

**Internal distribution code:**

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

**Datasheet for the decision  
of 25 November 2005**

**Case Number:** T 0454/01 - 3.3.02

**Application Number:** 91102986.6

**Publication Number:** 0438183

**IPC:** A61K 31/71

**Language of the proceedings:** EN

**Title of invention:**

Injectable ready-to-use solutions containing an antitumor anthracycline glycoside

**Patentee:**

PHARMACIA & UPJOHN S.p.A.

**Opponents:**

Hexal Aktiengesellschaft  
Durachemie GmbH & Co. KG

**Headword:**

Anthracycline glycoside solution/PHARMACIA

**Relevant legal provisions:**

EPC Art. 54, 87(1),(3),(4), 106, 107, 108, 123(2)  
EPC R. 64

**Keyword:**

"Main request - priority (no), subsequent application mentioned in the patent for claiming priority is not a first application within the meaning of Article 87(1) EPC; allowability of the disclaimer (no) - anticipation under Article 54(2) EPC to be excluded not accidental."  
"Auxiliary request - priority (no) - idem"  
"Novelty (no) - anticipation published before the invalidly claimed priority date"

**Decisions cited:**

G 0002/98, T 0012/81, T 0116/84, T 0198/84, T 0073/88,  
T 0255/91, G 0001/03, G 0002/03, T 0211/93, T 0175/86,  
T 0401/94

**Catchword:**

-



Case Number: T 0454/01 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 25 November 2005

**Appellant I:**  
(Opponent I) Hexal Aktiengesellschaft  
Industriestr. 25  
D-83607 Holzkirchen (DE)

**Representative:** Beszédes, Stephan G.  
Patentanwalt  
Münchener Strasse 80a  
D-85221 Dachau (DE)

**Party as of right**  
(Opponent II) Durachemie GmbH & Co. KG  
Pfaffenriederstrasse 7  
D-82515 Wolfratshausen (DE)

**Representative:** Beszédes, Stephan G.  
Patentanwalt  
Münchener Strasse 80a  
D-85221 Dachau (DE)

**Appellant II:**  
(Patent Proprietor) PHARMACIA & UPJOHN S.p.A.  
Via Robert Koch, 1.2  
I-20152 Milano (IT)

**Representative:** Woods, Geoffrey Corlett  
J.A. KEMP & CO.  
I-20152 Milano (IT)

**Representative:** Woods, Geoffrey Corlett  
J.A. KEMP & CO.  
Gray's Inn  
14 South Square  
London WC1R 5JJ (GB)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
19 February 2001 concerning maintenance of the  
European patent No. 0438183 in amended form.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** G. Rampold  
J. Willems

## Summary of Facts and Submissions

- I. European patent No. 0 438 183 (the "patent") was granted with effect from 8 November 1995 on the basis of European patent application No. 91 102 986.6, which was filed on 28 February 1991 as a divisional application to European patent application No. 87 310 632.2 on which European patent No. 0 273 603 has been granted. In the patent, priority is claimed from
- (a) a national application filed on **5 December 1986** in Great Britain (GB 86 291 93) and
  - (b) a national application filed in the United States on **22 June 1987** (Serial No. 64 653).

The patent relates to injectable ready-to-use solutions containing an antitumor anthracycline glycoside.

- II. The patent contains for all designated Contracting States, except ES and GR, 10 claims. The independent claims as granted read as follows:

"1. A storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution which is sealed in a container, which consists essentially of 4'-epi-doxorubicin hydrochloride dissolved in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml, which has not been reconstituted from a lyophilizate and the pH of which has been adjusted to from 2.5 to 4.0 solely by means of a physiologically acceptable acid.

9. A process for producing the sealed storage stable, sterile, pyrogen-free, injectable solution of any one of the preceding claims, which process comprises
- (i) dissolving the 4'-epi-doxorubicin hydrochloride, which is not in form of a lyophilizate in the physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml;
  - (ii) optionally, adding one or more formulation adjuvants selected from co-solubilizing agents, tonicity adjustment agents, preservatives and pharmaceutically acceptable chelating agents,
  - (iii) adding solely a physiologically acceptable acid to adjust the pH to from 2.5 to 4.0 as desired;
  - (iv) sealing the solution in a container; and the process being effected in such a manner that the resultant solution is sterile and pyrogen-free."

III. The separate set of claims for the Contracting States ES and GR consists of 9 claims; the only independent claim of which reads as follows:

- "1. A process for producing a sealed storage stable, sterile, pyrogen-free, injectable solution of 4'-epi-doxorubicin, which process comprises
- (i) dissolving 4'-epi-doxorubicin hydrochloride, which is not in form of a lyophilizate in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml;
  - (ii) optionally, adding one or more formulation adjuvants selected from co-solubilizing agents,

tonicity adjustment agents, preservatives and pharmaceutically acceptable chelating agents, (iii) adding solely a physiologically acceptable acid to adjust the pH to from 2.5 to 4.0 as desired; (iv) sealing the solution in a container; and the process being effected in such a manner that the resultant solution is sterile and pyrogen-free."

IV. The patent was opposed by two parties in the following sequence:

opponent I (Hexal Aktiengesellschaft, hereinafter also referred to as appellant I) filed opposition on 7 August 1996 with a letter of the same date;

opponent II (Durachemie GmbH & Co., party to the appeal proceedings as of right under Article 107 EPC, second sentence) filed opposition on 8 August 1996 with a letter of the same date.

Both opponents requested revocation in full of the patent under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC).

V. Of the numerous documents cited in the course of the first instance opposition and subsequent appeal proceedings, the following remain relevant to this decision:

- (1) UK priority application No. 86 29 193 of 5 December 1986;
- (2) DE-A-3 621 844, published on 5 March 1987, . i.e. in the period between the earlier first priority

date of 5 December 1986 and the later second priority date of 22 June 1987 claimed in the patent;

(2c) UK priority application No. 85 19 452 of 2 August 1985;

(8) DE-A-3 536 896

VI. In its interlocutory decision pronounced at the close of the oral proceedings on 18 January 2001, with written reasons notified on 19 February 2001, the opposition division refused the proprietor's main request, filed on 2 June 1999 with a letter dated 24 May 1999, and maintained the patent in amended form on the basis of claims 1-9 in the proprietor's first and sole auxiliary request filed during oral proceedings on 18 January 2001.

