).

Claim 14 of document (10) relates to the pharmaceutical composition as defined in claim 1 of the said document, in the form of a tablet having the following formulation:
"from about 5 to about 70% by weight ifetroban sodium salt; from about 1 to about 10% by weight of basifying agent which is magnesium oxide, calcium carbonate, sodium bicarbonate or aluminium hydroxide, to impart a pH of at least 7; further including from about 10 to about 90% by weight of a filler which is mannitol, microcrystalline cellulose, lactose, and/or dicalcium phosphate dehydrate; optionally including from 2 to about 20% by weight microcrystalline cellulose, starch and/or polyvinylpyrrolidone as a binder; **optionally** including from about 2 to about 8% by weight of croscarmellose sodium or crospovidone as a disintegrant; and further including from about 0.5 to about 2% by weight magnesium stearate as lubricant" (emphasis added).

It is self-evident that claim 14 does not require the presence of a superdisintegrant such as croscarmellose sodium or crospovidone as a mandatory feature.

Furthermore, if dicalcium phosphate dihydrate (water insoluble calcium salt) is present, the amounts are not necessarily within the range of 2-40%.

Hence, the subject-matter of claim 1 of the main request is not directly and unambiguously derived from claim 14 of document (10).

An inspection of the description and examples of document (10) shows that in case that dicalcium phosphate dihydrate is used (see examples 3, 10, 11, 14) the highest amounts are meant (ca 85-90% by weight), owing to the fact that this particular water insoluble calcium salt is used as filler (this functionality is also stated in claim 14). Moreover, only example 3 of document (10) discloses a tablet containing a water insoluble calcium salt (dicalcium phosphate dihydrate), but the amounts are 85.95% by weight. The description does not include any further information concerning the specific amounts to be chosen for dicalcium phosphate dihydrate.

The description of document (10) states that if the composition is in the form of a tablet, then it will include one or more disintegrants, and gives a list of options. However, the list includes both disintegrants such as microcrystalline cellulose and superdisintegrants such as croscarmellose or crospovidone, without pointing to the superdisintegrants as preferred components.

Therefore, document (10) does not disclose in a direct and unambiguous manner a tablet according to claim 1 of the main request.

Contrary to the appellant's view, a possible generic overlap between claim 14 of document (10) and claim 1 of the main request does not suffice for a successful novelty attack, since document (10) teaches away from including in the formulation an insoluble calcium salt in amounts of 2-40% by weight, together with a superdisintegrant in amounts of 0.5-30% by weight.

Document (8) discloses a pharmaceutical oral dosage form of azithromycin which can be administered to a mammal that has eaten (page 3, first paragraph). The dosage form of document (8), which may be for instance in the form of a powder ready for suspension in water, or a tablet for ingestion, does not exhibit an adverse food effect. In this respect document (8) states that the dosage forms "either provide azithromycin ready for dissolution in the GI (gastrointestinal) tract essentially following ingestion (suspensions), or they **disintegrate rapidly following ingestion (tablets)** and thereby provide azithromycin rapidly for dissolution" (page 4, lines 49-51) (emphasis added).

Therefore, the "fast dissolving" tablets disclosed in document (8) require a good dissolution profile **in the stomach**, after swallowing. This is further shown by the dissolution profile of the dosage form of document (8) of at least 90% of azithromycin dissolved within about 30 minutes (preferably 15 minutes) in a USP-2 dissolution apparatus in a pH 6.0 medium (i.e. mimicking the conditions of the stomach fluids) (page 5, first paragraph).

The tablets of document (8) disintegrate after ingestion, i.e. they disintegrate by rapidly dissolving **in the stomach fluid**.

Moreover, the tablet disclosed in example 9 is a film coated tablet with Opadry^{R}, whereby the film coating "serves to improve **ease-of-swallowing** and tablet appearance" (page 16, lines 4-5). This is a further indication that the tablet of document (8) is not a fast disintegrating tablet but a fast dissolving tablet in the stomach fluid.

