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D E C I S I O N
of 24 September 1996

Case Number: T 1104/92 - 3.3.2

Application Number: 86903120.3

Publication Number: 0222834

IPC: A61K 31/29

Language of the proceedings: EN

Title of invention:
Treatment of non-ulcer dyspepsia with bismuth salts

Applicant:
THE PROCTER & GAMBLE COMPANY

Opponent:
-

Headword:
Bismuth salts/PROCTER & GAMBLE

Relevant legal provisions:
EPC Art. 54, 69, 111(1), 123(2)
EPC R. 86(3); 66(1)

Keyword:
"Late filed claims admitted"
"Reasons for refusing the applications under Article 54 EPC no more relevant"
"Remittal to Examining Division"

Decisions cited:
T 0047/90

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1104/92 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 24 September 1996

Appellant: THE PROCTER & GAMBLE
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 7 August 1992 refusing European patent application No. 86 903 120.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
R. E. Teschemacher

Summary of Facts and Submissions

I. European patent application No. 86 903 120.3 with the European Patent Office publication No. 0 222 834 is based on the international application No. PCT/AU86/00106 filed on 18 April 1986 and published with the international publication No. WO 86/05981, claiming priority of an application filed in Australia on 18 April 1985.

II. The first communication pursuant to Article 96(2) and Rule 51(2) EPC by the Examining Division dated 23 July 1991 was based on a set of claims 1 to 10 filed with letter dated 30 April 1987 before the supplementary European Search Report was established. Claims 1 and 6 (claim 6 is dependent on claim 1 via claims 2 to 5) were worded as follows:

"1. A pharmaceutically acceptable bismuth salt for use in the manufacture of a medicament for treating non-ulcer dyspepsia associated with Campylobacter pyloridis infection.

6. A bismuth salt according to claim 5 wherein both Amoxycillin and Tinidazole are used with the bismuth salt."

The examination revealed among other deficiencies that claim 1 lacked novelty with respect to document

(3) The Medical Journal of Australia, vol. 142, 15 April 1985, pages 439 - 444.

Since the priority document disclosed only bismuth compounds, the priority date of 18 April 1985 was not recognized for the subject matter of the said claim 6 and each of the other claims relating to a combination

of a bismuth salt and one or more antibiotics. According to the said first communication the subject matter of claim 6 did not involve an inventive step in the light of the disclosure of document

(4) Campylobacter III, Proceedings of the Third International Workshop on Campylobacter Infection, Ottawa, 7-10 July 1985, PHLS, Public Health Laboratory Service, London 1985, pages 165/166, Abstract no. 100,

which described the combination of DeNol with amoxycillin or tinidasol. The Examining Division argued as follows: "the cumulative use of antibiotics which can be used **alternatively**, would seem obvious to the person skilled in the art" (emphasis added).

In rebutting these objections, the Appellant inter alia made reference to page 442 of document (3) indicating that "clinical studies are referred to on a 56-year old woman with undiagnosed dyspepsia where treatment with DeNol and erythromycin eradicated *Campylobacter pyloridis* and resolved gastritis".

III. The European patent application was refused by the Examining Division. The decision was based on claims 1 to 6 filed with letter dated 31 January 1992. Claim 1 was worded as follows:

"1. The use in the manufacture of a medicament for treating non-ulcer dyspepsia associated with Campylobacter pyloridis infection of a pharmaceutically acceptable bismuth salt."

Claims 2 to 6 were dependent on claim 1.

II. The ground for the refusal was that the subject-matter of claims 1 and 2 did not meet the requirements of Article 54 EPC and the subject matter of claims 3 to 6 did not meet the requirements of Article 56 EPC.

The Examining Division considered that both document

(2) Austral. New Zealand Journal of Med., 1984, Suppl. 4, 14, (6), page 907

and document (3) disclosed the treatment with DeNol (colloidal bismuth subcitrate) of dyspeptic patients who had no ulcer but having Campylobacter pyloridis and thus each of these documents destroyed novelty of the subject matter of present claims 1 and 2. Although the reported symptoms of the dyspeptic patients without an ulcer might not have been sufficient to diagnose non-ulcer dyspepsia for each of the patients because other diseases could not be excluded, the person skilled in the art realised in the light of the disclosure of documents (2) or (3) that at least some of these patients would suffer from non-ulcer dyspepsia.