Claim 1 of the **main request** before the opposition division for all designated Contracting States, except ES and GR, reads as follows (with the amendments to claim 1 as granted highlighted in bold italic letters below):

"1. A storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution which is sealed in a container, which consists essentially of 4'-epi-doxorubicin hydrochloride dissolved in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml, which has not been reconstituted from a lyophilizate and the pH of which has been adjusted to from 2.5 to 4.0 solely by means of a physiologically acceptable acid;



excluding solutions with a pH of about 3 either in sterile water alone or in sterile water containing one or more components chosen from ethanol, propylene glycol, N,N-dimethylacetamide, polyethyleneglycol 400 and polyvinylpyrrolidone."

The independent claims of the **first auxiliary request** before the opposition division for all designated Contracting States, except ES and GR, read as follows (with the amendments to claim 1 as granted highlighted in bold italic letters below):

- "1. A **product which is a** storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution which is sealed in a container, which consists essentially of 4'-epi-doxorubicin hydrochloride dissolved in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml; **which solution also contains a tonicity adjustment agent selected from dextrose, lactose and mannitol,** has not been reconstituted from a lyophilizate and the pH of which has been adjusted to from 2.5 to 4.0 solely by means of a physiologically acceptable acid.
  
9. A process for producing **a product according to** any one of the preceding claims, which process comprises:
  - (i) dissolving the 4'-epi-doxorubicin hydrochloride, which is not in form of a lyophilizate in the physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml;

(ii) *adding a tonicity adjustment agent selected from dextrose lactose and mannitol* and optionally one or more formulation adjuvants selected from co-solubilizing agents, preservatives and pharmaceutically acceptable chelating agents,  
(iii) adding solely a physiologically acceptable acid to adjust the pH to from 2.5 to 4.0 as desired;  
(iv) sealing the solution in a container; and the process being effected in such a manner that the resultant solution is sterile and pyrogen-free."

VII. The essence of the reasoning of the opposition division in its interlocutory decision was as follows:

(i) As regards the proprietor's main request (see VI above), the opposition division found that the disclaimer introduced into claim 1 (see VI above) was not acceptable under Article 123(2) EPC.

(ii) It further noted that the earlier priority of 5 December 1986 (see document (1)) claimed in respect of the disputed patent was not valid because, in the opposition division's judgment, the subsequent application (1) from which priority was claimed was not to be considered to be the "first application" within the meaning of Article 87(1) EPC, due to the existence of the previous application (2c), the priority of which had already been claimed in respect of document (2). The opposition division accordingly concluded that the content of citation (2) formed part of the state of the art within the meaning of Article 54(2) EPC and was therefore prejudicial to the novelty of claim 1,

irrespective of whether or not the disclaimer was considered to be acceptable.

(iii) As regards the proprietor's first auxiliary request, the opposition division considered that the subject-matter of claim 1 as amended, stipulating the presence of a tonicity agent selected from dextrose, lactose and mannitol be present in the 4'-epi-doxorubicin hydrochloride solution (see VI above), was entitled to the priority date of 5 December 1986 and that the content of citation (2) did not, therefore, form part of the state of the art. The opposition division further considered that the claimed subject-matter in the first auxiliary request was novel and inventive over citation (8) and that the patent could thus be maintained in amended form on the basis of the first auxiliary request.

VIII. Two parties involved in the opposition proceedings appealed against this decision in the following sequence:

appellant I (opponent I) filed an appeal on 19 April 2001 by letter of the same date, requesting the cancellation of the above decision and revocation of the patent in its entirety;

appellant II (proprietor of the patent) filed an appeal on 23 April 2001 with its letter of 20 April 2001, requesting in its **main request** that the above decision be set aside and that the board uphold the patent on the basis of the main request corresponding to the main request before the opposition division (see V above).

As its **first and sole auxiliary request** (hereinafter referred to as "auxiliary request"), appellant II requested maintenance of the patent in amended form on the basis of a set of claims which correspond closely to those upheld by the opposition division. Claim 1 for all designated contracting states, except ES and GR, reads as follows, with lettering added by the appellant:

"1. A product which is a storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution which is sealed in a container, wherein (a) the solution consists essentially of 4'-epi-doxorubicin hydrochloride dissolved in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml; (b) the solution also contains a tonicity adjustment agent selected from dextrose, lactose and mannitol, (c) the solution has not been reconstituted from a lyophilizate and (d) the pH of the solution has been adjusted to from 2.5 to 4.0 solely by means of a physiologically acceptable acid."

Claims 2 to 9 are identical to those maintained by the opposition division.

- IX. Both appellants paid the appeal fees and filed their statements of grounds of appeal within the prescribed time limit.
  
- X. Both appellants and opponent II (party to the appeal proceedings as of right under Article 107 EPC, second sentence) were represented in the oral proceedings held before the board of appeal on 25 November 2005.

Appellant I and opponent II were represented by the same representative.

XI. The arguments of appellant I as submitted in writing and during the oral proceedings, in so far as they are relevant to the present decision, can be summarised as follows:

[1] The opposition division was correct in its finding that the claimed subject-matter in the main request was not entitled to priority from UK patent application No. 86 29 193 of 5 December 1986 **(1)**.

[2] In this context, it was recalled by appellant I that the range of the pH value of the solutions of anthracycline glycosides disclosed in the subsequent UK patent application **(1)** was 2.5 to 4.0 compared to the range of 2.5 to 6.5 disclosed in previous UK patent application No. 85 19 452 of 2 August 1985 **(2c)**. This meant that solutions claimed in claim 1 of the main request having a pH of 2.5 were not entitled to priority from the subsequent application **(1)** because in this respect the latter was not the first application within the meaning of Article 87(1) EPC.

[3] Appellant I then referred to paragraph II:iii of the Reasons on page 5 of the contested decision where the opposition division drew, in the appellant's opinion, the correct conclusion that, even if the disclaimer in claim 1 was considered to be acceptable (which in fact it was not), citation **(2)** was nevertheless prejudicial to the novelty of the claimed subject-matter in the main request because the disclaimer did not exclude solutions (products) having

a pH of 2.5. Such solutions were already disclosed in citation (2).

[4] Appellant I went on to state that not only the individual pH values of 2.5 and 3.0 but also the entire range of the pH from 2.5 to 4.0 claimed in claim 1 of the main request were not entitled to priority. It drew attention to the consistent case law of the boards of appeal and concluded therefrom that the marginally broader range of the pH from 2.5 to 5.5 which was explicitly mentioned in the previous application (2c) must be deemed to embrace and, accordingly, to disclose the sub-range of 2.5 to 4.0 mentioned in the subsequent application (1) and in present claim 1.

[5] Since the main request was not entitled to the priority of the subsequent application (1), citation (2) formed part of the state of the art under Article 54(2) EPC and destroyed the novelty of claim 1 in its entirety.