Furthermore, fast disintegrating tablets are known in the prior art before the effective date of the contested patent (for example in document (1)) to be tablets disintegrating in the mouth within a short lapse (about 60 seconds or less). In fact, document (1) is acknowledged as relevant prior art in the patent in suit (see example 1, 1A on page 6 of the patent in suit), although the prior art document actually cited is the US family document of document (10), namely US 5464632.

Fast disintegrating tablets have to compromise between two essential physical characteristic shown by two parameters, namely disintegration rate and friability (which acts in an opposite way to the compression forces). The skilled person is able to make a clear distinction between such tablets and a film coated tablet easy to swallow and designed for dissolving in the stomach fluid.

Therefore, the extent to which the functional *terminus technicus* "fast disintegrating tablet" reflects the

upper limit of the time in which the tablet is fully disintegrated may be disputed, but a coated tablet (such as that of document (8)) designed for "fast dissolving" in the stomach fluid is certainly not a fast disintegrating tablet suitable for disintegrating in the mouth within a short time lapse.

5.1.2 Therefore the subject-matter of claim 1 of the main request meets the requirements of novelty over the cited prior art.

5.2 *Auxiliary requests*

5.2.1 The subject-matter claimed in claim 1 of the first and second auxiliary requests is also novel over the cited prior art for analogous reasons to those given above for the main request.

The parties did not advance any additional arguments in respect to the novelty analysis of the auxiliary requests.

6. *Inventive step*

6.1 *Main request*

6.1.1 Document (1), which discloses fast disintegrating tablets, represents the closest prior art.

The tablets of document (1) disintegrate in less than 60 seconds in the mouth (page 1, first paragraph).

The fast disintegrating tablets of document (1) contain a drug in a multiparticulate form (page 1, lines 3-4).

Moreover, it has not been disputed by the parties that the tablets disclosed in document (1) contain amounts of water insoluble components falling within the range of 50-99.5% by weight.

Additionally, the tablets disclosed in document (1) contain two or more disintegrants such as a carboxymethylcellulose (modified cellulose), cross-linked polyvinylpyrrolidone, one or more swelling agents such as a carboxymethylcellulose, modified starches or a microcrystalline cellulose (page 2, second paragraph).

It becomes apparent from the reading of the patent in suit that the disintegrants specifically mentioned in document (1) and the swelling agent "modified starches" fall within the functional definition of superdisintegrants given in the contested patent (page 4, lines 17 to 23 of patent in suit).

The tablets of document (1) also contain, as a mandatory ingredient, a sugar derivative suitable for direct compression (see page 2 and example 1). Other excipients may also be present in the tablets of document (1), for instance magnesium stearate (as lubricant), flavour excipients or colloidal silica (see example 1). However, the tablets of document (1) do not contain any water insoluble calcium salt and there is no mention in the whole document of any water insoluble calcium salt.

Thus, the problem to be solved lies in the provision of fast disintegrating tablets, alternative to those known.

The solution lies in the replacement of part of the excipients (e.g. filler or diluent) of the known tablets by a water insoluble calcium salt, in amounts of 2-40% by weight.

As acknowledged by both parties, the skilled person knows that disintegration rate and friability are parameters conflicting with each other, for which a balance has to be attained, for example, by choosing the adequate compression forces during the manufacture of the tablets. This is shown, for instance, in example 1 of the patent in suit, where two different tablets are prepared from the same formulation. The experimental data obtained in example 1 show that the friability values of the 15mm tablets were improved from 4.4% to 1.4% by increasing the compression forces from 20kN to 25KN. The tablets show very good disintegrating times of about 20 and 21 seconds respectively (paragraph [0058] of the patent in suit).

Furthermore, it is quite normal for the skilled person, when facing the simultaneous optimisation of conflicting parameters, to encounter technical limitations. Thus, the skilled person may choose less demanding friability requirements for fast disintegrating tablets (designed to spontaneously disintegrate in the mouth in a very short time) than for conventional tablets (designed to be swallowed), and provide for adequate and more careful manufacturing techniques (as well as adequate blister packages).

