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Datasheet for the decision of 9 March 2012

Case Number: T 1676/08 - 3.3.02

Application Number: 96102992.3

Publication Number: 722730

IPC: A61K 31/485, A61K 9/20, A61P 25/04

Language of the proceedings: EN

Title of invention:
Controlled release oxycodone compositions

Patent Proprietors:
The Purdue Pharma Company
Mundipharma GmbH
Napp Pharmaceutical Holdings Limited
Norpharma A/S
Mundipharma Pharmaceuticals S.R.L.
Mundipharma Laboratories GmbH
Mundipharma Pharmaceuticals BV
Mundipharma AB
Mundipharma AG
Mundipharma Farmaceutica LDA
Mundipharma Pharmaceuticals SL
Mundipharma GesmbH
Mundipharma CVA

Opponent:
Lannacher Heilmittel Ges.m.b.H.

Headword:
Controlled release oxycodone compositions/THE PURDUE PHARMA COMPANY

Relevant legal provisions:
EPC Art. 106, 112a(2), 117(1)(d), 117(1)(e), 117(2)
EPC R. 106, 117, 118(2), 119(3), 121, 124, 152(1)
RPBA Art. 12(2), 13(1), 13(3), 15(1), 20(1) first sentence, 21
European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 Art. 6(1)
Business distribution scheme of the Technical Boards of Appeal for the year 2012 Art. 4
Decision of the President of the EPO dated 12 July 2007 on the filing of authorisations Art. 2 first sentence

Relevant legal provisions (EPC 1973):
EPC Art. 21(4)(b), 100(c), 112(1)(a), 113(1)

Keyword:
"Legal practitioner duly sub-authorised (yes) (point 3)"

"Duty of board to give detailed reasons for change in board's composition under Article 21(4)(b) EPC 1973 (no) - no decision within meaning of Article 106 EPC (point 4)"

"Admission of expert opinion D100 (no) - not identifiable as of particular relevance among submissions of over a thousand pages - adverse party taken by surprise and disadvantaged due to insufficient time to prepare and respond properly - no exceptional circumstances preventing earlier submission of expert opinion D100 - inconsistent conduct of appellants during appeal proceedings (point 5.2)"

"Admission of request under Article 117(1)(e) EPC for board to find and appoint expert (no) - adjournment of oral proceedings inevitable given filing of request at oral proceedings and mandatory procedure laid down in Implementing Regulations for taking such evidence (point 5.3)"

"Admission of request under Article 117(1)(e) EPC filed at oral proceedings to hear party's expert during these proceedings (no) - adjournment of oral proceedings inevitable to give adverse party fair opportunity to prepare questions and comment on testimony of expert (point 5.4)"

"Admission of oral presentation from party's accompanying person (no) - criteria set out in decision G 4/95 not fulfilled (point 6)"

"Party entitled to advance indications of board's assessment of what board considers disclosed in earlier application to skilled person using common general knowledge (no) - such assessment of technical facts in the light of patent law is part of decision and therefore a matter for board - by making such assessment members of board do not become witnesses within meaning of Article 117(1)(d) EPC or experts within meaning of Article 117(1)(e) EPC (point 7)"

"Main request allowable (no) - subject-matter of claim 1 remaining after introduction of disclaimer extends beyond content of earlier application (point 8)"

"Admission of auxiliary requests 1, 2, 3, 4 and 7 (no) - amendment of case in each request due to addition of single claim forming basis for decision under appeal on maintenance of patent in amended form - examination of additional claim not excluded by prohibition of *reformatio in peius* - additional claim raised new issues which could not be dealt with without adjournment of oral proceedings (point 9.1)"

"Admission of auxiliary requests 1a and 2a (no) - new issues raised requiring complex discussions (points 9.2 and 9.3)"

"Admission of auxiliary requests 5 and 6 (no) - filing at such late stage of proceedings not justified by alleged confusion about procedural situation - requests were singled out of bundle of 94 new auxiliary requests filed one month before oral proceedings and further amended (point 9.4)"

"Power of board to examine auxiliary request 8 (no) - prohibition of *reformatio in peius* (point 9.5)"

"Referral to the Enlarged Board of Appeal (no) - questions submitted by letter of 6 April 2009 already answered in decision G 2/10 (point 10.4)"

"Referral to the Enlarged Board of Appeal (no) - questions submitted as referral suggestion 1 can be answered beyond all doubt by board itself - principles developed in decision G 2/10 are also to be applied in assessment of added subject-matter in claims comprising structural and functional features (point 10.5)"

"Referral to the Enlarged Board of Appeal (no) - questions submitted as referral suggestion 2 can be answered beyond all doubt by board itself - board was not required to give detailed reasons for change in board's composition under Article 21(4)(b) EPC 1973 and was not bound by opinion expressed by board in its former three-member composition (point 10.6)"

"Objection 1 under Rule 106 EPC (dismissed) - established jurisprudence recognises that general principles of procedural law are applied in appeal proceedings - one of these principles is laid down in Article 6(1) ECHR - in *inter partes* proceedings involving opposing parties' interests the boards of appeal must be impartial - board would have been in breach of its duty of neutrality if it had given appellants guidance on presenting their case in oral proceedings (point 11)"

"Objection 2 under Rule 106 EPC (dismissed) - party has no right to have evidence filed or offered during appeal proceedings admitted at any stage of appeal proceedings (point 12)"

"Objection 3 under Rule 106 EPC (dismissed) - parties had proper opportunity to comment on Article 100(c) EPC 1973 and to reply to objections and arguments presented by adverse party (point 13)"

Decisions cited:
G 0009/92, G 0001/93, G 0007/93, G 0004/95, G 0001/03, G 0002/03, G 0001/05, G 0002/08, G 0003/08, G 0002/10, R 0001/08, R 0002/08, R 0012/09, R 0015/10, R 0006/11, R 0011/11, J 0005/81, J 0022/95, T 0271/85, T 0023/86, T 0198/88, T 0395/91, T 0230/92, T 0951/92, T 0142/94, T 0253/95, T 1024/96, T 0375/00, T 1139/00, T 0311/01, T 0302/02, T 1107/06, T 1068/07

Catchword:
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Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1676/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 March 2012

Appellants: (Patent Proprietors)

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 30 June 2008 concerning maintenance of European patent No. 722730 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
T. Karamanli
A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 0 722 730 (P1) was granted on European patent application No. 96102992.3 (P2), which is a divisional application of earlier European patent application No. 92925406.8, based on the international application published as WO 93/10765 (parent application P4). Mention of the grant of the patent was published in European Patent Bulletin 2002/44 on 30 October 2002.

II. The present appeal lies from an interlocutory decision of the opposition division maintaining the patent in amended form on the basis of the sole claim according to the ninth auxiliary request filed during oral proceedings which took place before the opposition division on 21 April 2008.

The **sole claim of this ninth auxiliary request** reads as follows:

"1. A controlled release oxycodone formulation for administration to human patients, comprising:

(a) an analgesically effective amount of spheroids comprising oxycodone salt and a spheronising agent such that the total dosage of oxycodone salt in said dosage form is from 10 to 40 mg oxycodone hydrochloride salt;

(b) each spheroid having a diameter of between 0.5 mm and 2.5 mm being coated with a film coating which includes ethyl cellulose which controls the release of the oxycodone salt at a controlled rate in an aqueous medium

(c) whereby said dosage formulation provides an in-vitro dissolution of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, between 12.5% and 42.5% (by wt) oxycodone released after 1 hour, between 25% and 55% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 hours, the in vitro release rate being independent of pH,

(d) and wherein at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml is obtained in vivo at 2 to 4.5 hours after administration, and a mean minimum plasma concentration of 3 to 30 ng/ml is obtained in vivo at 10 to 14 hours after administration."

III. The patent proprietors (hereafter "appellants") filed an appeal against said decision on 22 August 2008.

IV. The companies ratiopharm GmbH (intervener in the opposition proceedings, opponent O5), Cimex AG (intervener in the opposition proceedings, opponent O3), and Sandoz Limited (intervener in the opposition proceedings, opponent O4) filed appeals against said decision on 21 August 2008 and on 28 August 2008, respectively. However, opponents O3 (at that time Acino-Pharma AG) and O5 withdrew their oppositions by letters received on 18 August 2011 and opponent O4 withdrew its opposition by letter received on 23 November 2011.

V. Opponent O1 is a party as of right to the present appeal pursuant to Article 107, second sentence, EPC 1973, and is respondent to the appellants' appeal.

VI. The company ratiopharm Arzneimittel Vertriebs-GmbH (opponent O6) filed an intervention pursuant to Article 105 EPC in the appeal proceedings. However, opponent O6 withdrew its intervention by letter received on 18 August 2011.

VII. In its interlocutory decision, the opposition division came to the following conclusions.

The main request (patent as granted) was regarded to contravene Article 76(1) EPC in view of the introduction of the disclaimer in claim 1 of this request. The first to seventh auxiliary requests were held unallowable. The eighth auxiliary request was not admitted into the proceedings.

The ninth auxiliary request filed during the second oral proceedings on 21 April 2008 before the opposition division was admitted into the proceedings. The opposition division found that the ninth auxiliary request (claims and adapted description) was allowable since it fulfilled the requirements of the EPC and that the patent could be maintained on that basis under Article 101(3)(a) EPC.

VIII. The national decisions cited during the appeal proceedings included the following:

D40 "Ratiopharm GmbH v. NAPP Pharmaceutical Holdings Ltd", High Court (England and Wales), [2008] EWHC

3070 (Pat) (a copy was filed with letter of 6 April 2009).

D40a "Napp Pharmaceutical Holdings Ltd v. Ratiopharm GmbH and Sandoz Ltd", Court of Appeal (England and Wales), [2009] EWCA Civ 252 (a copy was filed with letter of 6 April 2009).

D78a "Mundipharma Pharmaceuticals B.V. v. Sandoz B.V.", District Court of The Hague, 7 April 2010, case no. 340373/09-2029 (a copy and a translation (D78) were filed with letter of 23 July 2010).

D107 "Lawrence v. The General Medical Council", High Court (England and Wales), [2012] EWHC 464 (Admin) (a copy was submitted during oral proceedings on 9 March 2012).

IX. In a communication under Article 15(1) RPBA (Rules of Procedure of the Boards of Appeal, OJ EPO 2007, 536), annexed to the summons to oral proceedings dated 24 March 2009, the board in a three-member composition expressed its provisional and non-binding opinion on the appeals pending at that date and on claim 1 as granted.

X. By letter dated 6 April 2009, the appellants requested *inter alia* that the following question be referred to the Enlarged Board of Appeal under Article 112(1)(a) EPC, if the board intended to decide that the disclaimer in granted claim 1 or in some of the auxiliary requests on file contravened Article 76 EPC:

"*Is an amendment to a claim by the introduction of a disclaimer which has been introduced for the sole reason to delimit the subject matter of a divisional application from the subject matter of the (granted) parent case to avoid double patenting unallowable under Art. 123(2) EPC and/or Art. 76 EPC?*"

The appellants argued *inter alia* that the board seemed to consider in its preliminary opinion "*the disclaimer as such unallowable as it was based on a divisional filing*". Furthermore, in the appellants' view, in decision T 1139/00 a disclaimer had been found allowable in a situation which was analogous to that of the disclaimer in the patent in suit.

XI. With a letter dated 13 August 2009, the appellants filed new auxiliary requests. They also filed several documents as annexes thereto, including D70, a paper of eight pages entitled "Allowability of the disclaimer in claim 1 of EP 722730 B1".

XII. The first oral proceedings were held before the three-member board on 13 and 14 October 2009. During those oral proceedings the appellants filed *inter alia* several sets of claims and renumbered their requests. They also filed a reworded request for referral to the Enlarged Board of Appeal:

"*Is an amendment to a claim by the introduction of a disclaimer which has been introduced for the sole reason to delimit the subject matter of a divisional application from the subject matter of the (granted) parent case to avoid double patenting allowable under Art. 123(2) EPC and/or Art. 76 EPC?*

If so, does it matter whether the disclaimer's subject matter was disclosed in the case as originally filed?"

At the oral proceedings on 14 October 2009, the chairman declared that the debate was closed for the main request and auxiliary requests I to Vb. With regard to the further requests VI to VIb, which contained only medical use claims, the chairman informed the parties that the board considered the pending referral before the Enlarged Board of Appeal in case G 2/08 to be relevant for these medical use claims and that, therefore, the proceedings would be suspended until the decision in case G 2/08 was issued.

At the end of the oral proceedings the chairman announced that "*the proceedings will continue in writing*".

XIII. Decision G 2/08 of 19 February 2010 of the Enlarged Board of Appeal (OJ EPO 2010, 456) was posted on 22 February 2010.

XIV. A summons to oral proceedings to be held on 19 October 2010 was sent to the parties on 22 March 2010.

XV. By an interlocutory decision of 25 June 2010 in case T 1068/07 (OJ EPO 2011, 256), Board of Appeal 3.3.08 referred the following question to the Enlarged Board of Appeal (case G 2/10):

"Does a disclaimer infringe Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed?"

XVI. By a letter dated 22 July 2010 the appellants submitted that the outcome of pending referral G 2/10 was decisive for the decision on the patent in dispute in the present appeal case and gave reasons in support of that submission. Furthermore, they requested suspension of the proceedings until the Enlarged Board of Appeal decided on case G 2/10.

XVII. By letters dated 13 August 2010, opponents O3, O4 and O5 objected to the appellants' requests. By a letter dated 23 August 2010 the respondent also objected to the suspension of proceedings and argued that the disclaimer in the present case was not comparable to the disclaimer in referral T 1068/07.

XVIII. By a letter dated 19 August 2010 the appellants filed *inter alia* further auxiliary requests IIIb, IIIc, IIId, IIIe, VII, VIIa, VIII, VIIIa and IX and arguments in support. The appellants submitted that the filing of the auxiliary requests was justified *inter alia* in view of Enlarged Board of Appeal decision G 2/08 of 19 February 2010, which set out the principles for dosing regimen features in claims. They further reiterated their request that the proceedings be suspended in view of case G 2/10. They also maintained their request to refer questions to the Enlarged Board of Appeal.

XIX. The board informed the parties by a communication dated 26 August 2010 that the date for oral proceedings (19 October 2010) was maintained and that the board was disinclined to reopen the debate which had been closed

in the oral proceedings of 13 and 14 October 2009 for the main request and auxiliary requests I to Vb.

XX. By a letter dated 5 October 2010, the appellants requested *inter alia* the appointment of an additional technically qualified board member and an additional legally qualified board member in the present appeal case, that the debate be reopened for the main request and for auxiliary request I, and that the proceedings be suspended in view of pending case G 2/10. They also gave reasons in support of their requests.

XXI. The second oral proceedings before the three-member board took place on 19 October 2010.

The appellants stated that they had not requested but only suggested changing the composition of the board from three to five members, in view of the complexity of the case.

Furthermore, the appellants requested that the debate be reopened for the main request and auxiliary requests I to Vb and that the proceedings be suspended in view of case G 2/10 pending before the Enlarged Board of Appeal.

The respondent and opponents O3, O4, O5 and O6 requested that the debate on the main request and auxiliary requests I to Vb should not be reopened and the proceedings not be suspended.