[6] Appellant I went on to state that the disclaimer in claim 1 of the main request was not admissible. Contrary to the assertion of appellant II, citation (2) was part of the state of the art under Article 54(2) EPC and as such relevant to an assessment not only of novelty, but also of inventive step and was therefore certainly not an accidental disclosure. As citation (2) was prejudicial to the novelty of claim 1, lack of inventive step was the unavoidable consequence. The appellant argued that in line with the boards' established case law, a disclaimer could be used to make an inventive teaching which overlaps with the

state of the art novel but it could not make an obvious teaching inventive.

[7] As regards the auxiliary request, it was pointed out by appellant I that the sole limitation of claim 1 in the auxiliary request over claim 1 in the main request consisted in the additional feature stipulating the presence of a tonicity adjustment agent selected from dextrose, lactose and mannitol in the claimed products (solutions). In this context appellant I referred to the opposition division's conclusions in the contested decision, namely that the three tonicity agents dextrose, lactose and mannitol recited in claim 14 of the subsequent application (1) represented a selection from the broader list of tonicity adjusting agents disclosed in previous UK patent application (2c), thereby conferring novelty by selection on the products disclosed in the subsequent UK patent application (1).

[8] Appellant I disagreed with the above conclusions of the opposition division on the grounds that the disclosure of the list of possible tonicity adjustment agents was identical in the previous application (2c) (see page 5, lines 1 to 4) and in the subsequent application (1) (see page 5, lines 3 to 7 from the bottom), in both these applications reading as follows: *"Suitable tonicity adjustment agents may be, for example, physiologically acceptable inorganic chlorides, e.g. sodium chloride, dextrose, lactose, mannitol and the like"*.

[9] From the foregoing it was in the opinion of appellant I clear that, also as far as the addition of a tonicity agent selected from dextrose, lactose and

mannitol was concerned, the subsequent UK patent application (1) from which the contested patent claimed priority and claim 1 of the auxiliary request were not novel over the disclosure in the previous application (2c). Said **subsequent** patent application (1) was thus not a first application within the meaning of Article 87(1) EPC and could not serve as a basis for claiming priority in respect of the claimed subject-matter in the auxiliary request.

[10] Since the auxiliary request was also not entitled to the priority date of 5 December 1986, the earliest possible priority date in respect of the claims in the auxiliary request was the filing date of US patent application Serial No. 64 653, filed on **22 June 1987**. The content of citation (2) was accordingly comprised in the state of the art under Article 54(2) EPC.

[11] Citation (2) disclosed products (solutions) containing all the technical features of claim 1 of the auxiliary request, including the presence of a tonicity adjusting agent selected from inorganic chlorides, e.g. sodium chloride, dextrose, lactose and mannitol (see page 4, lines 13-14). In these circumstances appellant I maintained that the first auxiliary request could also not serve as the basis for the maintenance of the patent on the grounds of lack of novelty.

XII. The arguments presented by appellant II in its written submissions and at the hearing before the board, in so far as they are relevant to the present decision, are summarised below:



[12] It was pointed out by appellant II that in the judgment of the opposition division the claims of the main request were not entitled to priority from subsequent UK patent application No. 86 29 193 of 5 December 1986 **(1)**, because the subject-matter of these claims was already disclosed in previous UK patent application No. 85 19 452 of 2 August 1985 **(2c)**. In the opinion of appellant II, the opposition division was incorrect in its finding that subsequent UK patent application No. 86 29 193 of December 1986 **(1)** was not the "**first application**" within the meaning of Article 87(1) EPC for determining priority, due to the existence of previous application **(2c)** from which, inter alia, citation **(2)** claimed priority.

[13] Appellant II argued that the products specified in the claims of the main request differed from those disclosed in UK patent application **(2c)** in a crucial respect. That was the pH of the 4'-epi-doxorubicin solutions. Thus the pH of the solutions disclosed in the subsequent application **(1)** and specified in claim 1 of the main request was from 2.5 to 4.0. In contrast thereto, the pH of the solutions disclosed in application **(2c)** could be from 2.5 to 6.5.

[14] According to appellant II, the effect of this important difference between the products claimed in the main request and those disclosed in **(2c)** was that the former could be derived from the generic disclosure in previous application **(2c)** only by selecting particular values from two parameters which could vary widely in application **(2c)**. In particular, the solutions specified in the main request could be derived from application **(2c)** only by selecting 4'-epi-

doxorubicin from the list of anthracycline glycosides set out in claim 3 and by further selecting a pH range of 2.5 to 4.0 from the broad range of 2.5 to 6.5 disclosed in application **(2c)**. Appellant II argued that products which could only be derived by selecting from two parameters in this way could not be said to be directly and unambiguously disclosed in application **(2c)**, according to the strict test set out in G 2/98 (OJ EPO, 2001, 413).

[15] In contrast, the pH range from 2.5 to 4.0 was explicitly disclosed in claim 1 of priority application **(1)**. Thus, although it was necessary to select 4'-epi-doxorubicin from the list of anthracycline glycosides set out in claim 3 of application **(1)** to arrive at the subject-matter claimed in the main request, no significant further selection was required. This was because the remaining features of the main request could be found in priority application **(1)** at page 4, lines 9 to 13, page 8, line 21, and claims 1, 2, 6 and 12. In this respect appellant II noted that options disclosed in a single list were, of course, each regarded as being directly and unambiguously disclosed. Accordingly, the 4'-epi-doxorubicin solutions specified in the main request were directly and unambiguously derivable from subsequent application **(1)**. The subject-matter claimed in the main request was therefore entitled to priority from the subsequent UK patent application **(1)**.

[16] The disclaimer in the main request was limited to solutions which lacked novelty over citation **(2)**. This citation prejudiced claims in the present patent only to the extent that such claims were not entitled to

priority from UK patent application No. 86 29 193 **(1)**. The disclaimer in claim 1 of the main request was exactly co-terminous with the corresponding disclaimer in **(1)** (see page 4, lines 9 to 18). As was discussed in the foregoing paragraphs, all of the products specified in the main request which were outside the disclaimer were fully entitled to priority from **(1)**, and were thus novel over citation (2). The disclaimer in the claims of the main request accordingly operated to avoid overlap with the "novelty-only citation" **(2)**. It must therefore be regarded as allowable under Article 123(2) EPC.

[17] Appellant II maintained that the opposition division was correct in its opinion that claims entitled to priority were novel and inventive over the complete prior art cited in the opposition.