Therefore, the examples contained in the patent in suit make it plausible that the above defined problem is solved.

It remains to be investigated whether the proposed solution is obvious to the skilled person in the light of the prior art.

The skilled person is aware of the Handbook of Pharmaceutical Excipients, document (4), which shows that the water insoluble calcium salt "dibasic calcium dihydrate" is known as a tableting excipient in pharmaceutical technology. This has not been disputed by the parties.

In particular, document (4) states: "dibasic calcium phosphate is one of the most widely used tableting excipients in the US, particularly in the health food sector...dibasic calcium phosphate is increasingly being used in ethical pharmaceuticals due to its relatively low cost and desirable flow and compression characteristics. The dihydrate is available in milled and unmilled forms, and is used primarily for direct compression or wet granulation processes" (page 2, left-hand column).

Document (4) further states that "Dibasic calcium phosphate has good compression characteristics, compaction taking place primarily by brittle fracture for both the dihydrate and anhydrous forms" (page 2, left-hand column).

Document (4) specifies that "Tablets produced with dibasic calcium phosphate do not disintegrate readily and a disintegrant such as starch, povidone, sodium starch glycolate or crosscarmellose sodium is necessary" (page 2, left-hand column).

Hence, document (4) teaches the skilled person that dibasic calcium phosphate should not be used alone as a filler-binder in tablets, but together with a superdisintegrant, in order not to jeopardise a good disintegration of the tablet.

The content of document (4) cannot be seen, however, as a general prejudice which would have deterred the skilled person from trying this water insoluble calcium salt as an excipient in fast-disintegrating tablets. The skilled person would have tried, with reasonable expectation of success in the light of document (4), low amounts of dibasic calcium phosphate (always together with a superdisintegrant) as a solution to the above stated problem. Nothing else has been claimed in claim 1 of the main request, where the lower limit for the range of the amounts of water insoluble calcium salt is 2% by weight.

Document (12) confirms this assessment, because it shows by means of a model based on three-phase diagrams of a particular experiment with prednisolone (active drug), dicalcium phosphate dihydrate, croscarmellose sodium (superdisintegrant) and β-lactose (filler-binder) that it is in principle possible to optimise formulations with relative fast disintegrating times (approx. 70 seconds) by choosing the appropriate water insoluble calcium salt/ superdisintegrant/ filler-diluent ratio.

Therefore, there is no general prejudice in the prior art against the use of a water insoluble calcium salt,

and hence the subject-matter claimed in claim 1 of the main request lacks an inventive step.

6.2 As regards the argument submitted by the respondent that the addition to the formulation of a water insoluble calcium salt unexpectedly improved the disintegration time vis-à-vis the tablets of the closest prior art, the following has been considered:

If an unexpected effect or improvement is advanced as an indication of the presence of an inventive step, due care has to be given to providing a straight comparison with the prior art, since the formulations to be chosen are those **encompassed by the contested claims** which are the closest approximation possible to the formulation exemplified in the closest prior art.

In the present case, the comparative tests provided by the respondent (example 1 versus 1A in the patent in suit, and in the additional technical data filed during the appeal proceedings) always take the formulation of example 1 of the patent in suit. However, this formulation is not the closest approximation possible to the known formulations of the closest prior art encompassed by claim 1. First of all, the active drug of example 1 of document (1) is encapsulated paracetamol and not multiparticulate ibuprofene. Since the active drug is present in high relative amounts in the tested formulations, the nature of the solid active drug plays a role in the compressibility and flowability of the formulation and hence has a bearing on the friability/disintegration time of the obtained tablets. This point has been confirmed by some of the experiments provided by the appellant with the grounds

of appeal. The respondent uses for all its comparisons the same active drug, but the drug should have been multiparticulate (encapsulated) paracetamol, and not multiparticulate ibuprofene, in order to be closest to the specific formulations of document (1).