At the end of those oral proceedings, the board informed the parties that "*in view of the discussion during the oral proceedings, it, on its own motion,*

intended to refer questions to the Enlarged Board of Appeal concerning, inter alia, the allowability of a disclaimer in a claim wherein the subject-matter was delimited by both, structural and functional features".

The respondent and opponents O3 and O4 objected to a referral to the Enlarged Board of Appeal. The appellants were in favour.

XXII. By a letter dated 12 January 2011 opponent O4 requested that further oral proceedings be held in order to give the parties the opportunity for further discussions before a point of law was referred to the Enlarged Board of Appeal, in particular to discuss any questions the board intended to refer.

XXIII. A summons to oral proceedings to be held on 14 to 16 November 2011 was sent to the parties on 10 May 2011. This summons indicated the enlargement of the board to five members.

XXIV. By a fax letter dated 25 August 2011 opponent O4 filed further submissions and also opinions of Mr Morck, Mr Frieß and Mr Steffen.

XXV. On 31 August 2011 the Enlarged Board of Appeal's decision of 30 August 2011 in case G 2/10 was posted.

XXVI. By its fax communication dated 25 October 2011 pursuant to Article 15(1) RPBA the board informed the parties that it intended to reopen the debate for all requests then on file in view of the enlargement of the board to five members (Article 21(4)(b) EPC) and of decision G 2/10.

XXVII. In reply to the board's communication of 25 October 2011 the appellants filed a letter on the same day requesting that the oral proceedings appointed for 14 to 16 November 2011 be postponed by at least two months.

They argued *inter alia* that the legal questions mentioned in the minutes of the oral proceedings of 19 October 2010 remained unanswered and had in fact not yet been precisely formulated by the board, so that a discussion on that issue was still necessary. Before these questions were clarified, it was, in their view, premature to reopen the discussion of the merits of the present case merely because decision G 2/10 had been taken. Further they submitted that they had received the board's communication only three weeks before the scheduled oral proceedings and that this period was too short for them to prepare all the issues properly.

With regard to decision G 2/10 the appellants submitted that they had to rely on experts in view of its Headnote 1a and that they were unable to obtain and submit the necessary expert evidence in time before 14 November 2011.

Moreover, the appellants argued that opponent O4 had filed new observations, including new expert opinions, and that they should therefore be given enough time to submit relevant evidence well before the oral proceedings and before the board formed its (preliminary) opinion.

XXVIII. The board informed the parties by communication dated 26 October 2011 that the oral proceedings appointed for 14 to 16 November 2011 were cancelled.

XXIX. On 17 November 2011, a summons to oral proceedings scheduled to take place from 7 to 9 March 2012 was sent to the parties.

XXX. On 22 November 2011 the board sent a communication pursuant to Article 15(1) RPBA. Referring to its communication of 25 October 2011, the board reiterated *inter alia* that the debate would be reopened for all requests on file in view of the enlargement of the board to five members in accordance with Article 21(4)(b) EPC and of decision G 2/10. The board also clarified that, in view of the parties' submissions, the issue of referral to the Enlarged Board of Appeal was fully open, and that, consequently, the board in its new composition did not intend to refer questions to the Enlarged Board of Appeal at this stage of the proceedings.

XXXI. The appellants filed a letter dated 5 December 2011 in which they requested "*a preliminary non-binding opinion by the Board on the issues the Board intends to discuss at the Oral Hearing*". They asked for guidance on the nature of the legal issues and, in case the board wanted to open the debate on the pending requests already during the oral hearing, the opposition grounds that the board wanted to discuss at the hearing, in order to enable the appellants to prepare properly for addressing the legal concerns of all the board's members, and to prepare appropriate requests allowing a detailed and concise discussion of the board's concerns.

XXXII. By a communication dated 18 January 2012 the board informed the parties that the oral proceedings scheduled for 7 to 9 March 2012 would not be postponed and that the board, exercising its discretion under Article 15(1) RPBA, would not issue a further preliminary and non-binding opinion before the oral proceedings.

XXXIII. In a one-page letter dated 7 February 2012 and received on the same day, the appellants indicated that they would be accompanied by "*Dr. Robert Kaiko, Mr Benjamin Oshlack, Prof. Dr. Alf Lamprecht and Prof. Dr. Harald Schweim*".

They further submitted: "*If necessary Dr. Kaiko and Mr Oshlack will comment on the background and the effects of the claimed invention, Dr. Lamprecht will comment on aspects relating to pharmaceutical technology and Dr. Schweim will comment on aspects relating to the meaning and the determination of in-vivo pharmacokinetic parameters*".

For the CVs of these accompanying persons, the appellants referred to their previous submissions.

XXXIV. On 7 February 2012 the appellants filed a second letter, to which the following documents (which altogether comprised more than 1000 pages) were attached:

- claim sets of auxiliary requests 1 to 94;
- D96: overview of auxiliary requests;
- D97: table of auxiliary requests;
- D98: "Overview of documents cited by Patentee for EP 1 810 679 B1" listing D98-1 to D98-15;

- D98-1: opinion of Mr A. Lamprecht of 21 January 2010 with attachments;
- D98-2: opinion of Mr A. Lamprecht of 29 January 2010 with attachments;
- D98-3: opinion of Mr A. Lamprecht of 2 March 2010 with attachments;
- D98-4: opinion of Mr A. Lamprecht of 15 March 2010 with attachments;
- D98-5: opinion of Mr A. Lamprecht of 2 September 2010 with attachments;
- D98-6: opinion of Mr A. Lamprecht of 11 November 2010;
- D98-7: opinion of Mr A. Lamprecht of 12 December 2010;
- D98-8: opinion of Mr A. Lamprecht of 14 April 2011 with attachments;
- D98-9: opinion of Mr A. Lamprecht of 8 June 2011;
- D98-10: opinion of Mr A. Lamprecht of 20 October 2011 with attachments;
- D98-11: opinion of Mr U. Diederichsen of 17 November 2010 with attachments;
- D98-12: opinion of Mr U. Diederichsen of 14 December 2010;
- D98-13: opinion of Mr H. Schweim of 12 March 2011 with attachments;
- D98-14: opinion of Mr R. Teschemacher of 25 March 2011 with attachments;
- D98-15: opinion of Mr R. Teschemacher of 14 April 2011;
- D99: paper comprising 66 pages entitled "The invention";

- D99-1: Ritschel, W. and Bauer-Brandl, A., Die Tablette, Handbuch der Entwicklung, Herstellung und Qualitätssicherung, 2nd edition, 2002, p. 499-500;
- D99-2: About NDTI: The National Disease and Therapeutic Index, internet printout dated 12 July 2009;
- D99-3: Melnikova, I., Nature Reviews, 2010, Vol. 9, p. 589-590;
- D99-4: OxyContin Total Appearances 1996-1998 / MS Contin Total Appearances 1996-1998;
- D99-5: opinion of Mr G. Geisslinger of 18 October 2010 with several attachments;
- D99-6: second declaration of Mr D. B. Williams of 23 September 2010;
- D99-7: experimental data entitled "Determination of the Intrinsic Dissolution Rate of Oxycodone Base and Oxycodone Hydrochloride" dated 3 November 2010;
- D99-8: two untitled and unidentified pages containing some definitions of technical terms;
- D100: opinion of Mr A. Lamprecht of 7 February 2012;
- D100-1: curriculum vitae of Mr A. Lamprecht;
- D100-2: Bauer K. et al., Pharmazeutische Technologie, 1986, p. 546-551;
- D100-3: Sucker, H. et al. (eds.), Pharmazeutische Technologie, 2nd edition, 1991, p. 199-201 and p. 376-378;
- D101: EP 0 722 730;
- D102: WO 93/10765.

XXXV. By its communication dated 17 February 2012 the board informed the parties that, since the appellants' letters dated 7 February 2012 and their annexes comprised more than 100 pages, the board would provide the respondent with an electronic storage medium containing a copy of these documents, applying *mutatis mutandis*, Article 2 of the decision of the President of the EPO dated 12 July 2007 on the inspection of files (OJ EPO 2007, Special edition No. 3, 123).

Regarding the accompanying persons indicated in their letter of 7 February 2012, the appellants were referred to decision G 4/95 (OJ EPO 1996, 412).

As far as the appellants' requests and written submissions were concerned, the board referred to Article 13(1) and (3) RPBA and informed the parties that the board considered decisions R 11/08 and R 11/11 relevant to the present case.

XXXVI. By a letter of 1 March 2012 the appellants sought specific guidance from the board. They also filed three opinions from legal experts (Mr Melullis (D103), Mr van Nispen (D104), and Mr Teschemacher (D105)) on the right to be heard. The appellants also commented on decisions R 11/08 and R 11/11. They furthermore reserved their right to request the hearing of an expert in accordance with Article 117 and Rule 117 EPC, if this should become necessary.

XXXVII. By a letter dated 2 March 2012 and received on the same day, the appellants indicated that they would be co-represented in the oral proceedings by Mr Michael Tappin and Mr James Segan and filed a sub-authorisation

for both of them as well as a Barrister's certificate for Mr Michael Tappin. With a letter dated 5 March 2012 and received on the same day, the appellants also filed a Barrister's certificate for Mr James Segan.

XXXVIII. By a letter dated 5 March 2012 the appellants filed *inter alia* a further opinion from a legal expert, namely Ms Monica Carss-Frisk (D106), and referred to items 44 and 51 of that opinion.

XXXIX. On 6 March 2012 the respondent submitted arguments in relation to decision G 2/10 and granted claim 1 of the patent in suit. In particular, it analysed which matrices were singled out after the introduction of the disclaimer and assessed whether they were disclosed in the divisional application as originally filed (P2), coming to the conclusion that they were not.

XL. Oral proceedings took place from 7 to 9 March 2012 before the five-member board.

(a) On the first day of the oral proceedings (7 March 2012) the appellants asked the board *inter alia* why it had considered it necessary to extend the board to five members. The appellants also filed two sets of questions ("referral suggestion 1" and "referral suggestion 2") which they requested be referred to the Enlarged Board of Appeal.

(i) Referral suggestion 1 reads as follows:

"*Does a disclaimer which exempts subject matter needs consideration in addition to*

G 2/10 for the mere fact that the claim comprises structural and functional features?

If so, does it matter whether the exempted subject matter was originally in the application as originally filed or in the parent application?"

(ii) Referral suggestion 2 reads as follows:

"*1. Is there, in a situation where one or more of the following criteria is/are fulfilled:*

i. The Technical Board of Appeal has been enlarged from a 3 member panel to a 5 member panel according to Art. 21(3)b) EPC in the course of the proceedings for the sole reason of "the complexity of the case", despite no intervening change in relevant facts or arguments had occurred,

ii. The Technical Board of Appeal deviates from a legal position taken earlier in the proceedings with respect to the relevance of a decision of the Enlarged Board of Appeal or a pending referral question, or

iii. The Technical Board of Appeal deviates from its earlier intention to refer a fundamental point of law to the Enlarged Board of Appeal of its own motion,

an obligation for said Technical Board of Appeal to explain the factual and legal aspects which are decisive for the change of its position in due time before the matter can be discussed in oral proceedings in order to safeguard the right to be heard of the parties to the proceedings?

2. If the answer to question 1 is in the affirmative for at least one of the alternatives i) to iii), does the Technical Board of Appeal have to inform the parties to the proceedings in a Communication in particular on

a. the reasons of the increased complexity, despite no intervening change in facts or arguments occurred,

b. the reasons why it changed its position on the decision of the Enlarged Board of Appeal or a pending referral question and what the Board's new position is,

c. the point of law in due time before the hearing independently whether or not the Board still intends to refer said point of law to the Enlarged Board of Appeal?"

(b) On the second day of the oral proceedings (8 March 2012) the appellants filed the following further requests:

(i) "*We request evidence should be obtained under Art. 117(1)(e) EPC on the issue of the nature and extent of the disclosure of WO 93/10765 (P4, parent application) in the eyes of a skilled person as required by G 2/10.*"

(ii) "*We request evidence should be obtained under Art. 117(1)(e) EPC on the issue of the nature and extent of the disclosure of WO 93/10765 (P4, parent application) in the eyes of a skilled person as required by G 2/10, by hearing Prof. Dr. Alf Lamprecht's opinion.*"

(iii) "*If and insofar as the Board proposes to use only its own technical expertise to decide the issue of whether the subject matter remaining after the disclaimer was disclosed, implicitly or explicitly, to the skilled person using common general knowledge in the parent application P4 ("the G 2/10 issue") the Board shall, before it comes to a decision on the G 2/10 issue, set out for the parties the evidence or grounds pursuant to Art. 113 EPC, on which such decision is to be based, and offer the parties a proper opportunity to comment.*"

The appellants further requested that Mr Lamprecht be allowed to make submissions as an accompanying expert in line with the criteria set out in decision G 4/95 if he was not heard as an expert pursuant to Article 117(1)(e) EPC.

(c) On the third day of the oral proceedings (9 March 2012) the appellants submitted auxiliary requests 1, 1a, 2, 2a and 3 to 8.

(d) The appellants also filed the following objections under Rule 106 and Article 112a EPC.

(i) Objection 1 filed on 7 March 2012 reads as follows:

"*1) Board has failed to give proper and adequate or any notice as to what the fundamental legal issue, as referred to by the 3-member Board and reaffirmed by the 5-member Board is.*

2) Failure to give proper and adequate notice of the Board's changing position regarding the relevance and applicability of G 2/10."

(ii) Objection 2 filed on 8 March 2012 reads as follows:

"*The Patentees object under Rule 106 EPC / Article 112a EPC against a fundamental violation of Article 113 EPC (as meant in Article 112a(2)(c) and/or any other fundamental procedural defect as defined in the Implementing Regulations (Article 112a(2)(d)), in particular the refusal by the Board to allow the Patentees to present expert evidence in support of*

their position that the remaining subject matter in claim 1 of EP 0722730 is disclosed in the parent application (P4), by:

1. *the refusal to admit D100;*
2. *the refusal to admit the requests made under Article 117 EPC which are attached hereto as Annex A and Annex B,*
3. *the refusal to allow the opinion of party expert Professor Lamprecht to be heard according to G4/95 as announced in the Patentees' letter of 7 February 2012 (attached hereto as Annex C) and confirmed in the oral proceedings.*"

Annex A is reproduced in point (b)(i) above.
Annex B is reproduced in point (b)(ii) above.
Annex C is referred to in point XXXIII above.

(iii) Objection 3 filed on 9 March 2012 reads as follows:

"*The Patentees object under Rule 106 EPC / Article 112a EPC against a fundamental violation of Article 113 EPC (Article 112a(2)(c))and/or any fundamental procedural defect as defined in the Implementing Regulations (Article 112a(2)(d)), in particular the Board's refusal to:*

1. *disclose the grounds and/or evidence upon which it intends to determine the question of whether the subject-matter*

of claim 1 of EP 0 722 730 B1 is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge in the parent application as filed (Document P4), as required by G2/10; and

2. give the parties concerned an opportunity to present their comments thereon."