[18] The claims of the first auxiliary request corresponded closely to those upheld by the opposition division. Appellant II supported the conclusion of the opposition division that these claims were formally allowable and also fully entitled to priority from UK patent application No. 86 29 193 of 5 December 1986 **(1)**. In the opinion of appellant II, the opposition division was also correct in its finding in the impugned decision that the subject-matter claimed in the first auxiliary request was novel in that the solutions disclosed in the closest prior art **(8)** were not stored in a sealed container before lyophilisation took place. It was also correct in holding the claimed subject-matter to be based on an inventive step because **(8)** stipulated that the lyophilisation of the compositions was a requirement in order to obtain storage-stable

products. Thus the teaching of (8) taught away from the claimed invention in the patent.

XIII. Both appellants I and II maintained at the oral proceedings their requests already filed in the written appeal proceedings (see VII above).

Thus, the appellants (appellant I, opponents) requested that the decision under appeal be set aside and that the patent be revoked.

The appellant (appellant II, patentee) requested that the decision under appeal is set aside and that the patent be maintained in amended form on the basis of the main request or, alternatively, the auxiliary request filed with the grounds of appeal dated 27 June 2001.

### **Reasons for the decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

#### ***Main request of appellant II***

2. ***Priority***

- 2.1 The contested patent relates to injectable ready-to-use solutions containing an antitumor anthracycline glycoside. It is based on European patent application No. 91 102 986.6, filed on 28 February 1991 by appellant II as a divisional application to European

parent application No. 87 310 632.2, which was filed on **3 December 1987**, claiming two priorities from

- (a) UK patent application No. 86 291 93 **(1)**, filed on **5 December 1986** (hereinafter referred to as the "**subsequent application**") and
- (b) US patent application Serial No. 64 653, filed on **22 June 1987**.

Both applications from which priority is claimed were thus filed less than 12 months before the date of filing the parent application and, accordingly, before the **effective filing date** of the present divisional application of 3 December 1987.

2.2 However, appellant II had already filed on **2 August 1985**, i.e. more than 12 months before the date of filing the parent application and the effective filing date of the present divisional application, UK patent application No. 85 194 52 **(2c)**, likewise relating to injectable ready-to-use solutions containing an antitumor anthracycline glycoside (hereinafter referred to as the "**previous application**").

2.3 According to Article 87(1) EPC, a right of priority may be enjoyed for the same invention only during a period of twelve months from the date of filing of the **first** application.

Article 87(4) EPC rules that "*a **subsequent** application for the same subject-matter as a **previous** application filed in or in respect of the same State shall be considered as the **first** application for the purposes of determining priority, provided that, at the date of filing the **subsequent** application, the **previous***

*application has been withdrawn, abandoned or refused, without being open to public inspection, and without leaving any right outstanding, and has not served as a basis for claiming a right of priority. The **previous** application may not thereafter serve as a basis for claiming a right of priority".*

2.3.1 This means that where, in addition to the **subsequent** application whose priority the applicant claims in the European patent application (European patent), the same applicant has already filed a **previous first** application - in particular, before the priority interval - there is no entitlement to priority if the invention claimed in the European patent application (European patent) has already been disclosed in this **previous** application. This, of course, does not apply where Article 87(4) EPC is applicable, i.e. the **previous** application has left no rights outstanding.

2.4 The first question to be decided in this appeal is therefore whether appellant II is correct when it states that, in contrast to the finding of the opposition division, **subsequent** UK patent application No. 86 291 93 (1), filed on **5 December 1986**, should be considered as the **first application** for determining priority.

2.4.1 As regards the main request, in the board's view the opposition division was entirely correct in its opinion in the decision under appeal (see Reasons, paragraph IIIi) that the priority claimed from **subsequent** UK patent application No. 86 291 93 (1), filed on **5 December 1986**, is not valid because this application could not be considered to be the "**first application**"

within the meaning of Article 87(1) and (3) EPC, due to the existence of **previous** UK patent application No. 85 194 52 (**2c**), filed on **2 August 1985**, the priority of which has been claimed, for example, in respect of citation (**2**). The exception of Article 87(4) EPC is therefore **not** applicable to the present case (see 2.3 and 2.3.1 above).

2.4.2 In accordance with decision G 2/98 (*loc. cit.*, see especially Reasons, point 8.2) the same criteria are to be applied in assessing

(i) whether a claim in a later European patent application is in respect of the **same invention** as the priority application pursuant to Article 87(1) EPC and

(ii) whether an application is to be regarded as the **first application** pursuant to Article 87(1) and (3) EPC for the purposes of determining priority.

2.4.3 In its decision G 2/98 (*loc. cit.* see especially Reasons, point 8.4), the Enlarged Board of Appeal ruled: *"If the invention claimed in a later European patent application constitutes a so-called selection invention - i.e. typically, the choice of individual entities from larger groups or of sub-ranges from broader ranges of numerical values - in respect of the subject-matter disclosed in a first application whose priority is claimed, the criteria applied by the EPO with a view to assessing novelty of selection inventions over the prior art must also be considered carefully when assessing whether the claim in the European patent application is in respect of the same invention as the priority application within the meaning of Article 87(1) EPC. Otherwise, patent*

*protection for selection inventions, in particular in the field of chemistry, could be seriously prejudiced if these criteria were not thoroughly complied with when assessing priority claims in respect of selection inventions. Hence, such priority claims should not be acknowledged if the selection inventions in question are considered "novel" according to these criteria."*

2.4.4 It is clear from the observations in foregoing point 2.4.3 that the criteria applied by the EPO with a view to assessing novelty of selection inventions over the prior art must also be considered carefully when assessing in the present case whether or not **subsequent** UK patent application No. 86 291 93 **(1)** is to be regarded as the **first application** pursuant to Article 87(1) and (3) EPC, , for the purposes of determining priority, in spite of the existence of the previous UK patent application **(2c)**. For assessing whether or not the UK priority application **(1)** is actually the first application within the meaning of Article 87(1) and (3) EPC, it is thus necessary to determine whether the previous UK patent application **(2c)** already discloses the same invention as claim 1 of the main request, i.e. whether it destroys its novelty according to the criteria outlined in 2.4.2 above (see for instance T 255/91, OJ EPO 1993, 318; T 116/84 of 28 November 1984).

2.5 Claim 1 of the main request reads as follows (paragraph lettering added):

- (a)** a storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution
- (b)** which is sealed in a container,



- (c) which consists essentially of 4'-epi-doxorubicin hydrochloride
- (d) dissolved in a physiologically acceptable aqueous solvent therefor
- (e) at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml,
- (f) which has not been reconstituted from a lyophilizate and
- (g) the pH of which has been adjusted to from 2.5 to 4.0
- (h) solely by means of a physiologically acceptable acid;

provided that the solution is not a solution with a pH of about 3 either in sterile water alone or in sterile water containing one or more components chosen from ethanol, propylene glycol, N,N-dimethylacetamide, polyethyleneglycol 400 and polyvinylpyrrolidone.