The Examining Division furthermore took the view that the priority date of 18 April 1985 could not be accepted for claims 3 to 6 relating to the use of a combination of a bismuth salt and one or more antibiotics. Accordingly, document (4) and document

(5) J. Clin. Pathol. 1986, vol. 39, pages 353 - 365,

formed part of the state of the art under Article 54(2) EPC with regard to the subject matter of these claims.

In the opinion of the Examining Division the difference between the state of the art as represented by document (3) and the subject matter of said claims 3 to 6 was "the combination in the claims of bismuth with

one or more antibiotics". Starting from this prior art, the problem to be solved was the provision of a more active medicament for treating non-ulcer dyspepsia.

Since both document (4) and document (5) disclosed that dyspepsia in the presence of an ulcer might be treated by a therapy directed against Campylobacter pyloridis infection by using bismuth salts in combination with antibiotics, and since document (3) explicitly stated that for therapy the presence of an ulcer may be irrelevant, it was obvious for a person skilled in the art that such a combination could also be effective in non ulcer dyspepsia associated with Campylobacter pyloridis infection. If either document (4) or (5) were considered as the closest state of the art the same conclusion would be reached.

IV. The Appellant lodged an appeal against this decision. Oral proceedings took place on 24 September 1996. At the opening of the oral proceedings the Appellant submitted a new set of claims 1 to 6. Claims 1 and 5 were worded as follows:

"1. A pharmaceutically acceptable bismuth salt in conjunction with amoxycillin and tinidazole for use in the treatment of non-ulcer dyspepsia associated with Campylobacter pyloridis infection.

5. A pharmaceutical composition comprising a pharmaceutically acceptable bismuth salt, amoxycillin and tinidazole and a pharmaceutically acceptable carrier or diluent."

As a reason for the late filing of the amended claims the appellant argued that the Inventor resided in Australia, the Applicant, Procter & Gamble Company, was situated in the United States of America and that the authorised Representative's bureau was in Great

Britain. For these reasons serious communication problems arose. In view of the submitted set of amended claims, it was pointed out in particular that the specific combination of two antibiotics and a bismuth salt now claimed would represent an improvement over prior art compositions. Such improvement could be derived from Example 1 of the application documents originally filed.

V. The Board deplored the late filing of the claims and warned the Appellant that should these claims be admitted into the proceedings having regard to the facts on file, in particular in view of a change of argumentation, a remittal of the case might be considered. It was furthermore pointed out that the new independent claims 1 and 5 related to a pharmaceutical composition per se and that document (3) on page 442 already described a pharmaceutical composition comprising the combination of a bismuth salt and an antibiotica.

VI. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance on the basis of claims 1 to 6 as submitted in the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. The late filing of the new set of claims 1 to 6 raises the procedural problem of their admissibility.

The Board notes that it is the purpose of oral proceedings to enable a final decision to be reached. In general, amendments requiring detailed further

examination are not premissible at this stage in the proceeding. In view of modern communication technologies, the mere reference to communication problems caused by a long distance, without any further reasoning, is not a sufficient ground for admitting late filed claims.

In the present case, however, it is to be noted that the amendments to the new claims a priori did not give rise to any problems regarding their support by the application documents originally filed. The subject matter of the new independent claims relating to a pharmaceutical composition per se is now restricted to a single combination of active compounds which combination for the first time is alleged by the Appellant to involve a particular effect. Furthermore, it has to be taken into account that the Appellant presented a set of amended claims only once during the examining procedure and that during the appeal proceedings a communication has not been issued.

Also considering the degree of success which **might** be achieved in a further examination procedure by the restriction of claims to a very special combination of active compounds, the Board exercises its discretion under Rules 66(1) and 86(3) EPC in favour of the Appellant. Thus, it is decided to admit the new set of claims 1 to 6 into the proceedings.