A copy of the decision "Lawrence v The General Medical Council", High Court (England and Wales), [2012] EWHC 464 (Admin), was submitted in support of objection 3 (D107, 128 pages). Paragraphs 229 and 231, which were cited by the appellants, read as follows:

"*229. In my judgment the observations of Beldam LJ Peter Gibson LJ and Dyson J (as recorded by Beldam LJ) support the proposition that a specialist tribunal including a GMC FTPP remains bound by the rules of natural justice; that the rules of natural justice preclude members of a specialist tribunal including expert members from giving evidence to themselves which the parties have no opportunity to challenge and that where a specialist tribunal drawing on its own knowledge and experience independently identifies an important fact or matter which may influence its decision but which has not been the subject of evidence adduced by or submissions advanced by the parties, it*

should state this openly and give the parties an opportunity to seek to adduce evidence and/or make submissions on it."

"*231.* See also *R(L) v London Borough of Walton Forest Special Educational Needs and Disability Tribunal* [2003] EWHC 2907 (Admin) at [14] : "… where the specialist Tribunal uses its expertise to decide an issue, it should give the parties an opportunity to comment on its thinking and to challenge it. That is established in the mental health tribunal context by the Clatworthy case, and in the context of this Tribunal in *Lucie M V Worcestershire County Council*." (per Beatson J)."

(e) Upon the board's invitation, at the end of oral proceedings, to itemise any further requests other than claim requests, in particular requests for referral, the appellants only maintained their request for referral to the Enlarged Board of Appeal submitted with letter of 6 April 2009 (page 2).

XLI. The set of fourteen **claims as granted** contains two independent product claims, namely claims 1 and 6, which relate to different controlled release formulations.

Claim 1 as granted reads as follows:

"1. A controlled release oxycodone formulation for oral administration to human patients, comprising:

(a) oxycodone salt in an amount equivalent to 10 mg to 160 mg of the oxycodone hydrochloride salt, and

(b) a controlled release dosage matrix, other than an acrylic resin matrix selected so that the formulation provides pH-independent dissolution characteristics,

(c) wherein said formulation provides, at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 240 ng/ml at 2 to 4.5 hours after administration and a mean minimum plasma concentration of oxycodone of 3 to 120 ng/ml at 10 to 14 hours after administration."

XLII. **Claim 5 of the parent application (P4)** reads as follows:

"5. A solid controlled release oral dosage form, comprising

(a) oxycodone or a salt thereof in an amount from about 10 to about 160 mg;

(b) an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing; and

(c) a suitable amount of a suitable pharmaceutical diluent, wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about

14 hours after repeated administration every 12 hours through steady-state conditions."

XLIII. **Claims 1 and 2 of auxiliary request 1** read as follows:

"1. A controlled release oxycodone formulation for oral administration to human patients, comprising:

(a) 10 mg to 160 mg of the oxycodone hydrochloride salt, and

(b) an effective amount of a controlled release dosage matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons, having from 8 to 50 carbon atoms, namely fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils and waxes, polyalkylene glycols, and mixtures of any of the foregoing, except an acrylic resin matrix selected so that the formulation provides pH-independent dissolution characteristics, and

(c) a pharmaceutical diluent, wherein said formulation provides, at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 240 ng/ml at 2 to 4.5 hours after administration and a mean minimum plasma concentration of oxycodone of 3 to 120 ng/ml at 10 to 14 hours after administration.

2. A controlled release oxycodone formulation for administration to human patients, comprising:

(a) an analgesically effective amount of spheroids comprising oxycodone salt and a spheronising agent such that the total dosage of oxycodone salt in

said dosage form is from 10 to 40 mg oxycodone hydrochloride salt;

(b) each spheroid having a diameter of between 0.5 mm and 2.5 mm being coated with a film coating which includes ethyl cellulose which controls the release of the oxycodone salt at a controlled rate in an aqueous medium

(c) whereby said dosage formulation provides an in-vitro dissolution of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, between 12.5% and 42.5% (by wt) oxycodone released after 1 hour, between 25% and 55% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 hours, the in vitro release rate being independent of pH,

(d) and wherein at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml is obtained in vivo at 2 to 4.5 hours after administration, and a mean minimum plasma concentration of 3 to 30 ng/ml is obtained in vivo at 10 to 14 hours after administration."

XLIV. The **sole claim of auxiliary request 1a** is identical to claim 1 of auxiliary request 1.

XLV. **Claim 1 of auxiliary request 2** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. A controlled release oxycodone formulation for oral administration to human patients, comprising:

(a) 10 mg to 40 mg of the oxycodone hydrochloride salt, and

(b) an effective amount of a controlled release dosage matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons, having from 8 to 50 carbon atoms, namely fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils and waxes, polyalkylene glycols, and mixtures of any of the foregoing, except an acrylic resin matrix selected so that the formulation provides pH-independent dissolution characteristics,

(c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, is between 12.5% and 42.5% (by wt) oxycodone released after 1 hour, between 25% and 56% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 hours, the in vitro release rate being substantially independent of pH, such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation, and

(c) a pharmaceutical diluent, wherein said formulation provides, at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration and a mean minimum plasma concentration of

oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration."

XLVI. The **sole claim of auxiliary request 2a** is identical to claim 1 of auxiliary request 2.

XLVII. **Claim 1 of auxiliary request 3** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. A controlled release oxycodone formulation in the form of a solid dosage form for oral administration to human patients, comprising:

(a) 10 mg to 40 mg of the oxycodone hydrochloride salt, and

(b) a controlled release dosage matrix, other than an acrylic resin matrix, the controlled release dosage matrix including a material selected from the group consisting of cellulose ethers, digestible long chain (C_8-C_{50}) substituted or unsubstituted hydrocarbons selected from fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils and waxes,

(c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, is
between 12.5% and 42.5% (by wt) oxycodone released after 1 hour,
between 25% and 56% (by wt) oxycodone released after 2 hours,
between 45% and 75% (by wt) oxycodone released after 4 hours and
between 55% and 85% (by wt) oxycodone released

after 6 hours,
the in vitro release rate being substantially independent of pH,
such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation,

(d) wherein said formulation provides, at steady state after repeated administration at 12-hour intervals,
a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration and
a mean minimum plasma concentration of oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration."

XLVIII. **Claim 1 of auxiliary request 4** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. Use of a controlled release oxycodone formulation in the form of a solid dosage form for oral administration to human patients, comprising:

(a) 10 mg to 40 mg of the oxycodone hydrochloride salt, and

(b) a controlled release dosage matrix, other than an acrylic resin matrix, including a material selected from the group consisting of cellulose ethers, digestible long chain (C_8- C_{50}) substituted or unsubstituted hydrocarbons selected from fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils and waxes,

(c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6

and 7.2) at 37°C, is
between 12.5% and 42.5% (by wt) oxycodone released after 1 hour,
between 25% and 56% (by wt) oxycodone released after 2 hours,
between 45% and 75% (by wt) oxycodone released after 4 hours and
between 55% and 85% (by wt) oxycodone released after 6 hours,
the in vitro release rate being substantially independent of pH,
such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation,

(d) wherein said formulation provides, at steady state after repeated administration at 12-hour intervals,
a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration and
a mean minimum plasma concentration of oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration;

for the manufacture of a medicament for the controlling of moderate to severe pain in approximately 90% of patients with 12-hourly doses of 10 to 40 mg controlled release oxycodone hydrochloride."

XLIX. **Claim 1 of auxiliary request 5** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. Use of a controlled release oxycodone formulation in the form of a solid dosage form for oral administration to human patients, comprising:

a) 10 to 40 mg oxycodone hydrochloride salt;

b) an effective amount of a controlled release dosage matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from 8 to 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing,
except an acrylic resin matrix
being selected so that the formulation provides pH-independent dissolution characteristics; and

c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, is
between 12.5% and 42.5% (by wt) oxycodone released after 1 hour,
between 25% and 56% (by wt) oxycodone released after 2 hours,
between 45% and 75% (by wt) oxycodone released after 4 hours and
between 55% and 85% (by wt) oxycodone released after 6 hours,
the in vitro release rate being independent of pH,
such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation,

d) a pharmaceutical diluent, wherein said formulation provides, at steady state after repeated administration at 12-hour intervals,
a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration
and a mean minimum plasma concentration of

oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration,

for the manufacture of a medicament for the controlling of moderate to severe pain in approximately 90% of patients with 12-hourly doses of 10 to 40 mg controlled release oxycodone hydrochloride."

L. **Claim 1 of auxiliary request 6** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. Use of a controlled release oxycodone formulation in the form of a solid dosage form for oral administration to human patients, comprising:

a) 10 to 40 mg oxycodone hydrochloride salt, and

b) a controlled release dosage matrix including materials selected from

aa) between 1% and 80% (by weight) of at least one hydrophilic polymer

bb) up to 60% (by weight) of at least one digestible, long chain C_8-C_{50} hydrocarbon,

cc) up to 60% (by weight) of at least one polyalkylene glycol,

said matrix optionally containing other materials selected from the group consisting of diluents, lubricants, binders, granulating aids, colorants, flavorants and glidants, other than an acrylic resin matrix

selected so that the formulation provides pH-independent dissolution characteristics,

c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, is

between 12.5% and 42.5% (by wt) oxycodone released after 1 hour,
between 25% and 56% (by wt) oxycodone released after 2 hours,
between 45% and 75% (by wt) oxycodone released after 4 hours and
between 55% and 85% (by wt) oxycodone released after 6 hours,
the in vitro release rate being independent of pH, such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation,

d) wherein said formulation provides, at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration and
a mean minimum plasma concentration of oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration,

for the manufacture of a medicament for the controlling of moderate to severe pain in approximately 90% of patients with 12-hourly doses of 10 to 40 mg controlled release oxycodone hydrochloride."

LI. **Claim 1 of auxiliary request 7** reads as follows (claim 2 is identical to claim 2 of auxiliary request 1):

"1. Use of a controlled release oxycodone formulation in the form of a solid dosage form for oral administration to human patients, comprising:
(a) 10 mg to 40 mg of the oxycodone hydrochloride salt, and

(b) a controlled release dosage matrix wherein the included controlled release matrix materials are selected from the group consisting of gums, cellulose ethers, protein derived materials, digestible substituted or unsubstituted hydrocarbons, having from 8 to 50 carbon atoms, and polyalkylene glycols,

(c) wherein the dissolution rate of the formulation in vitro, when measured by the USP Paddle Method at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C, is
between 12.5% and 42.5% (by wt) oxycodone released after 1 hour,
between 25% and 56% (by wt) oxycodone released after 2 hours,
between 45% and 75% (by wt) oxycodone released after 4 hours and
between 55% and 85% (by wt) oxycodone released after 6 hours,
the in vitro release rate being substantially independent of pH,
such that the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the formulation,

(d) wherein said formulation provides, at steady state after repeated administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 60 ng/ml at 2 to 4.5 hours after administration and
a mean minimum plasma concentration of oxycodone of 3 to 30 ng/ml at 10 to 14 hours after administration;

for the manufacture of a medicament for the controlling of moderate to severe pain in approximately 90% of

patients with 12-hourly doses of 10 to 40 mg controlled release oxycodone hydrochloride."

LII. The **sole claim of auxiliary request 8** is identical to the sole claim of the ninth auxiliary request filed during the oral proceedings before the opposition division which took place on 21 April 2008 (see point II above).

LIII. The appellants' arguments, as far as relevant for the present decision, may be summarised as follows:

Procedural issues

(a) It was necessary that the board explain the specifics of the complexity of the case, which was the reason given for extending the board to five members. This clarification was needed before any request could be affirmed or claim 1 of the main request could be discussed, since it was obvious from the course of the appeal proceedings that the five-member board had fundamentally changed its opinion. The board in its initial three-member composition had indicated first decision G 1/03 and then decision G 1/05 as the legal basis for reaching a decision. When the appellants had requested that the proceedings be stayed in view of the then pending case G 2/10 and suggested enlarging the board, the appeal proceedings had however been continued with the three-member board. In the oral proceedings of 19 October 2010, a fundamental legal issue, distinct from the issue in the then pending case G 2/10, had been identified by the board. Even in the summons to

the (subsequently postponed) oral proceedings scheduled for November 2011, the fundamental legal issue had been confirmed as still present. Instead of referring questions concerning the interaction between structural and functional features to the Enlarged Board of Appeal of its own motion as indicated in the oral proceedings of 19 October 2010, the board had been enlarged to five members. The board in its new composition had indicated that G 2/10 was to be discussed, which proved that the board had fundamentally changed its opinion. Therefore clarification was required before any discussion of the appellants' claim request started. Even if the appellants were aware of decision G 2/10 and of all decisions to which the board had referred, such clarification was relevant for the appellants because the five-member board had expressly stated that the fundamental legal issue remained fully open. If this were no longer the position of all five board members, it could still be the position of the three members who had been members of the three-member board. That could be decisive in the present case, since the two new members were a minority in the five-member board. Nor was it clear from the board's communication that decision G 2/10 had to be discussed first. Firstly, there was no particular order in which the points had to be discussed. Secondly, any discussion regarding decision G 2/10 had to come last, since the three-member board had said that there was a fundamental legal issue concerning the interaction between structural and functional features which required clarification by the Enlarged Board of Appeal

before any other discussion could continue and which had prevented the three-member board from taking a decision in the oral proceedings of 19 October 2010. Moreover, the five-member board had reaffirmed the issue, which however was not addressed in decision G 2/10. The appellants could not discuss claim 1 before this issue was resolved.

(b) The appellants wished to rely upon Mr Lamprecht's opinion (filed as document D100). As regards the admissibility of D100 into the proceedings, the appellants submitted that D100 concerned the question whether the claimed subject-matter remaining after the introduction of the disclaimer was directly and unambiguously derivable from the parent application (P4) and how the skilled person understood the meaning of the matrix and acrylic resins in the parent application. The belatedness of document D100 should only be measured in relation to the expert opinions filed with opponent O4's letter dated 25 August 2012 and the board's communication dated 25 October 2011 indicating that decision G 2/10 was relevant for the present case. Before that, there had been no need for the appellants to react, since they had expected a referral, as indicated by the board, and a communication from the board on the merits of the case. Moreover, page 18 of their 34-page submission of 7 February 2012 referred to document D100, so that document D100 was easily identifiable.

(c) The requests under Article 117(1)(e) EPC were not late-filed given the course of the proceedings.

After the oral proceedings on 19 October 2010, the appellants had been awaiting a discussion on the point of law which the board had envisaged referring to the Enlarged Board of Appeal. Only when they received the board's communication dated 18 January 2012 had they realised that the board intended to discuss the substance of the case. During preparation of the oral proceedings, it had come to the appellants' attention that a technical evaluation of the patent was needed for the discussion. Therefore, by letter of 7 February 2012 they had announced that Mr Lamprecht would attend the oral proceedings as an accompanying person, and by letter of 1 March 2012 they had reserved their right to request the hearing of an expert in accordance with Article 117 and Rule 117 EPC, if this should become necessary. The appellants had tried to stick to the deadlines set by the board. However, no specific deadline had been imposed by the board. Since decision G 2/10 in fact said what had to be established by a skilled person, it could well be construed as putting a duty on the board to order measures of inquiry as might be necessary. It appeared that the board had not even considered looking into the evidence of any other expert who had given evidence in other proceedings. The board therefore had to hear an expert under Article 117(1)(e) EPC, either one of the appellants' experts or another one. More specifically, Mr Lamprecht should be heard as an expert under Article 117(1)(e) EPC. If this request was not admitted into the proceedings or was not allowed, then Mr Lamprecht should be

allowed to speak as an accompanying person within the meaning of decision G 4/95.