Moreover, the claims of the contested patent do not exclude the presence of microcrystalline cellulose as an excipient in the formulation. Microcrystalline cellulose is not a superdisintegrant but this excipient does not only classify as a disintegrant, but also as a filler, owing to its good compression properties. In fact, several examples of the patent in suit illustrate formulations containing, apart from the water insoluble calcium salt, microcrystalline cellulose and at least a superdisintegrant (see, *inter alia*, examples 2, 4, 5-7). Hence, the formulation of example 1 is not the closest approximation possible to the specific formulation of example 1 of document (1), because both the sugar for direct compression (160 mg) **and the microcrystalline cellulose** (90 mg) of the formulation disclosed in document (1) have been replaced by dibasic calcium phosphate dihydrate (250 mg).

Another problem arising from an inadequate reproduction of the example of document (1) lies in the exchange of magnesium trisilicate by talc. This exchange has been contested by the appellant, and the data it has submitted with the grounds of appeal raise doubts about the technical reasons for the exchange.

Hence, the comparisons submitted by the respondent cannot serve to demonstrate that an improvement has been attained by the claimed tablets over the tablets

disclosed in document (1). Insofar, the alleged presence of an improvement cannot be used for the definition of a more ambitious technical problem to be solved.

However, it has to be mentioned for the sake of completeness that the formulation of example 1 of document (1) does not specify which is the actual "sugar for direct compression" employed, and a formulation using lactose for direct compression as the filler-binder does not contradict in principle the teaching of document (1).

As regards document (13), this document relates to comparative studies of the tableting properties (in particular compressional behaviour) of several calcium phosphates. Document (13) does not address fast disintegrating tablets and their conflicting requirements in terms of disintegration time/friability. Hence, the general comment about the high friability of tablets prepared from water insoluble calcium salts merely teaches the skilled person to look for appropriate amounts (for instance, low amounts) when he uses a water insoluble calcium salt in fast disintegrating tablets (where, as already said, a certain friability is admissible for attaining good disintegration times). Hence, document (13) cannot be considered to support a general technical prejudice against the use of a water insoluble calcium salt in fast disintegrating tablets. Furthermore, document (13) teaches how the tensile strength of tablets may be also positively influenced by the choice of an adequate lubricant such as magnesium stearate.

6.2.1 Consequently, the set of claims of the main request lacks inventive step (Article 56 EPC).

6.3 *First auxiliary request*

6.3.1 The above analysis in relation to the inventive step issue of the main request also applies *mutatis mutandis* to claim 1 of the first auxiliary request, where the lower limit for the range of the amounts of water insoluble calcium salt is 6% (instead of 2%) by weight.

The respondent did not advance any further argument for the first auxiliary request.

Hence, the set of claims of the first auxiliary request does not meet the requirements of Article 56 EPC.

7. *Remittal*

The decision under appeal concerning the maintenance of the patent in amended form on the basis of the main request does not hold for the reasons given in point 6.1 above. The set of claims of the second auxiliary request was filed during the oral proceedings before the board as a fair attempt to overcome the objections concerning the main request discussed in full for the first time at the said oral proceedings.

Furthermore, the respondent requested at the oral proceedings before the board that the case be remitted to the department of first instance on the basis of the second auxiliary request, in the event that its higher ranking requests were to be found not allowable. In particular, the respondent submitted that the difficult

technical assessment of inventive step justified the request for remittal because it would permit the decision in such an essential matter to be considered by two instances.

The appellant did not disagree with the remittal to the department of first instance for the consideration of inventive step with regard to the subject-matter claimed in the second auxiliary request.

Under these circumstances the board considers it appropriate to allow the subject-matter of the set of claims of the second auxiliary request to be considered by two instances with regard to the substantive issue of inventive step (Article 56 EPC).

Consequently, the board uses its discretion under Article 111(1) EPC by remitting the case to the opposition division for further prosecution on the basis of the second auxiliary request filed at the oral proceedings before the board.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the first instance for further prosecution on the basis of the second auxiliary request.

The Registrar: The Chairman:

M. Schalow U. Oswald