2.5.1 UK priority application No. 86 291 93 **(1)**, as a whole, filed on **5 December 1986** contains in respect of the features **(a)** to **(h)** in claim 1 of the above main request the following disclosures (emphasis added by the board):

- (a) the present invention relates to a **storage stable, injectable, ready-to-use solution** of an antitumor anthracycline glycoside ..... (see page 1, first paragraph);  
the present invention provides a sterile, pyrogen free, anthracycline glycoside solution ..... (see page 3, lines 10-11);  
**a storage stable, sterile, pyrogen-free, anthracycline glycoside solution** which consists essentially of a physiologically acceptable salt

- of an anthracycline glycoside ..... (see claim 1);
- (b) preferably the solution of the invention is provided **in a sealed container** (see page 4, lines 19-20; claim 2);
  - (c) anthracycline glycoside solution which consists essentially of **a physiologically acceptable salt** of an anthracycline glycoside .... (page 3, lines 11-13; claim 1); preferably the anthracycline glycoside is chosen from the group consisting of doxorubicin, **4'-epi-doxorubicin (i.e. epirubicin)**, 4'-desoxy-doxorubicin (i.e. esorubicin), 4'-desoxy-4'-iodo-rubicin, daunorubicin and 4'-4-demethoxy-daunorubicin (i.e. idarubicin) (see page 4, lines 21-25; claim 3); the **salt with hydrochloric acid** is a particularly preferred salt (see page 4, last two lines; claim 6 in combination with claim 3);
  - (d) dissolved in a physiologically acceptable solvent therefor (see page 3, lines 13-14; claim 1); suitable solvents and co-solubilizing agents may be, for instance **water e.g. water for injections**; a 0.9% sodium chloride solution, i.e. physiological saline; an aqueous 5% dextrose solution ..... (see page 5, second full paragraph; claims 7 and 8); **water, physiological saline; and 5% dextrose solution** are particularly preferred (see page 6, lines 17-19);
  - (e) in the solutions of the invention the concentration of the anthracycline may vary within, preferably from 0.1 mg/ml to 100 mg/ml, in particular **from 0.1 mg/ml to 50 mg/ml** ..... (see page 7; first full paragraph; claim 10);

- (f) [solution] which has not been reconstituted from a lyophilizate (see page 3, lines 14-15; claim 1); and
- (g) the pH of which has been adjusted to from 2.5 to 4.0 (page 3, lines 15-16; claim 1);
- (h) to adjust the pH within the range of from 2.5 to 4.0 a **physiologically acceptable acid** or buffer is added as desired (see page 6, lines 20-23);

the exclusion embraces solutions with a pH of about 3 of anthracycline glycoside salts (such as the hydrochloride salt of doxorubicin, **4'-epi-doxorubicin**, 4'-desoxy-doxorubicin, 4'-desoxy-4'-iodo-rubicin, daunorubicin or 4'-4-demethoxy-daunorubicin) either in sterile water alone or in sterile water containing one or more components chosen from ethanol, propylene glycol, N,N-dimethylacetamide, polyethylene glycol 400 (polyoxyethylene glycol with a molecular weight of 400) and polyvinylpyrrolidone (see page 4, lines 9-18).

2.5.2 UK patent application No. 85 194 52 (**2c**), as a whole, filed on **2 August 1985**, contains in respect of the features (**a**) to (**f**) in claim 1 of the main request the following disclosures (emphasis added by the board):

- (a) The present invention relates to a **stable, intravenously injectable, ready-to-use solution** of an antitumor anthracycline glycoside ..... (see page 1, first paragraph); according to the present invention, there is provided a **sterile, pyrogen-free, anthracycline glycoside solution** ..... (see page 3, lines 1-2); **a sterile pyrogen-free, anthracycline glycoside solution** which consists essentially of a

- physiologically acceptable salt of an anthracycline glycoside ..... (see claim 1);
- (b) preferably the solution of the invention is provided **in a sealed container** (see page 3, lines 7-8); claim 2);
- (c) anthracycline glycoside solution which consists essentially of a **physiologically acceptable salt** of an anthracycline glycoside .... (page 3, lines 2-4; claim 1); preferably the anthracycline glycoside is chosen from the group consisting of doxorubicin, **4'-epi-doxorubicin (i.e. epirubicin)**, 4'-desoxy-doxorubicin (i.e. esorubicin), 4'-desoxy-4'-iodo-rubicin, daunorubicin and 4'-4-demethoxy-daunorubicin (i.e. idarubicin) (see page 3, lines 9-13; claim 3); the **salt with hydrochloric acid** is a particularly preferred salt (see page 3, lines 3-4 from the bottom; claim 6); ..... similar stability data can be observed also for analogous solutions containing **4'-epi-doxorubicin as hydrochloride salt** (see end of all Examples 1 to 13);
- (d) dissolved in a physiologically acceptable solvent therefor (see page 3, lines 4-5; claim 1); suitable solvents and co-solubilizing agents may be, for instance **water** e.g. **water for injections**; a 0.9% sodium chloride solution, i.e. physiological saline; an aqueous 5% dextrose solution ..... (see page 4, first full paragraph; claims 9 and 10); examples of preferred solvents are **water**, ethanol, polyethyleneglycol and dimethylacetamide as well as mixtures in various proportions of these solvents; **water** is a particularly preferred solvent (see page 5, fourth paragraph);

- (e) in the solutions of the invention the concentration of the anthracycline may vary within, preferably from 0.1 mg/ml to 100 mg/ml, in particular **from 0.1 mg/ml to 50 mg/ml** .....  
(see page 6; third full paragraph; claim 12);
- (f) [solution] which has not been reconstituted from a lyophilizate (see page 3, lines 5-6; claim 1); and
- (g) which has a **pH of from 2.5 to 6.5** (page 3, lines 15-16; claim 1);
- (h) to adjust the pH within the range of from 2.5 to about 6.5 a **physiologically acceptable acid** may be added as desired (see page 5, lines 16-18).

### 2.5.3 Comparison of

- the disclosure of the features **(a) to (h)** in previous UK patent application No. 85 194 52 **(2c)**, as a whole, filed on **5 August 1985** (see 2.5.2 above) with
- the disclosure of the corresponding features **(a) to (h)** in subsequent UK patent application No. 86 291 93 **(1)**, as a whole, filed on **5 December 1986** (see 2.5.1 above) from which the patent claims priority, and
- with the disclosure of the corresponding features **(a) to (h)** contained in claim 1 of the patent (see 2.5 above)

shows that the previous application **(2c)** does **not** differ from the subsequent application **(1)**, from which the patent claims priority, **and** from claim 1 of the patent with regard to features **(a) to (f)** and **(h)**. Since 4'-epi-doxorubicin is mentioned as an example of a suitable anthracycline glycoside

component in **(2c)** and in **(1)** and also in claim 1 of the patent, there is also agreement in respect of the anthracycline glycoside used in feature **(c)**, even if the latter is more broadly defined in both applications **(2c)** and **(1)** than in claim 1 of the patent.