Since no technical expert had been heard, the board had interpreted the disclosure of the parent application P4, using its own technical expertise. Thus the board had established the facts as technical experts on which it then based its legal analysis for taking the decision as a judge. However, if only the board established these facts without any further evidence, it had to provide the parties with information on those facts so that they were able to address them properly.

The appellants' claim requests

(d) The appellants submitted the following as regards the main request, Article 100(c) EPC and the subject-matter remaining after the disclaimer, in the light of decision G 2/10. It could be concluded from decisions G 1/05 and G 2/10 that a divisional application or patent derived therefrom could not contain subject-matter which was not disclosed in the parent application (Article 76(1) EPC). There was no difference in quality between structural and functional features. What was important was to read the answers given in decision G 2/10. For the technical assessment it had to be discerned what was the nature and extent of the disclosure in the (parent) application as filed and what was the nature of the disclaimed subject-matter and its relationship to the remaining subject-matter. The principles set out in decision G 2/10 were to be applied in relation

to the requirements of Article 123(2) EPC if the subject-matter disclaimed was disclosed in the application as filed. Decision G 2/10 stated that the rules of logic did not apply for the assessment of Article 123(2) EPC. As a consequence, it could not simply be said that since the disclaimer was not expressly defined in the application as filed then the group n-1 was not disclosed. An individual evaluation of the disclosure had to be made in every case.

The appellants explained what they considered to be their invention in relation to the meaning of the pharmacokinetic plasma profile in pain relief. The expressions "minimum effective concentration" for a particular individual and "minimum toxic concentration" were also explained. The object of the invention was how to treat a majority of patients with a medicament and achieve pain relief. This was a step forward for clinicians and patients. In their view, the materials constituting the matrix were irrelevant.

They argued that the invention concerned a controlled release formulation with a very specific active ingredient (oxycodone salt), which was released in a pH-independent manner, and with a release of the active ingredient defined by a special blood curve obtained when the formulation was administered twice a day. The appellants also referred to Figure 5 in the patent in suit. The pharmacokinetic profile was expressed in mean maximum and minimum plasma concentration values within certain ranges of time after administration.

The formulation comprised the oxycodone salt in a controlled release dosage matrix. The materials constituting the matrix were irrelevant since the problem addressed was pain relief, which was attained with the pharmacokinetic plasma profile. Thus, within this context, it was immaterial whether one used an acrylic resin matrix or a hydroxyalkylcellulose matrix. The nature and extent of the disclaimed subject-matter were formulations of oxycodone salt with pH-independent release characteristics, providing the particular plasma curve, in which the matrix included acrylic resins. The appellants cited page 4 (first full paragraph and second full paragraph) and page 5, line 6 ff of the parent application (P4) disclosing the range of amounts of the active compound, page 9, lines 20 to 24 disclosing the oxycodone salt, and page 9, line 25 ff and lines 11 to 15 disclosing the matrix. More specifically, the disclosure on page 9, line 25 ff concerned the kind of matrix to be used, how a controlled release matrix was designed and which materials were to be included (pages 9 and 10 of P4). Moreover, claim 5 of the parent application confirmed that the controlled release matrix was to be selected from the groups stated and that it achieved the plasma profile. The appellants further submitted that any matrix could be taken provided it had the required functionality, and cited pages 9 and 10 of the parent application (P4). There were many materials which could be included, all known *per se* to the skilled person (page 9, line 33 to page 10, line 16). Thus, in the appellants' opinion, the matrix could be any

matrix which had the properties of the acrylic resin matrix. The parent application concerned also disclosed alternatives not related to each other, so it was impossible that the teaching changed by virtue of the fact that one possible alternative was excluded. In this context, the appellants cited the second paragraph on page 40 of decision G 2/10 and reiterated that normally the remaining general teaching was not modified by the disclaimer. In the appellants' opinion specific evidence was required to demonstrate that it was not a normal case.

The appellants argued that the principles set out in decision G 2/10 had already been applied in the High Court's and the Court of Appeal's decisions D40 and D40a, since the essential principles were the same as those applied when following decision G 1/03, independently of whether or not decision G 1/03 was intended to cover all cases of disclaimers. In this context, the appellants cited decision T 1139/00, which was relied on in decision G 2/10. They also cited the decision of the District Court of The Hague D78a. Moreover, in the appellants' view, the EPO should be aiming at harmonisation. The appellants referred to points 3.8, 4.4.2 and 4.5.1 of the Reasons of decision G 2/10, which considered the national decisions useful and consistent in their assessment of Article 123(2) EPC. Decision G 2/10 stipulated that each case had to be decided on its own merits and, as had already been mentioned, that the rules of logic did not apply (point 4.5.3 of the Reasons of decision G 2/10). There was no suggestion that

the findings in decision T 1139/00 might have been wrong. Moreover, the criteria in decision G 2/10 included assessing whether the skilled person was presented with new technical information which could not be derived directly and unambiguously from the application as filed. Thus, the approach adopted in decision G 2/10 was that adopted by the Court of Appeal (D40a, paragraphs 68, 69, 71 and 85). The previous opponents had not been able to identify added technical information before the High Court and the Court of Appeal and no expert had suggested before those courts that the patent in suit contained added technical information as compared to the parent application. As regards the respondent's comments in relation to different types of acrylic resins, the appellants referred to the findings in the High Court's decision D40 (*inter alia* paragraphs 112, 125, 128, 129, 132 to 134, 145) and the Court of Appeal's decision D40a (paragraphs 86 and 90 to 94). In this context, they stressed that the parent application disclosed the teaching concerning pH-independent dissolution characteristics to be afforded by the appropriate choice of materials in the controlled release matrix. The appellants also cited the decision of the District Court of The Hague D78a (in particular points 4.14 and 4.15) and requested that the board conclude for the patent in suit as the courts did in the cited national decisions.

The disclosure in the parent application (P4) had to be evaluated. The parent application disclosed the controlled release matrix in a broad manner, and it disclosed in a specific manner the

functional features expressed as pharmacokinetic profile. The claimed subject-matter under discussion did not result from cherry-picking in the disclosure in the parent application, since pH-independency was disclosed throughout the parent application. Claim 5 of the parent application explicitly disclosed the combined range of values. Thus, taking also into account the contents of pages 4 and 5 of the description, the skilled person inevitably arrived at the entire range in claim 1 as granted. Claim 5 of the parent application linked the controlled release matrix to the blood curve. The parent application was not a loose bundle of paragraphs which were not related to each other. The range 10 to 160 mg was explicitly disclosed for oxycodone hydrochloride on page 9, lines 20 to 24 of the parent application. It was also stated that the dosage form could contain molar equivalent amounts of oxycodone salts. The diluent mentioned in claim 5 of the parent application was not relevant for the plasma levels stated in said claim. This component was not compulsory according to page 12, lines 3 to 7 of the description. The mention of an "effective amount" in connection with the matrix in claim 5 of the parent application merely stressed that the release profile was to be achieved.

The skilled person was the specialist for whom it did not matter which materials were to be used and for whom it was not relevant that the wording of claim 5 of the parent application was not identical to that in claim 1 of the main request.

What counted was that the disclaimed matter was disclosed in the parent application and that the removal of this subject-matter did not add any new technical contribution. The remaining subgroup of matrices fulfilled the same functions defined in the same way as in the parent application. The disclaimer did not change the technical teaching of the parent application. It only restricted the invention by deleting some elements. The skilled person would be able to recognise the "core of the invention". The invention solved a medical problem which concerned how to achieve pain relief by titration in patients in form of a tablet. The invention was not about "a matrix". The examples did not only concern acrylic resin matrices. Hydroxyalkyl cellulose matrices were also exemplified. However, there was no reason why the claim should be restricted to a hydroxyalkyl cellulose matrix. If acrylic resins were not to be used, the specialist would use other materials, with or without diluent, and be able to achieve the plasma curve. There was no evidence from a specialist that there was a technical teaching or technical contribution different from that in the parent application (P4). The only difference, as acknowledged in the Court of Appeal's decision D40a, was that deriving from dividing the initial parent application.

The appellants cited decisions T 142/94 and T 1024/96. They further submitted that at the priority date of the patent in suit the skilled person would have been able to use the tool box provided by the parent application (P4) and

achieve the plasma values and the *in vitro* dissolution rate. Once the *in vitro* dissolution rate was set it was commonplace for the skilled person to adjust the formulations to obtain the plasma profile. The invention did not reside in a selection of materials and their specific amounts.

Additionally, the appellants referred to their written submission D70 (see point XI above) and to decision T 1107/06.

(e) The appellants requested that auxiliary requests 1 to 7, filed during the oral proceedings on 7 to 9 March 2012, be admitted into the proceedings since they all corresponded to requests previously on file. The appellants asserted that the expressions "formulation for oral administration" and "solid oral dosage form" were interchangeable in the present case. The appellants argued that the only difference from requests previously on file was claim 2, which was identical to the sole claim of the patent as maintained in amended form by the opposition division. If the sets of claims of auxiliary requests 1 to 7 were compared with the auxiliary requests previously on file, then the difference was that a new claim 2 had been added (or replaced a different claim 2). The appellants further stated that theirs was the only appeal pending in the present case, the opponents-appellants having withdrawn their appeals previously on file. In the appellants' view, claim 2 could thus no longer be challenged because of the principle of prohibition of *reformatio in peius*.

Auxiliary request 1 corresponded to auxiliary request II filed during the oral proceedings on 13 and 14 October 2009. This request had never been abandoned. It had been found not admissible in those oral proceedings, but the debate had now been reopened for all requests in view of the extension to a five-member board and decision G 2/10. Claim 1 in auxiliary request 1 was a fair attempt to respond to the findings in relation to the remaining subject-matter in view of decision G 2/10. The request was also *prima facie* allowable since claim 1 came closer to claim 5 of the parent application (P4) and the specification on pages 9 and 10. In view of decision G 2/10 the legal situation had changed (e.g. the rules of logic did not apply).

Following the same line of argumentation, the appellants stated that auxiliary request 2 corresponded to auxiliary request IIa filed during the oral proceedings on 13 and 14 October 2009. They further indicated that an obvious typing error in claim 1 had been corrected. Claim 1 in auxiliary request 2 was a fair attempt to overcome the objections under Article 100(c) EPC by defining the claimed subject-matter more specifically. This request had not been admitted into the proceedings at the oral proceedings on 13 and 14 October 2009, but the situation had now changed. The reason for modifying the range of amounts was that the *in vitro* release profile was disclosed in particular for the range 10 to 40 mg. In the appellants' view, the respondent had also

had enough time to look into this auxiliary request.

Similarly, the appellants argued that auxiliary request 3 had initially been filed with letter of 19 August 2010 as auxiliary request IIId, to which an independent claim 2 had been added. The admissibility of auxiliary request IIId had not yet been decided. Moreover, the amendments in claim 1 were a fair attempt to come closer to the specification on pages 9 and 10 and the introduction of the *in vitro* profile. This set of claims had been pending since 19 August 2010 and, therefore, the respondent had had ample opportunity to consider it. Thus, auxiliary request 3 should be admitted into the proceedings. The appellants also submitted that the structure of the features in claim 1 was similar to that in auxiliary request VI (as renumbered during the oral proceedings of 13 and 14 October 2009). The pH-independency had been moved from its initial position to feature (c), but that should not be a problem.

The appellants further submitted that auxiliary request 4 had initially been filed with letter of 19 August 2010 as auxiliary request IIIe, to which an independent claim 2 had been added. Claim 1 largely corresponded to what had been previously discussed. Features and structure in claim 1 were similar to those of auxiliary request VI as renumbered during the oral proceedings of 13 and 14 October 2009. Those proceedings had been suspended because case G 2/08 (*dosage regime*) had

been pending at the time. This auxiliary request had not been filed in February 2012 for the first time, but in 2010, with a reasonable number of requests. In the appellants' view, the respondent could thus not have been surprised. Moreover, the respondent had chosen not to comment on those requests until now.

The appellants conceded that auxiliary requests 5 and 6 had been filed with a very large number of other auxiliary requests on 7 February 2012, but this had been due to the confusion about the procedural situation according to the state of the file, and the lack of guidance from the board, although such guidance had been expressly requested in writing in preparation for the oral proceedings of 7 to 9 March 2012. The appellants had therefore not known which course the proceedings would take.

The appellants also argued that they could not find any case law with regard to structural and functional features. Thus, when they received the summons to the oral proceedings appointed for 14 to 16 November 2011 they had been lost from a legal point of view and had "desperately" waited for some guidance from the board. Then the board had informed the parties in the communication dated 25 October 2011 that decision G 2/10 was to be discussed and that the issue of referral to the Enlarged Board of Appeal was still open (see communication dated 22 November 2011).

The appellants further stressed that they had asked several times for guidance. In the absence of such guidance they had to reserve their rights. So, in order to be diligent, they could only have done what they actually did. In view of the lack of a preliminary opinion of the board (see appellants' request in letter dated 5 December 2011 and the board's communication dated 18 January 2012) the appellants were obliged to file various sets of claims in order to safeguard their rights.

The review decisions R 11/08 and R 11/11 cited in the board's communication dated 17 February 2012 did not apply to the present case. In particular, the "pick and mix" approach had not been applied by the appellants, since the requests submitted with letter of 7 February 2012 had not been filed conditionally and in a loose sequence. The appellants had tried to explain the structure of all the claims by filing additional supporting material.

The requests filed with letter of 7 February 2012 had also been filed one month before the oral proceedings, which was accepted practice in proceedings before the EPO. Therefore, and because there was no time limit in appeal proceedings such as the one of Rule 71a EPC, their filing at that stage of proceedings should have been fine. Moreover, the respondent had never opposed or objected under Article 100(c) EPC.

The appellants also submitted that they had drastically reduced the number of auxiliary requests. Auxiliary requests 5 and 6 had been filed as auxiliary requests 31 and 34. These two requests were attempts to overcome potential objections under Article 100(c) EPC in the light of decision G 2/10. The amount ranges were restricted to 10 to 40 mg, the disclaimer had been maintained, and the language of pH-independent dissolution characteristics retained. A claim 2 had been attached relating to the subject-matter maintained by the opposition division. The definitions came closer to what had been defined in claim 5 of the parent application (P4) and the specification on pages 9 and 10. All arguments in favour of the introduced amendments had been filed in writing and were available in the online dossier.

Auxiliary request 7 corresponded to auxiliary request VII filed with letter dated 19 August 2010. This request, which was directed to the use, had been filed after decision G 2/08 of 19 February 2010 was issued. Claim 1 specified *inter alia* that it was a solid oral dosage form, defined the medical indication and incorporated the *in vitro* profile for the range of amounts of 10 to 40 mg. A claim 2 directed to the subject-matter maintained by the opposition division had been added. The "pick-and-choose" argument did not apply to the choice of auxiliary request 7, since it was one of a reasonable number of auxiliary requests filed in 2010.