3. The Appellant has now submitted independent product claims 1 and 5 relating to a pharmaceutical composition *per se*. By the change of category, the extent of protection afforded by these claims within the meaning of Article 69 EPC maybe broader than that afforded by the set of claims on which the decision of the Examining Division is based. This is allowable at this stage, provided no subject matter extends beyond the

content of the application as filed. Claims 1 and 5 are based on claims 1, 6 and 8 originally filed; claims 2, 4 and 6 can be derived from claims 2 and 9 originally filed and claim 3 finds support in "Example 1". The requirements of Article 123(2) EPC are accordingly satisfied.

4. According to the decision under appeal, the objection under Article 54 EPC for lack of novelty is based on a main use claim formulated as a so-called second medical use claim relating to the use of a bismuth salt as the only essential pharmaceutical active compound.

As a consequence of the amendments, the Appellant has restricted the subject matter claimed to the combination of a bismuth salt, amoxycillin and tinidazole.

Furthermore, the new independent claim 3 relating to a second medical use is also restricted to the use of a combination of a bismuth salt, amoxycillin and tinidazole in the manufacture of a medicament. Accordingly, the reasons given in the appealed decision for refusing the application under Article 54 EPC cannot be maintained.

5. The Board notes that the Examining Division already discussed during the examination procedure the matter of novelty and inventive step of a **dependent** claim 6 relating to the use of a bismuth salt in combination with amoxycillin and tinidazole (cf. paragraph II above - novelty was accepted but inventive step denied in view of the provision of an obvious alternative composition in the light of document (4) -).

In the absence of any additional technical information or further evidence provided by the Applicant at this stage of the procedure, however, the Examining Division was not in a position to take into account the alleged unexpected effect or improvement achieved by the combination of a bismuth salt and antibiotics.

The Board notes furthermore that Example 1 of the application as originally filed shows an improvement when administering a bismuth salt in combination with amoxycillin and tinidazole instead of a bismuth salt alone (DeNol). Said Example 1, however, cannot be taken into account as a bismuth salt alone is not illustrative of the closest state of the art presently considered as being document (3). At the oral proceedings, in response to the submission of the amended set of claims, the Board pointed out that, in contrast to what is said in the decision of the Examining Division, document (3) does not disclose the use of DeNol alone but already made reference to a combination of a bismuth salt and an antibiotic. Since the Appellant agreed that document (3) may be taken into account as the closest prior art, a comparison with DeNol alone is clearly not sufficient to demonstrate an unexpected effect or an improvement over the pharmaceutical composition described therein.

The application as originally filed discloses a variety of classes of suitable antibiotics and a list of four antibiotics, namely amoxycillin, erythromycin, tetracycline and tinidazole, found to be particularly efficacious. The Board is prepared to accept that the combination of a bismuth salt with amoxycillin and tinidazole according to Example 1 of the application document, now forming the subject matter of the claims

relating to the pharmaceutical composition, represents a preferred embodiment of the invention. This is in accordance with the common practice of several national patent offices requiring such a correspondence between the main claim and the worked examples.

Under these circumstances, the Board sees no reason to conclude without any further examination, that this invention would not show an improvement over a closest prior art such as document (3) describing a combination of a bismuth salt and an antibiotic compound.

Since there is a need for further evidence in regard to such an improvement, and since at the oral proceedings the Appellant, confronted for the first time with such a prerequisite, was not in a position to provide this evidence, it seems appropriate to give the Appellant the opportunity to present the relevant material in written proceedings.

6. It does not seem appropriate at the present state of the proceedings for the Board to carry out an investigation on the basis of totally new facts not forming the basis for the decision of the Examining Division since the Appellant would be deprived of an instance of jurisdiction. The essential function of appeal proceedings is to determine whether the decision of the first instance was correct (T 47/90, OJ EPO 1991, 486).

Accordingly, the Board has decided to invoke its powers under Article 111(1) EPC to remit the case to the first instance for further examination on the basis of the newly filed claims, thus enabling the Appellant to provide proper and complete comparative data, clearly

showing whether the claimed combination of a bismuth salt and the two specific antibiotics show an improvement or unexpected effect in comparison with a closest prior art already describing a combination of a bismuth salt and one antibiotic compound for example known from document (3).

Order

for these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 6 as submitted in the oral proceedings.

The Registrar: The Chairman:

P. Martorana P. A. M. Lançon