2.5.4 The sole difference between the **previous** application **(2c)**, on the one hand, and the **subsequent** application **(1)**, from which the patent claims priority, and claim 1 of the patent, on the other, consists in the definition of feature **(g)**. According to the **previous** application **(2c)**, the solutions of the anthracycline glycoside are adjusted to a pH value within the broader range **from 2.5 to 6.5** compared to the sub-range **from 2.5 to 4.0** in the **subsequent** application **(1)** and in claim 1 of the patent.

2.5.5 In its written and oral submissions appellant II considered this difference as crucial for the assessment of novelty. The board cannot agree and makes the following three principal observations in this respect.

2.5.6 **First**, as regards the novelty of the products (solutions) disclosed in the subsequent application **(1)** and in present claim 1, which have been adjusted to the selected sub-range of the pH value of **from 2.5 to 4.0**, over products (solutions) disclosed in previous application **(2c)** and adjusted to the broader range of **from 2.5 to 6.5**, the principles applied by the boards as part of their established case law on the novelty of a selected sub-range of numerical values from a broader range of numerical values can be summarised briefly as

follows (see T 198/84, OJ EPO 1985, 209): a selection of a sub-range of numerical values from a broader range is new when **both** of the following criteria are satisfied:

- (i) the selected sub-range should be narrow;
- (ii) the selected sub-range should be sufficiently far removed from the preferred part of the known range (as illustrated in the examples given in the prior art).

2.5.7 As will be demonstrated below, the criteria set forth above for the novelty of a sub-range of numerical values selected from a broader range are not met in present claim 1:

- (i) neither represents the selected sub-range of the pH value from **2.5 to 4.0** for the solutions in **(1)** and in claim 1 of the main request a small or narrow specimen from the broader range extending from **2.5 to 6.5**, let alone from the preferred marginally broader ranges extending from **2.5 to 5.5** and from **3 to 5.2** disclosed for the solutions in **(2c)** - see page 6, line 11-12; claim 7;
- (ii) nor is the sub-range of **2.5 to 4.5** in any way removed from the ranges of **2.5 to 6.5** or **2.5 to 5.5** or **3 to 5.2** as disclosed in **(2c)**. On the contrary, the lower limit of the pH of **2.5** is **identical** for the ranges disclosed in the previous application **(2c)** and for the range disclosed in **(1)** and in claim 1 of the patent.

Moreover, as appellant I correctly pointed out in its submissions, previous application **(2c)** already

discloses on page 6, lines 13-14, and on page 8, lines 12-13, that a pH of about **3**, falling in the middle of the selected sub-range of **2.5 to 4.0** is a particularly preferred value. The same disclosure is found in priority application **(1)** on page 6, last two lines ("a pH of about **3** is particularly preferred .....") and in the patent (see claim 8 which is dependent on claim 1).

Notwithstanding the board's finding referred to in paragraph 3 below that the disclaimer in present claim 1 is not admissible, that disclaimer and the co-terminous disclaimer in **(1)** would exclude the pH value of **3** only for solutions with certain specific solvents. It would therefore be insufficient to exclude the novelty-destroying effect on present claim 1 of the pH value of **3** which is disclosed in **(2c)** in general and which is not limited to the specific solvents excluded by the disclaimer.

2.5.8 For the foregoing reasons it is clear that the products (solutions) the pH of which has been adjusted to from 2.5 to 4.0, as disclosed in subsequent application **(1)** and claimed in claim 1 of the main request, do **not** represent for patent law purposes a **novel selection** from the products (solutions) adjusted to a pH from 2.5 to 6, as disclosed in **(2c)**.

2.6 **Second**, appellant II also argued that the solutions specified in claim 1 of the main request can be derived from application **(2c)** only by selecting 4'-epi-doxorubicin from the list of anthracycline glycosides set out in the description and claim 3 of **(2c)** (see 2.5.1 **(c)** above) and by further selecting a pH range of



from 2.5 to 4.0 from the broad range of 2.5 to 6.5 disclosed in application **(2c)** and that products which can only be derived by selecting two parameters in this way cannot be said to be directly and unambiguously disclosed in application **(2c)**. This argument appears to the board to be misconceived because it seems to be based on a misunderstanding of the principles applied by the boards of appeal as part of their established case law on the novelty of selection inventions.

- 2.6.1 The previous application **(2c)** discloses a sterile pyrogen-free, anthracycline glycoside solution which consists essentially of a physiologically acceptable salt of an anthracycline glycoside dissolved in a physiologically acceptable solvent therefor **which has a pH from 2.5 to 6.5** (see page 3, first paragraph). Furthermore, in the following paragraph, application **(2c)** discloses that the anthracycline glycoside is selected from doxorubicin, **4'-epi-doxorubicin**, 4'-desoxy-doxorubicin, 4'-desoxy-4'-iodo-rubicin, daunorubicin and 4'-4-demethoxy-daunorubicin.
- 2.6.2 As far as the nature of anthracycline glycoside and the range of the pH value of the solutions (products) are concerned, these are specified in **previous** application **(2c)**
- (i)** by one **variable parameter, i.e.** the examples of the six anthracycline glycosides given in the list at page 3, first paragraph, and in claim 3, consisting of doxorubicin, **4'-epi-doxorubicin**, 4'-desoxy-doxorubicin, 4'-desoxy-4'-iodo-rubicin, daunorubicin and 4'-4-demethoxy-daunorubicin and

- (ii) by one **invariable parameter**, i.e. the range of the pH value from 2.5 to 6.5.

It necessarily follows that the following six possible options of products (solutions) are, of course, each regarded as being directly and unambiguously disclosed in **(2c)** by explicit description:

- (a) solutions containing as the anthracycline glycoside doxorubicin and having a pH from 2.5 to 6.5;
- (b) solutions containing as the anthracycline glycoside **4'-epi-doxorubicin** and having a pH from 2.5 to 6.5;
- (c) solutions containing as the anthracycline glycoside 4'-desoxy-doxorubicin and having a pH from 2.5 to 6.5;
- (d) solutions containing as the anthracycline glycoside 4'-desoxy-4'-iodo-rubicin doxorubicin and having a pH from 2.5 to 6.5;
- (e) solutions containing as the anthracycline glycoside daunorubicin and having a pH from 2.5 to 6.5;
- (f) solutions containing as the anthracycline glycoside 4'-4-demethoxy-daunorubicin and having a pH from 2.5 to 6.5.