As the board had informed the parties that the principle of prohibition of *reformatio in peius* could not be invoked for the admission of auxiliary requests in which a new claim 2 had been added, and that the arguments presented by the respondent in relation to the amendments being *prima facie* non-allowable also applied under Article 123(3) EPC, the appellants had filed two further auxiliary requests (1a and 2a) in which claim 2 had been deleted. As regards claim 1 in auxiliary request 1a, the appellants added that the disclaimer had been worded similarly to claim 1 as granted and the definitions had been restricted in accordance with the parent application (P4). Claim 1 of each auxiliary request had long been on file. The construction of each claim 1 came closer to claim 5 of the parent application. The disclaimer did not change anything in relation to granted claim 1. In relation to claim 1 in auxiliary request 2a, the appellants further submitted that its wording was a response to the objection that the teachings in relation to the pharmacokinetic profile on pages 4 and 5 of the parent application could not be combined. The amendments in auxiliary requests 1a and 2a did not infringe Article 123(2) and (3) EPC.

Requests for referral to the Enlarged Board of Appeal

(f) As regards the requests for referral of questions to the Enlarged Board of Appeal as suggested in the appellants' letter of 6 April 2009, the appellants argued that deviating from the ruling of decision T 1139/00 would result in conflicting

decisions at the level of the boards of appeal, which was not desirable, and that the ruling of decision T 1139/00 had been applied in national decisions such as the High Court's decision D40, which had been confirmed by the decision of the Court of Appeal D40a (in particular paragraphs 68 to 97).

(g) As regards referral suggestion 1 filed during the oral proceedings of 7 March 2012, the appellants insisted that it raised fundamental legal questions which should be referred to the Enlarged Board of Appeal. Moreover, the board in its composition of three members had declared at the end of the oral proceedings of 19 October 2010 that it intended to refer questions to the Enlarged Board of Appeal concerning the allowability of a disclaimer in a claim wherein the subject-matter was delimited by structural and functional features. None of decisions G 1/03, G 1/05 or G 2/10 dealt with this aspect of a disclaimer. Hence this issue needed to be addressed before discussion of decision G 2/10, and the suggested referral was indeed pertinent for the present case.

(h) As regards referral suggestion 2 filed during the oral proceedings of 7 March 2012, it was necessary to refer the suggested questions to the Enlarged Board of Appeal since they concerned a party's right to be heard pursuant to Article 113(1) EPC and thus a fundamental point of law. If a board changed from a three-member to a five-member composition according to Article 21(3)(b) EPC, the

parties to the appeal proceedings had a right according to Article 113(1) EPC to be informed in detail, in a communication and before the matter could be discussed during oral proceedings, about the factual and legal aspects which were decisive for the change of the board's composition. The same applied if the board deviated from a legal position taken earlier in the appeal proceedings or from its earlier intention to refer a fundamental point of law to the Enlarged Board of Appeal. This was in particular the case when no change in relevant facts or arguments had occurred. Consequently, it was not sufficient if, as in the present case, the only reason given to the parties for changing the composition of the board was the "complexity of the case". Since the board had provided no explanation of the major legal issue which made it necessary to have a five-member board in the present case, the appellants' right to be heard had been infringed. The conduct of the board indicated that there were issues regarding the claim. However, these issues could not be understood by the parties without any further explanations from the board, since decision G 2/10 and other case law did not clarify them. Without knowledge of what the issue was, it could not be addressed by the parties, in particular by the appellants. Therefore, they felt "handicapped" in properly presenting their case.

Objections under Article 112a(2) and Rule 106 EPC

(i) Objection 1 had been made because the board had continued the oral proceedings without answering

the appellants' fundamental questions concerning the relationship between decision G 2/10 and the still open fundamental legal question initially indicated by the three-member board. The present appeal proceedings were therefore unfair in view of Article 125 EPC 1973 and Article 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 (ECHR) and of Article 113 EPC 1973, as could be derived from decision G 3/08 of 12 May 2010, point 7.2.1 of the Reasons and the four expert opinions from legal experts filed with letters dated 1 and 5 March 2012. The requirements of fairness were mandatory for the board. Therefore, the appellants had to be fully informed about the board's fundamental legal issues and had to be given due time to react. If they were not given enough time to deal with these issues, the proceedings would not be fair. Therefore, if a decision was taken in this hearing before the board had given guidance on these matters, there would be a breach of the appellants' right to be heard.

(j) Objection 2 had been raised because, although the board had to decide whether the remaining subject-matter in claim 1 of the main request was disclosed explicitly or implicitly to the skilled person, it had cut off all the evidence offered by the appellants, since it had not admitted document D100 or the requests under Article 117(1)(e) EPC into the proceedings and, applying decision G 4/95, did not allow Mr Lamprecht to make oral submissions as an accompanying person of the appellants at the oral proceedings of 7 to 9 March

2012. Moreover, the board did not want to consider the national decisions and had refused all of the appellants' requests for information or clarification. Since the board had set the parties no deadline for filing submissions, the evidence could not be excluded as belated in view of Article 13 RPBA and decision G 7/93.

(k) Objection 3 had been raised because the board had not given any grounds and/or evidence in respect of its assessment of the disclosure of the parent application (P4). The effect of this conduct was that the board would use its own expertise to create evidence, without giving any indication of what this evidence was. However, this evidence was used as the basis for the board's decision. However, the principles laid down in Article 113 EPC and the decisions referred to in the "Case Law of the Boards of Appeal of the European Patent Office", 6th edition 2010, page 438, and decision T 951/92, had to be applied. Article 6 ECHR had also not been complied with, as could be seen from the decision "Lawrence v The General Medical Council", High Court (England and Wales), [2012] EWHC 464 (Admin), paragraphs 229 and 231.

The appellants cited decision G 3/08 of 12 May 2010 anew in support of their submissions in relation to the right to a fair hearing, respect of fundamental principles of law and predictability.

LIV. The respondent's arguments, as far as relevant to the present decision, may be summarised as follows:

Procedural issues

(a) The board had indicated the complexity of the case as the reason for the change in its composition. However, there was no obligation for the board to give any further detailed reasons for this change. The appellants were speculating about a board's decision based on principles upon which they had not had any opportunity to comment. Their submissions did not make any sense since the discussion on claim requests or possible referrals had not yet taken place before the five-member board. Moreover, if there had been a legal problem it might no longer exist. In the respondent's opinion the appellants' conduct amounted to a delaying tactic to prevent a decision being announced at the end of the oral proceedings on 7 to 9 March 2012.

(b) As regards the late-filed document D100, the respondent requested that it should not be admitted into the proceedings. This document had been filed by the appellants together with more than a thousand other pages shortly before the oral proceedings of 7 to 9 March 2012. It could not reasonably be expected to study such lengthy submissions at short notice. It had not been possible to identify D100 as being of particular relevance among all the other documents and pages submitted. Therefore an adjournment of the oral proceedings would have been necessary. Furthermore, the average skilled person was not a particular professor and therefore Mr Lamprecht was not in a

position to speak as if he were such a person. Hence document D100 was not relevant. There had been no need for the appellants to await a communication from the board before they could take action, for example by filing document D100.

(c) The appellants' requests under Article 117(1)(e) EPC should not be admitted into the proceedings. These requests could have been filed earlier, since the issue for which evidence was sought had been known to the appellants for a long time. Also, the first request was unspecific. Moreover, the requests for expert evidence aimed at the hearing of an opinion on the knowledge of an average skilled person. Such evidence was, however, not necessary in view of the technical expertise of the technical members of the board.

The request that Mr Lamprecht make oral submissions as an accompanying person if he was not heard in accordance with Article 117(1)(e) EPC should not be allowed, because this would lead to the absurd situation that Mr Lamprecht's expert opinion was admitted after all. Moreover, this request had been made at a late stage of proceedings.

The appellants' claim requests

(d) The respondent submitted that the appellants, in their explanation of their invention, had wrongly given the impression that, according to the disclosure of the parent application (P4), the nature of the matrix did not matter. Moreover, the

appellants had presented the invention as if it concerned the first time that a controlled release oxycodone formulation had been made available. This was not correct in the light of the cited prior art. Thus, the appellants' position relied on inaccurate assertions. The choice of the controlled release matrix related to the technical contribution and it was wrong to claim that the nature of the matrix did not play any particular role for the claimed subject-matter.

The respondent further argued that the appellants had given as the basis for claim 1 of the main request an arbitrary combination of separate passages in the parent application, and therefore the subject-matter of claim 1 was not directly derivable from the parent application. In particular, the respondent pointed to the combination of the specific pharmacokinetic plasma profile and the range of amounts of the oxycodone salt in connection with the nature of the matrix. The parent application (P4) did not refer to the matrix in any of the passages concerning pharmacokinetic profiles. The appellants' arguments in relation to claim 5 of the parent application confused the concept of disclosure with the concept of the extent of protection sought. The parent application did not disclose that each controlled release matrix was capable of attaining the pharmacokinetic profile; not every matrix falling within claim 5 of the parent application was necessarily disclosed. The disclosure of the controlled release matrix on pages 9 and 10 concerned an enumeration of

possible materials which could be included. However, it was not disclosed that any matrix containing all possible combinations of materials was able to provide for a particular pharmacokinetic profile of the formulation for the ranges of amounts specified in claim 1.

The respondent also submitted that claim 1 of the main request was not restricted in relation to pH-independent dissolution characteristics of the formulation or in relation to a particular *in vitro* release profile. The claim encompassed subject-matter which was not disclosed in the parent application. Moreover, the claim encompassed formulations comprising a matrix which included acrylic resins which did not afford pH-independent release. This was in contrast to the requirements specified for the matrix on page 9 of the parent application (P4). Claim 1 of the main request contained a limitation in relation to the definition of the matrix which was not derivable from the parent application and which created an "artificial subgroup" not disclosed in the parent application. The decisions of the High Court (D40), of the Court of Appeal (D40a), and of the District Court of The Hague (D78a) had been issued before decision G 2/10 was taken. Therefore, these national decisions were not relevant for determining the application of decision G 2/10 to the present case. Moreover, the board was not bound by national decisions and had to decide in an independent manner. The decision of the District Court of The Hague D78a did not refer to the decisions of the High Court and the Court of

Appeal D40 or D40a. Additionally, the paragraph of the decision of the District Court of The Hague D78a cited by the appellants (namely paragraph 4.15) referred to decision G 1/03, which was not applicable to the present case. The passages cited by the appellants from the Court of Appeal's decision D40a (paragraphs 69 ff), which referred to the application of Article 123(2) EPC or to decision G 1/93, were not relevant for the analysis of Article 76(1) EPC in the present case.

The respondent further submitted that the subject-matter remaining after the disclaimer was introduced was not disclosed in the parent application since the remaining subgroup of matrices was not disclosed in combination with the rest of the features in the claim. The definitions of the materials in the controlled release matrix given in claim 5 of the parent application did not correspond to the remaining subgroup of matrices in claim 1 of the main request. There was no mention of the absence of acrylic resins, or of the pH-independent release characteristics in claim 5 of the parent application. Decision G 2/10 stipulated in point 4.5.4 that it had to be assessed in each individual case whether the "subgroup" created after the introduction of the disclaimer was disclosed in the application as filed. There was added matter since the insertion of the disclaimer resulted in singling out a subgroup of controlled release matrices which was not directly derivable from the parent application. The national decisions cited by the appellants did

not deal with the examination of the remaining subject-matter, as required by decision G 2/10.

Additionally, following decision G 2/10 the rules of logic did not apply for the disclosure test. Therefore, it had to be denied that the subject-matter created after exclusion of a part by means of a disclaimer had always to be considered as disclosed. The situation in claim 1 of the main request concerned the classical arbitrarily created "subgroup", which was not allowable. One had to use criteria like those for novelty examination. The skilled person would not conclude that the parent application disclosed that any matrix would be able to afford the pharmacokinetic plasma profile. As a matter of fact, the disclosure in the parent application was very thin in relation to the specific materials constituting a matrix able to provide that curve. The question whether or not it was to be expected that a controlled release matrix constituted with materials analogous to those specifically disclosed in the parent application was able to afford the pharmacokinetic plasma profile had to do with inventive step criteria.

Moreover, the appellants should not be allowed to refer to experts' opinions given in national proceedings, which did not form part of the present proceedings and to which the respondent had not been a party. Additionally, university professors were not the average skilled person in the field.

Decisions T 142/94 and T 1024/96, cited by the appellants, were not relevant for the analysis of Article 76(1) EPC since one dealt with inventive step and the other with Article 84 EPC.

(e) The respondent submitted that auxiliary requests 1 to 7 received during the oral proceedings should not be admitted into the proceedings.

Both auxiliary request 1 and auxiliary request 2 were *prima facie* not allowable under Article 123(2) and 76(1) EPC. Additionally, restricting the range of amounts to 10 mg to 40 mg did not resolve any problems but opened new issues for discussion, further complicating the case. Furthermore, the addition of a new claim 2 in the auxiliary requests was not justified and should not be allowed. If those auxiliary requests were admitted, then claim 2 was also open for discussion, since each set of claims taken as a whole had to be decided on.

Auxiliary request 3 was *prima facie* not allowable in view of the fact that the selection of the excluded acrylic resin matrix was no longer linked to pH-independent dissolution characteristics in the formulation. Such a rewording opened new issues for discussion.

Auxiliary request 4 was *prima facie* not allowable since the definition of the excluded subject-matter had been modified. The amendments introduced opened new issues, *inter alia* in relation to clarity. In particular, the use

claimed addressed simultaneously moderate and severe pain.

As regards the argument that auxiliary requests 3 or 4 had been on file for a long time it had to be said that they had been picked out arbitrarily from a list of 117 auxiliary requests. The respondent could not possibly be expected to foresee which requests, amongst that unacceptably high number, the appellants would wish to proceed with.

Auxiliary requests 5 and 6 were part of a bundle of 117 auxiliary requests filed shortly before the oral proceedings. The board in its communication dated 17 February 2012 had correctly reminded the parties of Article 13 RPBA. It was the patent proprietors' duty to provide for an allowable request and it was not the board's duty to give guidance to discharge the patent proprietors from their duty. The fact that some requests had now been picked out from the huge bundle did not make them admissible. They were belated. The 117 auxiliary requests related to variations and permutations in claims' wordings. It was unacceptable to require the respondent to deal with them in such a short time. The auxiliary requests opened many new issues for discussion, *inter alia* under Article 84 EPC. It was further inadmissible to add a new product claim 2 to auxiliary requests 5 and 6, in which claim 1 was a use claim. The written arguments to which the appellants had referred were part of more than a thousand pages they had filed on 7 February 2012.

The EPO had provided the respondent with a CD containing all those pages ten days later.

As regards auxiliary request 7, the respondent submitted that claim 1 did not contain any disclaimer. Therefore, the claim opened new issues for discussion. The claim was not *prima facie* allowable since there was either a problem under Article 123(3) EPC or the "subgroup" now created was not disclosed in the application (or parent application) as filed. The definition of the medical indication did not meet the requirements of Article 84 EPC.

As regards auxiliary requests 1a and 2a, they were clearly not allowable and thus should not be admitted into the proceedings. Moreover, they did not overcome the objections to the remaining subject-matter in the light of decision G 2/10. The disclaimer had been worded differently from the disclaimer in granted claim 1, so the new wording would have to be investigated. There was also a lack of support for the combination of materials required to achieve the release profiles as defined in the claim. Claim 5 of the parent application (P4) related to a "solid oral dosage form" and not to a "formulation".

Requests for referral to the Enlarged Board of Appeal

(f) Regarding the referral suggestion 1 filed during the oral proceedings of 7 March 2012, there was no legal ground for referring these questions to the Enlarged Board of Appeal because there was no

apparent reason why decision G 2/10 did not already answer them. Furthermore, the board in its five-member composition was not bound by what had been said by the board in its three-member composition during the oral proceedings of 19 October 2010.

Objections under Article 112a(2) and Rule 106 EPC

(g) Objection 1 was not justified because, in the proceedings before the five-member board, no fundamental legal issue had become relevant. Moreover, the five-member board had confirmed that the issue of referral to the Enlarged Board of Appeal was fully open. Therefore the appellants' right to be heard had not been violated.

(h) Objection 2 was not justified because the board had rightly not admitted document D100 and the requests under Article 117(1)(e) EPC into the appeal proceedings under Article 13 RPBA and not allowed Mr Lamprecht to make oral submissions in view of decision G 4/95. Moreover, the board itself had technically qualified members.

(i) Regarding objection 3, the decision "Lawrence v The General Medical Council", High Court (England and Wales), [2012] EWHC 464 (Admin) (D107 as numbered by the board) was not binding on the board.

LV. The appellants (patent proprietors) requested that the decision under appeal be set aside and the patent maintained in amended form on the basis of the main

request dated 13 October 2009 or, alternatively, on the basis of auxiliary requests 1, 1a, 2, 2a and 3 to 7 received during the oral proceedings on 9 March 2012.

LVI. The respondent (opponent 01) requested that the appeal be dismissed.

Reasons for the Decision

1. The present decision was taken after the entry into force of the revised European Patent Convention (EPC) on 13 December 2007. At that time, the European patent in suit had already been granted. The board has therefore applied the transitional provisions in accordance with Article 7(1), second sentence, of the Revision Act of 29 November 2000 and the decisions of the Administrative Council of 28 June 2001 (OJ EPO 2007, Special edition No. 1, 197) and 7 December 2006 (OJ EPO 2007, Special edition No. 1, 89). Articles and rules of the revised EPC and of the EPC valid until that time are cited in accordance with EPO citation practice (see the 14th edition of the European Patent Convention, page 6).

2. The appeal is admissible.

Procedural issues

3. *Sub-authorisation given to Mr Segan*

In view of the documents submitted by the appellants at the oral proceedings on 9 March 2012 the board no longer had reason to doubt that Mr Segan, a legal

practitioner entitled to act as a representative, was duly sub-authorised in the present case (Article 133 and Rule 152(1) EPC and Article 2, first sentence, of the decision of the President of the EPO dated 12 July 2007 on the filing of authorisations, OJ EPO 2007, Special edition No. 3, 128).

Moreover, on the same day of the oral proceedings, the professional representative, Mr Maiwald, stated as a precautionary measure that he endorsed any submission made by Mr Segan during these oral proceedings.

4. *Request of the appellants that the board give the reasons why it considered it necessary to extend itself to five members*

4.1 By their letter dated 5 October 2010, the appellants had asked for the appointment of an additional technically qualified member and an additional legally qualified member. During the oral proceedings dated 19 October 2010, the appellants stated that they had not requested but only suggested changing the composition of the board from three to five members in view of the complexity of the case. When the change in composition was communicated to the parties with the summons to oral proceedings sent on 10 May 2011, the appellants neither objected to this enlargement nor asked for clarification. Their request at the oral proceedings held from 7 to 9 March 2012 to obtain from the board detailed reasons for the change in the board's composition is thus in manifest contradiction to their previous submissions and conduct. The board further notes that the appellants did not elucidate in what respect they considered themselves negatively

affected by the change in the composition of the board, which was actually in accordance with their earlier submissions. The alleged "change of position" in relation to the relevance of decision G 2/10 or a pending referral question allegedly taken earlier in these proceedings by the three-member board is not decisive for the present case, because the five-member board is not bound by any position expressed by the board in its three-member composition since such a position is not a decision but only an opinion. Hence the board does not accept the appellants' argument that, in the oral proceedings of 7 to 9 March 2012, the discussion regarding decision G 2/10 had to come last.

4.2 The board further points out that under Article 21(4)(b) EPC 1973, for appeals from a decision of an opposition division the board consists of three technically and two legally qualified members if the opposition division consisted of four members, or if the board considers that the nature of appeal so requires. To comply with this last provision, it was sufficient for the board to indicate in the order of 3 May 2011 (EPO Form 3303.15) that the complexity of the case was the reason for enlarging the board from three to five members.

4.3 Thus, the board was not obliged to give a **detailed** reasoning as to why it considered the present case complex. In the board's view, a change in a board's composition with regard either to the number of its members under Article 21(4)(b) EPC 1973 or to the replacement of a member under Article 4 of the Business distribution scheme of the Technical Boards of Appeal for the year 2012 (see Supplement to OJ EPO 1/2012,

page 12) is not a decision within the meaning of Articles 106 EPC and 113(1) EPC 1973.

5. *Admission of document D100 (opinion of Mr Lamprecht entitled "Expert opinion concerning the technical circumstances of the disclaimer 'other than acrylic resin matrix'" dated 7 February 2012) and requests under Article 117(1)(e) EPC*

5.1 According to Article 12(2) RPBA the statement of grounds of appeal and the reply thereto must contain the party's complete case. Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion, which is to be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA). Amendments sought to be made after oral proceedings have been arranged are not to be admitted if they raise issues which the board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings (Article 13(3) RPBA).

It is clear from the provisions of Article 13 RPBA that the assessment of whether there is an "amendment to a party's case" within the meaning of said provisions does not depend on a due date set by the board.

5.2 *Admission of document D100*

5.2.1 Document D100 was filed with the appellants' letter of 7 February 2012, i.e. one month ahead of the oral proceedings of 7 to 9 March 2012. The filing of

document D100 is an amendment to the appellants' case within the meaning of Article 13(1) RPBA and that amendment was made after the oral proceedings had been arranged.

The appellants' submissions in the letters dated 7 February 2012, including all annexes, comprise more than a thousand pages (see also XXXIV above). In any event, through their volume alone such extensive submissions shortly before oral proceedings add significant complexity to the appeal proceedings, run counter to procedural economy and deprive the opposing party of a proper opportunity to respond. In the absence of exceptional circumstances such late submissions should therefore not be admitted into the appeal proceedings. This applies not only to such voluminous submissions as a whole but also to their individual parts, such as an annexed opinion, since neither the board nor the opposing party or parties can be reasonably expected to discern immediately the relevance of unspecified individual parts of such voluminous submissions, including their annexes, without carefully studying the complete submissions. In this respect, even if the appellants did refer to document D100 on page 18 of their 34-page letter of 7 February 2012, the board agrees with the respondent's argument that it was not possible for it to identify document D100 as being of particular relevance among the many documents submitted on 7 February 2012.

5.2.2 Moreover, the appellants' submission included a large number of so-called expert opinions attached as annexes, of which 11 were opinions from Mr Lamprecht (documents D98-1 to 98-10 and D100). In the board's view, a

careful study of such a large number of opinions within one month could not have been reasonably expected either of the board or the respondent, which had even less time at its disposal. The respondent could even less be expected to respond properly to these opinions, since this would have required involving its own experts. This also holds true with regard to individual document D100, the particular importance of which the respondent could not be expected to discern when confronted with the submissions of 7 February 2012. Hence, the admission of document D100 would have made an adjournment of the oral proceedings inevitable in order to safeguard the respondent's right to be heard and to adhere to the general rules of fairness which apply in *inter partes* proceedings. Thus, pursuant to Article 13(3) RPBA, the board had not to admit document D100.

5.2.3 The appellants argued that document D100 was filed in reaction to the expert opinions filed by one of the opponents no longer party to the present appeal proceedings (see opponent O4's letter of 25 August 2011). Even if this was the case, the board is not persuaded by the appellants' contention that they were acting diligently and could not have been reasonably expected to file their responding opinion sufficiently in advance of the oral proceedings of 7 to 9 March 2012 in order to avoid the respondent, which was by then the only other party, being taken by surprise and deprived of a proper opportunity to respond. The appellants did not argue that they were facing exceptional circumstances which prevented them from submitting the opinion earlier. Therefore, the board finds that

document D100 could have been filed at a far earlier stage in the appeal proceedings.

5.2.4 In addition, the board notes the inconsistency in the appellants' conduct during the proceedings. By letter of 25 October 2011, they requested that the oral proceedings arranged for 14 to 16 November 2011 be postponed **by at least two months**, "in case a discussion of and decision on the merits in such proceedings" was considered to be taken by the board. The appellants argued that the remaining **three weeks** did not allow proper preparation for several reasons. They argued that dealing with the submissions of opponent O4 (party to the present proceedings until 23 November 2011), which were filed with letter dated 25 August 2011 and included new expert opinions, required the appellants to involve their own experts and that the appellants should have enough time to submit relevant evidence well before the oral proceedings. They further argued that they also had to rely on experts in view of decision G 2/10 and its Headnote 1a and that they would not be able to obtain the necessary expert evidence and submit it timely before the oral proceedings or to announce the presence of their experts within the prescribed term of at least one month before the date of the oral proceedings. Additionally, the appellants stressed that three weeks were insufficient for the revision of their requests in the light of decision G 2/10. Thus, the board cancelled the oral proceedings and summoned the parties shortly thereafter to new oral proceedings to be held on 7 to 9 March 2012 (see points XXVIII and XXIX above), giving the appellants more than four months time, i.e. **more than the requested two months**, to prepare. Nevertheless, the appellants seem

to have considered it acceptable to confront the respondent and the board **one month** before oral proceedings with a large number of documents many of which, as is clear from their dates, had been available to the appellants for a considerable time prior to their request for postponement. By doing so, the appellants surprised the opposing party and placed upon it the burden of coping with the very time constraints and disadvantages of which they had complained in their letter of 25 October 2011.

5.2.5 For the above reasons, the board, considering the admission of evidence from the point of view of fair proceedings, did not admit document D100 into the appeal proceedings, in accordance with Article 13(3) RPBA.

5.3 *Request under Article 117(1)(e) EPC on the issue of the nature and extent of the disclosure of the parent application P4 in the eyes of a skilled person as required by decision G 2/10*

5.3.1 By this request, filed at the oral proceedings on 8 March 2012, the appellants sought an expert's opinion within the meaning of Article 117(1)(e) EPC on the knowledge of skilled persons in the technical field concerned and on their understanding of the disclosure of the parent application P4, without naming an expert. In fact, the appellants requested that the board find and appoint an expert under Article 117(1)(e) EPC. This request is an amendment to the appellants' case within the meaning of Article 13(1) RPBA and was made after the oral proceedings had been arranged.

5.3.2 If this request for the taking of evidence had been admitted and allowed, it would have inevitably meant adjourning the oral proceedings in order to find and appoint an expert within the meaning of Article 117(1)(e) EPC and then to commission him in accordance with Article 117(2) and Rule 121 EPC to write an opinion or, in the case of a hearing, to duly summon him in accordance with Article 117(2) and Rule 118 EPC on the basis of a formal decision by the board on the taking of evidence under Article 117(2) and Rule 117 EPC, and to draw up the minutes of the hearing pursuant to Rule 124 EPC. Moreover, the parties would have had to be given the opportunity to respond to the result of the taking of evidence.

5.3.3 Moreover, in the board's view, this request was not a reaction to new circumstances which arose in or shortly before the oral proceedings. The appellants could have been expected to submit such a request sufficiently in advance of the oral proceedings since they were aware of the issues at the time of filing their request for postponement on 25 October 2011.

5.3.4 For the above reasons, this request was not admitted into the appeal proceedings, in accordance with Article 13(3) RPBA.

5.4 *Request under Article 117(1)(e) EPC that Mr Lamprecht's opinion be heard on the issue of the nature and extent of the disclosure of the parent application P4 in the eyes of a skilled person as required by decision G 2/10*

5.4.1 The appellants filed this request at the oral proceedings on 8 March 2012. Hence, this request is an

amendment to the appellants' case within the meaning of Article 13(1) RPBA and was made after the oral proceedings had been arranged.

5.4.2 The procedure for hearing an expert within the meaning of Article 117(1)(e) EPC in proceedings before the EPO is governed *inter alia* by Rules 117 and 118 EPC (Article 117(2) EPC). The board did not doubt that Mr Lamprecht, who was present at the oral proceedings of 7 to 9 March 2012, would have agreed to testify in these oral proceedings without having been duly summoned in accordance with Rule 118(2) EPC. However, it would have been necessary for the board to take a formal decision on the taking of evidence under Rule 117 EPC and to prepare the relevant questions to be put to Mr Lamprecht. This might have been possible without adjourning the oral proceedings. However, the respondent which, pursuant to Article 117(2) and Rule 119(3) EPC, could have attended the hearing of Mr Lamprecht and put relevant questions to him, would have had to have had a fair opportunity to prepare such questions and later to comment on the testimony, of which minutes would have had to have been drawn up in accordance with Rule 124 EPC. It is the board's view that such a fair opportunity could only have been given to the respondent by adjourning the oral proceedings. Therefore, this request was not admitted into the appeal proceedings, in accordance with Article 13(3) RPBA.

6. *Admission of an oral presentation from the accompanying person, Mr Lamprecht*

6.1 According to decision G 4/95 (OJ EPO 1996, 412), oral submissions by an accompanying person in opposition or opposition appeal proceedings cannot be made as a matter of right, but only with the permission of and at the discretion of the board (point 9 of the Reasons). When exercising its discretion the main criteria which the board has to consider are(see G 4/95, headnote and points 10 and 11 of the Reasons):

(i) the professional representative should request permission for such oral submissions to be made. The request should state the name and qualifications of the accompanying person, and should specify the subject-matter of the proposed oral submissions;

(ii) the request should be made sufficiently in advance of the oral proceedings so that all opposing parties are able to properly prepare themselves in relation to the proposed oral submissions;

(iii) a request which is made shortly before or at the oral proceedings should in the absence of exceptional circumstances be refused, unless each opposing party agrees to the making of the oral submissions requested;

(iv) the EPO should be satisfied that oral submissions by an accompanying person are made under the control of the professional representative.

6.2 In their one-page letter dated 7 February 2012 (see point XXXIII above) the appellants implicitly requested that four persons (including Mr Lamprecht) be allowed to make oral statements on technical issues at the scheduled oral proceedings, if necessary, and stated their names. Regarding the CVs of these announced accompanying persons, which can be assumed to say something about their qualifications, the appellants referred to their previous submissions, without however specifying which particular submission(s) they meant. In said letter the appellants indicated that Mr Lamprecht would comment on "*aspects relating to pharmaceutical technology*" and thus they described only in a very general manner the subject-matter on which Mr Lamprecht was to make oral submissions. Their written request therefore did not comply with criterion (i) above.