2.6.3 As demonstrated in 2.5.7 and 2.5.8 above, products (solutions) the pH of which has been adjusted to from 2.5 to 4.0, as disclosed in subsequent application **(1)** and claimed in claim 1 of the main request, do **not** represent for patent purposes a **novel selection** from products (solutions) adjusted to a pH from 2.5 to 6, as disclosed in **(2c)**. Thus, it requires only a moment's thought to appreciate that solutions containing as the

anthracycline glycoside **4'-epi-doxorubicin** and having a pH from 2.5 to 4.0, as claimed in claim 1 cannot be considered as a novel selection from previous application (**2c**), because the latter discloses explicitly and unequivocally solutions containing as the anthracycline glycoside **4'-epi-doxorubicin** and having a pH from 2.5 to 6.5 (see 2.6.2 above, option (b)).

2.6.4 For the sake of clarity and to avoid any misunderstanding, it should be noted that the present case is not comparable with those decided in landmark decision T 12/81 (OJ EPO 1982, 296) and the substantial body of case law which has been developed by the boards of appeal in this respect (see as a few examples only T 401/94 of 18 August 1994, see especially Reasons, point 4.4; T 211/93 of 11 July 1995, see especially Reasons, point 3; and T 175/86 of 6 November 1990, see especially Reasons, point 5; all referred to in "Case Law of the Boards of Appeal of the European Patent Office" 4th Edition, 2001, I.C.4., pages 73-76).

In all the above cases, selection is made from **two different lists** of some length of **variable parameters** given in each of the two lists. Combinations obtained in this way by selecting one variable parameter from the first list and another variable parameter from the second list result in **an exponential multiplication and widening** of the range of possible combinations. The new element - indispensable if a substance selection is to be recognised as new for patent law purposes - is attributable to the fact that the specific combination actually selected from the wide range of all theoretically (intellectually) possible combinations

has not been disclosed to the public in individualised form in the prior art document. This necessarily presupposes that a selection is made from both the range of variable parameters given in the first list and also from the range of parameters given in the second list because only in this case is the selected substance or composition the result of the combination of two variable parameters, the number of possible combinations thereby multiplying exponentially. As clearly shown in 2.6.2 above, this particular selection principle does not apply to the present case.

2.7 **Third**, at the end of all examples 1 to 13 in **(2c)** reference is made that similar satiability data [as those presented for doxorubicin.HCl] "can be observed for analogous solutions containing either doxorubicin hydrochloride or, inter alia, "4'-epidoxirubicin as hydrochloride salt at various concentrations, which are all covered by the broad range of concentration of from 0.1 mg/ml to 50 mg/ml given in claim 1 of the main request.

Notwithstanding the board's finding referred to below that the disclaimer in present claim 1 is not admissible, that disclaimer and the co-terminous disclaimer in **(1)** would certainly not exclude solutions having a pH value of 2.71 (see example 6), or a pH value of 2.62 (see example 10) or a pH value of 3.14 (see example 11), all falling within the scope of claim 1 and destroying its novelty over the disclosure in **(2c)**. This provides further evidence that the claimed subject-matter in claim 1 of the patent cannot be regarded as a "selection invention" which would be considered "novel" over the disclosure in **(2c)**

according to the criteria applied by the EPO with a view to assessing novelty of selection inventions over the prior art.

2.8 To summarise, it results from the preceding

- that the conditions of Article 87(4) EPC are not met;
- that the invention of the **subsequent** application **(1)** is only distinguished from the invention of the **previous** application **(2c)** by a sub-range of the pH value which cannot render novel, in the sense of a selection invention, the invention disclosed in **(1)** over that disclosed in **(2c)**;
- that the invention of UK patent application **(2c)** is the same as the invention of the subsequent UK patent application **(1)** from which priority is claimed and the invention of claim 1 of the main request;
- that the invention claimed in claim 1 of the main request is not a selection invention which could be considered "novel" over the invention of **(2c)** according to the criteria applied by the EPO with a view to assessing novelty of selection inventions over the prior art;
- that the invention claimed in claim 1 of the main request has already been disclosed in the **previous** application **(2c)**.

2.8.1 Therefore, said **subsequent** UK patent application No. 86 291 93 **(1)**, filed on **5 December 1986**, mentioned in the contested patent for claiming priority, is not a first application within the meaning of Article 87(1) EPC and, thus, the persons who have duly filed it cannot enjoy a right of priority with respect to

claim 1 of the main request (see T 73/88, OJ EPO 1992, 557).

2.8.2 Since the right of priority cannot be enjoyed, the earliest possible date of priority is the date of filing the second later priority application filed in the United States on 22 June 1987 (Serial No. 64 653). Since citation (2) was published on 5 March 1987, the content of (2) is comprised in the state of the art under Article 54(2) EPC.

3. ***Admissibility of the disclaimer in claim 1***

3.1 In the board's judgment, the opposition division was correct in its finding in the impugned decision that the disclaimer introduced *post grant* at the end of claim 1 (see V above) results in a contravention of Article 123(2) EPC.

3.2 In decisions G 1/03 and G 2/03 (OJ EPO, 2004, 413 and 448), the Enlarged Board ruled that a disclaimer which is not disclosed in the application as filed may be allowable in order to:

- restore novelty by delimiting a claim against state of the art under Article 54(3) and (4) EPC;
- restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC; an anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention; and

- disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for non-technical reasons.

3.3 Appellant II submitted in the statement setting out the grounds of appeal that the disclaimer was introduced to avoid overlap between the claims of the patent and the disclosure of citation **(2)** or, differently expressed that the disclaimer was introduced to restore novelty by delimiting the claims of the patent against citation **(2)** which is an anticipation under Article 54(2) EPC.

3.4 Citation (2) was called by appellant II in its written and oral submissions "a novelty-only citation". However, since the right of priority cannot be enjoyed, it is clear that citation (2) is relevant to the assessment of novelty **and** inventive step of the claimed subject-matter in the main request. As admitted by appellant II itself, the disclosure of citation **(2)** is the same as the disclosure of the previous application **(2c)** from which **(2)** claims priority. In view of these observations it goes without saying that citation **(2)** is certainly not an accidental anticipation and that the disclaimer in claim 1 of the main request is therefore not allowable according to the principles set out in the decisions of the Enlarged Board of Appeal referred to in 3.2 above.

#### 4. **Novelty**

4.1 Since the disclosure of citation **(2)** is the same as the disclosure of the previous application **(2c)**, from which **(2)** claims priority, it is clear from the observations in section 2 above that the opposition division was

correct in its opinion that the subject-matter of claim 1 of the main request lacks novelty over the prior art of **(2)**, even in the presence of the disclaimer in the current main request.