6.3 The present board agrees with the finding in decision T 302/02 that if an expert were allowed to make submissions on subject-matter not specified in some detail beforehand, the other party or parties would be placed at a disadvantage since they could not prepare themselves properly, and that this would be against the spirit and purpose of decision G 4/95 and should only be permitted if none of the parties to the proceedings objects (see point 1.1 of the Reasons). It was only at the oral proceedings that the appellants informed the board and the respondent that they wished Mr Lamprecht to be allowed to make oral submissions on the issue of the nature and extent of the disclosure of the parent application P4 in the eyes of a skilled person as required by decision G 2/10. Thus only then was criterion (i) complied with.

6.4 However, the fact that the subject-matter of the requested oral submissions was not specified to the respondent until the oral proceedings had the effect of shifting an unwarranted burden onto the respondent. Therefore, criterion (ii) was not met either.

6.5 Since the respondent objected to Mr Lamprecht making oral submissions, criterion (iii) was equally not complied with.

6.6 In view of the above, the board did not allow Mr Lamprecht to make submissions as an accompanying person of the appellants at the oral proceedings of 7 to 9 March 2012.

7. *Request that, if and insofar as the board proposes to use only its own technical expertise to decide the issue of whether the subject-matter remaining after the disclaimer was disclosed, implicitly or explicitly, to the skilled person using common general knowledge in the parent application P4 ("the G 2/10 issue"), the board, before it comes to a decision on the "G 2/10 issue", set out for the parties the evidence or grounds pursuant to Article 113 EPC 1973, on which such decision is to be based, and offer the parties a proper opportunity to comment*

7.1 According to the established jurisprudence of the Enlarged Board of Appeal in review cases, the board was not obliged to follow such a request. In its decision R 6/11, point 8.3 of the Reasons, the Enlarged Board of Appeal held that the "*Enlarged Board's jurisprudence clearly demonstrates the principle that parties are not*

entitled to advance indications of the reason or reasons for a decision before it is taken" and referred to the summary of the jurisprudence in decision R 12/09 of 15 January 2010, point 11 of the Reasons, and the several other decisions there cited, and to the subsequent decisions R 15/09, point 4 of the Reasons, R 18/09, points 14 to 15 and 18 of the Reasons, and R 15/10, points 7 to 9 of the Reasons).

The Enlarged Board of Appeal then continued in decision R 6/11: "*If that principle applies to the reasons for a decision generally, it must apply equally to a comment forming only a part of such reasons.*"

7.2 The board concludes from the above jurisprudence of the Enlarged Board of Appeal that the same must apply if the board including three technically qualified members assesses technical facts in the light of patent law and considers itself expert enough to decide upon a matter without technical assistance from an expert within the meaning of Article 117(1)(e) EPC. Firstly, such assessment is a matter for the board and not for a technical expert within the meaning of Article 117(1)(e) EPC. Only if the board did not consider itself in a position to decide upon a matter without technical assistance, would such expert evidence become appropriate (see also decisions T 395/91, point 5.3 of the Reasons, T 230/92, point 5.3 of the Reasons, T 375/00, point 1.2.2 of the Reasons, and T 311/01, point 5 of the Reasons). Secondly, such assessment does not mean that any member of the board becomes a witness within the meaning of Article 117(1)(d) EPC or an expert within the meaning of Article 117(1)(e) EPC who has to give evidence in accordance with the relevant

EPC provisions, as is clear from the provisions of Article 117(1)(d) and (e) and of Rules 117 and 118 EPC.

7.3 In view of the above, the appellants' request was refused by the board.

The appellants' claim requests

8. Main request

8.1 In its interlocutory decision the opposition division reached a conclusion on the issue of Article 100(c) EPC 1973 for the set of claims as granted. Consequently, the assessment of the grounds pursuant to Article 100(c) EPC 1973 is part of the legal framework of the present appeal proceedings.

8.2 According to Article 100(c) EPC 1973, opposition may be filed on the grounds that:

"the subject-matter of the European patent extends beyond the content of the application as filed, **or**, **if the patent was granted as a divisional application** or on a new application filed under Article 61, **beyond the content of the earlier application as filed**" (emphasis added).

The application underlying the patent in suit was filed as a divisional application of an earlier European application which was based on the international application published as WO 93/10765 (parent application P4).

Decision G 1/05 of 28 June 2007 (OJ EPO 2008, 271) states in point 3.6 of the Reasons:

"*Thus in opposition proceedings under Article 100(c) EPC it is a ground of revocation that the subject-matter of the European patent granted on a divisional application extends beyond the content of the earlier application as filed. Article 100 EPC does not state that it is a ground of revocation that the patent was granted on a divisional application whose subject-matter as filed extended beyond the content of the earlier application as filed. Article 100 EPC exhaustively sets out all the grounds of revocation that can be relied on, so the lack of any such ground of revocation suggests that the significant factor is the subject-matter at the time of grant and not whether the subject-matter of the divisional application as filed met the requirement of not extending beyond the content of the earlier application as filed.*"

8.3 The principles set out in decision G 2/10 with regard to the requirements to be met in order for amendments by the introduction of disclaimers for disclosed subject-matter to be allowable under Article 123(2) EPC also apply with regard to the requirements for divisional applications under Article 76(1) EPC (see decision G 2/10, point 4.6, fourth paragraph, of the Reasons). They therefore also apply to the examination under Article 100(c) EPC 1973 in the present case.

In decision G 2/10 the question referred to the Enlarged Board of Appeal is answered as follows:

"*1a. An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.*

1b. Determining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration, taking into account the nature and extent of the disclosure in the application as filed, the nature and extent of the disclaimed subject-matter and its relationship with the subject-matter remaining in the claim after the amendment."

In accordance with decision G 2/10, the disclosure of the parent application as filed has to be evaluated in comparison with the subject-matter remaining in the claim after the amendment.

8.4 Claim 1 of the main request is identical to claim 1 as granted. The appellants submitted that the disclaimer in claim 1 of the main request excluded subject-matter disclosed and claimed in the granted patent deriving from the parent application and referred to paragraph [0007] of the patent in suit (P1). Irrespective of whether or not this is the case, the following has to be considered. Such a procedural situation (which concerns the prosecution in a divisional application of the general teaching, whereas in the parent application the protection of a preferred embodiment is pursued) is

reflected in decision G 2/10, point 4.5.5, third paragraph, of the Reasons:

"*The applicant may, for example, be interested in obtaining a first quicker protection for a preferred embodiment and pursue the general teaching in a divisional application. Whether or not and, if so, under what circumstances, in such a case a disclaimer would be necessary in order to avoid the so-called prohibition on double protection is a different matter. It is sufficient to say that such procedural behaviour is not abusive and even legitimate*."

8.5 In order to assess what is the subject-matter claimed in claim 1 of the main request, the claim's construction has first to be investigated.

8.5.1 In accordance with Article 7(1), second sentence, of the Revision Act of 29 November 2000 and the decision of the Administrative Council of 28 June 2001 (Special edition No. 1, OJ EPO 2007, 197), revised Article 54(4) EPC is applicable, since the mention of the grant of the patent in suit was published in European Patent Bulletin before the entry into force of the revised EPC.

Oxycodone (as well as some oxycodone formulations) was known as a pharmaceutical drug before the effective date of filing of the patent in suit. Therefore, in accordance with Article 54(4) EPC, claim 1 of the main request, which relates to "a controlled release oxycodone formulation **for oral administration to human patients**", is a product claim in which the condition "for oral administration to human patients" merely

expresses the suitability of the formulation for oral administration.

8.5.2 Claim 1 of the main request relates to a controlled release formulation comprising oxycodone salt and a controlled release dosage matrix. The oxycodone salt is present in an amount equivalent to 10 mg to 160 mg of the oxycodone hydrochloride salt. The objective reading of the claim is that the oxycodone salt is included in the controlled release dosage matrix.

Moreover, the condition appearing in the definition of the controlled release dosage matrix "selected so that the formulation provides pH-independent dissolution characteristics" serves to define the controlled release dosage matrix as one that allows the formulation to release amounts of oxycodone (active compound) in a pH-independent manner. According to the wording in claim 1 of the main request, said condition must also apply to the matrix excluded from the claim by means of the disclaimer. Additionally, the expression "other than an acrylic resin matrix" excludes from the controlled resin matrices those which incorporate acrylic resins as suitable materials.

Therefore, the controlled release dosage matrix in the formulation according to claim 1 is any controlled release matrix which is not an acrylic resin matrix, and which allows the formulation to release oxycodone amounts without pH-dependent dose dumping.

8.5.3 Additionally, claim 1 defines the formulation as providing, at steady state after repeated administration at 12-hour intervals, a mean maximum

plasma concentration of oxycodone of 6 to 240 ng/ml at 2 to 4.5 hours after administration and a mean minimum plasma concentration of oxycodone of 3 to 120 ng/ml at 10 to 14 hours after administration.

These functional definitions require that the controlled release formulation comprising oxycodone salt in the lowest amount (i.e. an amount equivalent to 10 mg of oxycodone hydrochloride salt) be able to achieve (when administered at 12-hour intervals) at least the lowest values for the mean maximum plasma concentration and the mean minimum plasma concentration of the stated pharmacokinetic plasma profile at steady state conditions. By analogy, the controlled release formulation comprising oxycodone salt in the highest amount (i.e. an amount equivalent to 160 mg of oxycodone hydrochloride salt) must be able to achieve (when administered at 12-hour intervals) the highest values for the mean maximum plasma concentration and the mean minimum plasma concentration of the stated pharmacokinetic plasma profile at steady state conditions. Moreover, formulations comprising oxycodone salt within the range defined (i.e. amounts equivalent to 10 mg to 160 mg of oxycodone hydrochloride salt) and a controlled release dosage matrix, other than an acrylic resin matrix, must provide a pharmacokinetic plasma profile within the ranges defined in the claim (when administered at 12-hour intervals).

8.5.4 From the foregoing it follows that claim 1 of the main request conveys that the particular pharmacokinetic plasma profiles at steady state, characterised by identifiable Cmax and Cmin at particular times, are attainable by means of any controlled release dosage

matrix (as far as it does not cause pH-dependent dose dumping), without occurrence of acrylic resins.

8.6 It has to be investigated whether or not the parent application (P4) discloses the product claimed in claim 1 of the main request and whether the subject-matter in said claim included technical information which is directly and unambiguously derivable from the parent application.

8.6.1 The parent application (P4) discloses the general principle that "… administering *an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof … providing a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated "q12h" (i.e. every 12 hours) administration through steady-state conditions*" reduces the range in daily dosages required to control pain in substantially all patients (see page 4, lines 19 to 30 of the parent application P4). However, the disclosure of this general principle does not suffice as a basis for the product claimed in claim 1 of the main request.

8.6.2 The generic disclosure on page 5, lines 6 to 14 of the parent application P4 relates in general terms to "*controlled release oxycodone formulations comprising up to about 160 mg oxycodone or a salt thereof, said formulations providing a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration,*

and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated q12h administration through steady-state conditions". This disclosure does not suffice either as an allowable basis for the product claimed in claim 1 as granted. In particular, the basis for the lowest value of oxycodone salt "in an amount equivalent to 10 mg … of the oxycodone hydrochloride salt", the lowest mean maximum plasma concentration of oxycodone of 6 ng/ml, and the lowest mean minimum plasma concentration of oxycodone of 3 ng/ml are lacking.

8.6.3 The parent application P4 discloses controlled release formulations comprising a matrix. The matrix is defined in the parent application as "*… any matrix that affords in vitro dissolution rates of oxycodone within the narrow ranges required and that releases the oxycodone in a pH independent manner*" (page 9, lines 25 to 28). However, claim 1 of the main request does not require the controlled release dosage matrix to afford a particular *in vitro* dissolution rate. As a consequence, the definition of the matrix defined in claim 1 of the main request is broader in this respect than the definition given on pages 9 and 10 of the parent application.

8.6.4 The parent application P4 discloses generically the "materials" which are "suitable for inclusion" in a controlled release matrix by giving different broadly defined generic options (see page 9, lines 31 to 35 and page 10, lines 1 to 16). However, the particular options given for materials to be included in the matrix do not amount to a generic disclosure encompassing any thinkable controlled release matrix

capable of achieving the plasma profile given in claim 1 of the main request. The list of suitable materials which may be included in a controlled release matrix appearing on pages 9 and 10 of the parent application does not represent a complete and fully elaborated list of constituents covering each and every kind of controlled release matrices. Furthermore, the parent application does not disclose that the plasma profile defined in claim 1 of the main request is the immediate and direct result of any controlled release matrix just because it contains any of the materials listed on pages 9 and 10. Moreover, on page 10, lines 17 to 20, and on page 11, lines 14 to 19, some particular suitable matrices are disclosed which, however, do not cover any possible suitable controlled release matrix of claim 1. Thus, it cannot be derived from the content of the parent application that any controlled release matrix is able to provide the pharmacokinetic plasma profile required by claim 1 of the main request, or that any controlled release matrix can achieve the plasma profile without the occurrence of an acrylic resin.

8.6.5 The parent application P4 discloses controlled release matrices comprising hydrophilic polymers other than acrylic resins, namely it discloses suitable matrices comprising at least one water-soluble hydroxyalkyl cellulose and at least one C_{12}-C_{36} aliphatic alcohol (see page 10, lines 17 to 20 of the parent application). However, this particular subgroup is not a sufficient basis for the generic definition in claim 1 of the main request. Moreover, the constitution of the "suitable matrix" in this particular embodiment only confirms that the "suitable materials" listed on pages 9 and 10

do not represent singularised subgroups of a "suitable matrix" but generic options for materials to be selected and included in order that a "suitable matrix" is built.

8.6.6 Additionally, claim 5 of the parent application P4 explicitly requires a suitable pharmaceutical diluent to be present in the solid oral dosage form. Apart from the fact that this feature is lacking in claim 1 of the main request, claim 5 of the parent application does not give in its paragraph (b) any exhaustive list of all possible constituents forming a controlled release matrix. Moreover, claim 5 of the parent application does not teach that each and every constitution of the controlled release matrix is able to attain the pharmacokinetic plasma profile defined in claim 1 of the main request, or that said profile can be achieved by any combination of materials without the occurrence of acrylic resins.

The fact that claim 6 of the parent application P4 explicitly refers to a controlled release composition of claim 5, "wherein said controlled release matrix **comprises an acrylic resin**" (emphasis added) merely emphasises that controlled release matrices comprising an acrylic resin are preferred, but says nothing about the nature and effect of controlled release matrices without the occurrence of acrylic resins.

8.6.7 For the above reasons, the board concludes that the subject-matter of claim 1 of the main request remaining after the introduction of the disclaimer extends beyond the content of the parent application P4.

8.7 Turning now to the appellants' arguments:

8.7.1 The person skilled in the art is the **notional skilled person** working in the technical field at the effective date of filing. The notional skilled person is not represented by a particular scientific expert or specialist with almost twenty years of accumulated expertise and knowledge after the date of filing of the parent application.

Additionally, if an application requires additional technical information to interpret terms differently from an objective reading of them in the technical field, then the application as filed has to include explanations and/or citations of prior-art references to clarify those aspects. In the absence of such explanations and references in the parent application as filed, the terms and definitions employed are to be given their objective and generally accepted meaning. Nothing other than this has been done in the present case.