4.2 In these circumstances the appeal in so far as it relates to the main request of appellant II must be dismissed, as claim 1 of this request is not in conformity with Articles 54 and 123(2) EPC.

4.3 The conclusions above extend not only to the claims for all designated Contracting States except ES and GR but *mutatis mutandis* also for the separate claims for the Contracting States ES and GR.

#### **Auxiliary request of appellant II**

#### **5. Priority**

5.1 Claim 1 of the auxiliary request for all designated Contracting States, except ES and GR, reads as follows (paragraph lettering and emphasis added by the board):

- (a)** A storage stable, sterile, pyrogen-free, ready-to-use, injectable 4'-epi-doxorubicin solution
- (b)** which is sealed in a container,
- (c)** which consists essentially of 4'-epi-doxorubicin hydrochloride
- (d)** dissolved in a physiologically acceptable aqueous solvent therefor at a concentration of 4'-epi-doxorubicin of from 0.1 mg/ml to 50 mg/ml,
- (ee)** the solution contains tonicity agent selected from dextrose, lactose and mannitol



- (f) the solution has not been reconstituted from a lyophilizate and
- (g) the pH of which has been adjusted to from 2.5 to 4.0
- (h) solely by means of a physiologically acceptable acid.

5.2 The opposition division considered in the contested decision that claim 1 of the auxiliary request before it (see V above) was entitled to claim priority from UK patent application No. 86 291 93 **(1)**, filed on **5 December 1986**. The reason given was that the three tonicity agents referred to in claim 14 of the **subsequent** application **(1)** represented a new selection from the longer list of tonicity agents disclosed at page 5, lines 1-4, of the **previous** application **(2c)** and that for this particular reason the subject-matter claimed in claim 1 of the auxiliary request was entitled to the priority date of 5 December 1986.

5.3 The board does not share the opposition division's view as it disregards both (i) the basic requirements which must be fulfilled that substance selection is to be recognised as new for patent law purposes and (ii) the fact that the disclosure of the **previous** application as **a whole** and, likewise, the disclosure of the **subsequent** application **as a whole** must be taken into consideration in deciding which of the two applications is the **first** application pursuant to Article 87(1) EPC for determining priority.

5.3.1 As regards the tonicity agents (feature **(ee)**), **previous** application **(2c)** contains the following disclosure:  
*"The solution of the invention may also contain one or*

*more additional components such as a co-solubilizing agent, a tonicity adjustment agent and a preservative"* (page 4, lines 2-5). *"Suitable tonicity adjustment agents may be, for example, physiologically acceptable inorganic chlorides, e.g. sodium chloride, dextrose, lactose, mannitol and the like"*. The opposition division apparently failed to observe that, as regards the tonicity agents, the disclosure in the **subsequent** application **(1)** is not only identical in substance to that in **(2c)** but is also identically worded in both applications (see **(1)**, page 5, lines 4-7; lines 3-7 from the bottom).

5.4 For assessing whether or not the UK priority application **(1)** is actually the first application within the meaning of Article 87(1) and (3) EPC, it is thus necessary to determine whether the previous UK patent application **(2c)** already discloses the same invention as the subsequent application and claim 1 of the auxiliary request, i.e. whether it destroys its novelty according to the criteria outlined in 2.4.2 above.

5.4.1 The reasons that led to the conclusion that UK patent application No. 86 291 93 **(1)**, filed on **5 December 1986**, is not a first application within the meaning of Article 87(1) EPC in respect of the subject-matter claimed in the main request and that claim 1 of the main request cannot enjoy a right of priority from **(1)** apply equally to products (solutions) defined by the features **(a)** to **(e)** and **(f)** to **(h)** in claim 1 of the auxiliary request (see 4.1 above).

5.4.2 It is not contested that a "priority application" which adds features to a previous "priority application" can form the basis of a second, different patent application. However, it is to be noted that, in the present case, the additional feature **(ee)** added to claim 1 of the auxiliary request (see 5.1 above), taken either in isolation or in combination with the other features **(a)** to **(e)** and **(f)** to **(h)** cannot add a new element indispensable if a substance selection is to be recognised as new for patent law purposes. Both the previous application **(2c)** and the subsequent application **(1)** disclose directly and unequivocally the following options for the tonicity agent:

*"physiologically acceptable inorganic chlorides, e.g. sodium chloride, dextrose, lactose and mannitol."*

Reducing this list in claim 1 of the auxiliary request to the options dextrose, lactose and mannitol, by deleting the option sodium chloride from the list in both applications **(2c)** and **(1)**, cannot be considered as a selection which would confer novelty on claim 1 of the auxiliary request over the disclosure in the previous application **(2c)**, since all three options dextrose, lactose and mannitol are already explicitly disclosed in the previous application **(2c)** and in the subsequent application **(1)** as suitable tonicity adjusting agents. Appellant II itself admitted in point 4.1.5 of the grounds of appeal that *"options disclosed in a **single list** are, of course, each regarded as being directly and unambiguously disclosed."*

5.4.3 The above observations make it clear that, in the present case, the invention of the **subsequent application (1)** is the same as the invention of the

**previous application (2c)** and the invention of **claim 1** in the auxiliary request. Therefore, as it is the case in the main request, UK patent application No. 86 291 93 **(1)**, filed on **5 December 1986**, mentioned in the contested patent for claiming priority, is not a first application within the meaning of Article 87(1) EPC and, thus, the persons who have duly filed it cannot enjoy a right of priority with respect to claim 1 of the auxiliary request.

6. **Novelty**

6.1 Since the right of priority from the subsequent application **(1)** cannot be enjoyed, citation **(2)** belongs to the state of the art under Article 54(2) EPC. As admitted by appellant II itself, the disclosure of citation **(2)** is the same as the disclosure of the previous application **(2c)** from which **(2)** claims priority. It thus follows that the subject-matter of claim 1 of the auxiliary request is known from **(2)** (see the paragraphs above) and accordingly lacks novelty contrary to the requirements of Article 52(1) in conjunction with Article 54 EPC. Since this was not contested by appellant II, no further reasons need to be given.

6.2 Since a decision can only be taken on a request as a whole, none of the further claims of the auxiliary request need to be examined. In these circumstances, the auxiliary request of appellant II is refused and the appeal of appellant I against the interlocutory decision of the opposition division is allowed.

6.3 The conclusions above extend not only to the claims for all designated Contracting States except ES and GR but *mutatis mutandis* also to the separate claims for the Contracting States ES and GR.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

A. Townend

U. Oswald