Moreover, as regards the appellants' allegation that the pharmacokinetic plasma profile makes it possible for the person skilled in the art to identify a controlled release formulation as one according to the parent application P4, it has to be said that this is not the question to be answered for the assessment of added subject-matter. The question to be answered in the present case is whether the product claimed in claim 1 of the main request presents the skilled person with technical information which is not directly and unambiguously derivable from the parent application. As shown by the analysis above, the product claimed in

claim 1 of the main request presents the skilled person with new technical information relating to the constitution of the controlled release matrix suitable for attaining the particular pharmacokinetic plasma profile defined in the claim.

8.7.2 The appellants also submitted that according to decision G 2/10 (point 4.5.4, fourth paragraph, of the Reasons) the remaining subject-matter and the remaining general teaching will normally not be modified by excluding from protection, by means of a disclaimer, a group initially disclosed in the application as filed. However, decision G 2/10 also states in the same paragraph that a situation may arise in which the disclaimer has the effect of confining the subject-matter remaining in the claim to a subgroup of the originally claimed subject-matter which could not be regarded as disclosed in the application as filed even taking into account what the skilled person would have considered as implicitly disclosed.

In the present case there is an essential difference between what the appellants subjectively consider has been disclosed in their parent application P4 and the objective assessment of what has actually been, be it explicitly or implicitly, directly and unambiguously disclosed. The board considers that the concept of implicit disclosure has to be applied with great care. Therefore, subject-matter is implicitly disclosed to the skilled person in an application as filed if this subject-matter is necessarily derivable from said application.

8.7.3 The appellants made use in their submissions of the expressions "technical contribution", "technical information" and "technical teaching" as if they referred to the same concepts. However, when examining the subject-matter remaining after introduction of the disclaimer in the present case in the light of the principles set out in decision G 2/10, it has to be assessed whether the subject-matter claimed presents the skilled person with new technical information not directly and unambiguously derivable from the parent application as filed. On the other hand, the test relating to the technical contribution provided by a claim vis-à-vis the prior art does not apply to the present case, since the disclaimer was not introduced in view of any particular prior-art document. Moreover, the technical teaching in the patent in suit, which derives from the divisional application, is *per se* different from that in the parent application P4. This is due to the fact that the content of the divisional application as filed was restricted in comparison to the parent application P4. The fact that the content of a patent deriving from a divisional application is limited in relation to the parent application does not necessarily mean that there is a problem under Article 100(c) EPC 1973. However, if the limitations cause the "singling out" of intermediate generalisations (such as particular subgroups of elements) involving new technical information, then there is added subject-matter within the meaning of Article 100(c) EPC 1973.

Furthermore, the appellants argued that the disclosure of a certain pharmacokinetic profile in the parent application P4 means that the parent application

inevitably singles out each and every constituent and combination of constituents for the formulation. However, for the application of Article 123(2) EPC, Article 76(1) EPC 1973, or Article 100(c) EPC 1973, the disclosure test does not relate to alternatives which are not directly and unambiguously derivable from the application as filed.

8.7.4 Additionally, the appellants cited the High Court's decision D40 and the subsequent decision of the Court of Appeal D40a in support of their argument that the subject-matter claimed in claim 1 of the main request does not contain added subject-matter.

All the national decisions cited by the appellants predate the referral decision T 1068/07 and decision G 2/10. Decision G 2/10 leaves no doubt that it has to be investigated in each individual case whether the subject-matter remaining in the claim after the introduction of a disclaimer includes technical information which is not directly and unambiguously derivable from the parent application as filed.

As regards the passages cited by the appellants in said national decisions, it has to be stressed that the High Court in its decision D40 and the Court of Appeal in its decision D40a did not assess whether the subject-matter remaining in the claim after the introduction of the disclaimer was disclosed in the parent application as filed.

The same applies in relation to the decision of the District Court of The Hague (D78a).

8.7.5 The appellants also cited decisions T 142/94 and T 1024/96.

Decision T 142/94 deals with the assessment of the requirements of inventive step in relation to a claim relating to a solid controlled release dosage form characterised *inter alia* by means of *in vitro* release profile and *in vivo* release profile. Therefore, decision T 142/94 is not relevant for the examination under Article 100(c) EPC 1973. Decision T 1024/96 deals with the assessment of clarity of functional features under Article 84 EPC 1973. However, claim 1 of the present main request is identical to claim 1 as granted. Therefore, Article 84 EPC 1973 is not at issue (T 23/86, OJ EPO 1987, 316). Decision T 1024/96 is thus not relevant for the present case either. Finally, it has to be pointed out that, in contrast to the circumstances of the decisions cited by the appellants, the product of claim 1 of the main request is not characterised by the *in vitro* dissolution rate.

8.7.6 The appellants also referred to their written submissions made in document D70. In document D70 the appellants referred to decision T 1139/00 of 10 February 2005, and submitted that by analogy to said decision claim 1 as granted had to be considered as allowable since the disclaimer excluded subject-matter disclosed in the parent application as filed. However, even if it is established that the disclaimer excludes subject-matter disclosed in the parent application as filed, the analysis to be made according to decision G 2/10 is whether the subject-matter remaining after introduction of the disclaimer is directly and unambiguously disclosed in the parent application as

filed. Decision T 1139/00 was issued long before decision G 2/10, and thus only cites decisions G 1/03 (OJ EPO 2004, 413) and G 1/93 (OJ EPO 1994, 541). However, decision G 2/10 (point 4.3, last paragraph, of the Reasons) makes it clear that neither decision G 1/93 nor decision G 1/03 intended to modify the general definition of the requirements of Article 123(2) EPC. This finding is undoubtedly also applicable in the context of Article 100(c) EPC 1973 (see point 8.3 above).

8.7.7 The appellants also cited decision T 1107/06 to support their arguments in favour of the allowability of a claim with a disclaimer for excluding subject-matter disclosed in the application as filed. However, decision T 1107/06 predates decision G 2/10, which stipulates that the investigation as to whether the subject-matter remaining in a claim after the introduction of a disclaimer is disclosed in the parent application as filed has to be decided in each case individually, after an objective investigation of the disclosure in the parent application as filed.

8.8 For the above reasons, the main request fails under Article 100(c) EPC 1973 since the subject-matter of claim 1 extends beyond the content of the parent application as filed.

9. *Admission of the auxiliary requests 1, 1a, 2, 2a, 3, 4, 5, 6, and 7 received on 9 March 2012 at the oral proceedings*

As regards the relevant provisions of Article 13 RPBA reference is made to point 5.1 above.

9.1 *Auxiliary requests 1, 2, 3, 4 and 7*

9.1.1 The appellants argued that auxiliary requests 1, 2, 3, 4 and 7 corresponded to auxiliary requests on file for a long time. However, the board notes that said auxiliary requests were filed for the first time in the afternoon of the last day of the oral proceedings before the board, namely on 9 March 2012, since they differed from the auxiliary requests previously on file in that a **new** independent claim 2 had been introduced in each of them. Therefore, auxiliary requests 1, 2, 3, 4 and 7, which are an amendment to the appellants' case within the meaning of Article 13 RPBA, were clearly filed at a very late stage of the proceedings.

9.1.2 As stated in point IV above, all the opponents which had filed an appeal against the interlocutory decision underlying the present appeal had withdrawn their oppositions and were therefore from that time on no longer parties to the present appeal proceedings. Thus, the appellants had invoked the principle of prohibition of *reformatio in peius* in favour of the admission of auxiliary requests 1, 2, 3, 4 and 7 into the proceedings since claim 2 was identical to the sole claim of the patent as maintained in amended form by the interlocutory decision of the opposition division.

In its decision G 9/92 of 14 July 1994 (EPO OJ 1994, 875), the Enlarged Board of Appeal found that if the patent proprietor is the sole appellant against an interlocutory decision maintaining the patent in amended form, neither the board of appeal nor the non-appealing opponent as a party to the proceedings as of

right under Article 107, second sentence, EPC may challenge the maintenance of the patent as amended in accordance with the interlocutory decision. Therefore, the prohibition of *reformatio in peius* protects a sole appellant from a possible worse outcome in appeal proceedings compared to the order of the interlocutory decision of the opposition division under appeal. However, in the board's view, the prohibition of *reformatio in peius* does not mean that the board may not challenge the admissibility or the allowability of a request if one of the claims of this request is identical to a claim of the patent as maintained in amended form by the opposition division in the interlocutory decision under appeal. Therefore, the board does not accept the appellants' argument that claim 2 of the auxiliary requests 1, 2, 3, 4 and 7 is protected by the prohibition of *reformatio in peius* and cannot be subject to any further discussion or delay.

9.1.3 Such a discussion of claim 2, however, would have raised new issues which had not been discussed before in these oral proceedings and which could therefore not be expected to be dealt with by the board and the respondent without an adjournment of the oral proceedings, in view of the fact that the auxiliary requests comprising claim 2 were filed in the afternoon of the last day of the oral proceedings on 7 to 9 March 2012.

There was also no justification for such a late filing of these auxiliary requests because the appellants had known since receiving the letter dated 23 November 2011 from the former appellant-opponent O4 that they had become the sole appellants.

9.1.4 In view of the above, the auxiliary requests 1, 2, 3, 4 and 7 were not admitted into the appeal proceedings, in accordance with Article 13(1) and (3) RPBA.

9.2 *Auxiliary request 1a*

9.2.1 Auxiliary request 1a was filed on 9 March 2012. This request is identical to auxiliary request II filed on 14 October 2009 and maintained as auxiliary request 96 in the submissions of 7 February 2012. However, auxiliary request 96 was replaced by auxiliary request 1 submitted during oral proceedings on 9 March 2012. In view of the board's conclusion that the principle of the prohibition of *reformatio in peius* was not considered to apply regarding the addition of claim 2 in auxiliary request 1, the appellants filed auxiliary request 1a, which contains a single claim, which is identical to claim 1 of auxiliary request 1.

9.2.2 In comparison with claim 1 as granted, the features of claim 1 of auxiliary request 1a appearing under (b) have been redrafted, the disclaimer under (b) has been worded differently and feature (c) now includes "a pharmaceutical diluent". Furthermore, claim 1 of auxiliary request 1a is not identical to any of the claims of the auxiliary requests filed with the grounds of appeal. Hence it is an amendment to the appellants' case within the meaning of Article 13 RPBA.

The definitions given in claim 1 of auxiliary request 1a have to be assessed within their new context. Thus, the examination of the features in (b)

and of the remaining subject-matter in claim 1 has to be investigated on its own merits.

9.2.3 The formulation of claim 1 immediately raises new issues regarding the clarity of this claim because of the introduction of the passage "… selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons, having from 8 to 50 carbon atoms, namely fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils and waxes, polyalkylene glycols, and mixtures of any of the foregoing …". The amended wording of section (b) of claim 1 no longer allows it to be clearly determined whether the passage "… selected so that the formulation provides pH-independent dissolution characteristics" refers to the controlled release dosage matrix or whether it constitutes an integral part of the disclaimer. This clarity issue under Article 84 EPC 1973 would have required complex discussions.

9.2.4 In view of the above the board, exercising its discretion under Article 13(1) RPBA, did not admit auxiliary request 1a into the appeal proceedings. In view of this finding, the board did not have to decide on the admission of the respondent's arguments in its letter dated 6 March 2012.

9.3 *Auxiliary request 2a*

9.3.1 Auxiliary request 2a was filed on 9 March 2012. This request is identical to auxiliary request IIa filed on 14 October 2009 and maintained as auxiliary request 97 in the submissions of 7 February 2012. However,

auxiliary request 97 was replaced by auxiliary request 2 submitted during oral proceedings on 9 March 2012. In view of the board's conclusion that the principle of the prohibition of *reformatio in peius* was not considered to apply regarding the addition of claim 2 in auxiliary request 2, the appellants filed auxiliary request 2a, which contains a single claim which is identical to claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 2a shares with claim 1 of auxiliary request 1a the wording with regard to the features under section (b). Therefore, the reasons in point 9.2 and 9.2.3 above apply *mutatis mutandis* to auxiliary request 2a.

Therefore, auxiliary request 2a was not admitted into the appeal proceedings, in accordance with Article 13(1) RPBA.

9.4 *Auxiliary requests 5 and 6*

9.4.1 The board notes that claim 1 of auxiliary requests 5 and 6 filed during the oral proceedings on 9 March 2012 corresponds to claim 1 of auxiliary requests 31 and 34, respectively, filed on 7 February 2012 as part of a bundle of 94 new auxiliary requests and that a new independent claim 2 had been introduced in each of these two requests which is identical to the sole claim of the patent as maintained in amended form by the first-instance interlocutory decision. Hence auxiliary requests 5 and 6 were an amendment to the appellants' case within the meaning of Article 13 RPBA.

9.4.2 The appellants argued that, when deciding on the admission of auxiliary requests 5 and 6 into the appeal proceedings, the board should take into account that claim 1 of present auxiliary requests 5 and 6 corresponded to claim 1 of the afore-mentioned auxiliary requests 31 and 34, respectively, and that the filing of the bundle of 94 new auxiliary requests was due to confusion about the procedural situation according to the state of the file. In their view, the filing of these 94 new auxiliary requests was also caused by the absence of any guidance from the board, even though the appellants had several times asked the board to give them guidance. However, the board cannot accept these arguments for the following reasons.

9.4.3 First, the procedural situation should have been clear to the appellants, as it evidently was to the respondent. From the present board's communication pursuant to Article 15(1) RPBA dated 25 October 2011 (see point XXVI above), it was evident that the board in its new composition envisaged re-opening the debate for all requests on file in view of the enlargement of the board to five members pursuant to Article 21(4)(b) EPC 1973 and in view of decision G 2/10. The parties could thus not legitimately expect that a potential point of law to be referred to the Enlarged Board of Appeal as mentioned in the minutes of the oral proceedings held on 19 October 2010 before the three-member board would be the only issue to be discussed during oral proceedings arranged for three consecutive days or that it would be discussed in any event. On the contrary, in view of the fact that the board had been enlarged to five members and the Enlarged Board of Appeal had rendered its decision G 2/10, which is

relevant to the present case, a professional representative should rather have expected that the board in its new composition intended to discuss the case afresh.

9.4.4 By its communication pursuant to Article 15(1) RPBA dated 22 November 2011 (see point XXX above), the board further clarified that the issue of referral to the Enlarged Board of Appeal was also fully open and that, consequently, the board in its new composition did not intend to refer questions to the Enlarged Board of Appeal at that stage of the proceedings. Hence the board clearly informed the parties to the proceedings that the five-member board was not pursuing the issue of a referral as indicated by the three-member board in the earlier oral proceedings (see point XXI above).

9.4.5 The board thus considers that both its communications of 25 October 2011 and 22 November 2011, respectively, clarified that the main issue to be discussed during the oral proceedings of 7 to 9 March 2012 was the new decision G 2/10 in relation to the assessment of added subject-matter.

9.4.6 Second, according to the established jurisprudence of the Enlarged Board of Appeal in review cases, the board was not obliged to give the appellants any guidance for filing their requests.

In its decision R 12/09 of 15 January 2010, point 11 of the Reasons, the Enlarged Board of Appeal held:

"*It is for each party to make its own case and for a Board then to decide on the basis of the parties'*

submissions. In doing so a Board should not in inter partes proceedings assist one of the parties by giving it a hint in advance, either during oral proceedings (see R 11/08 of 6 April 2009, Reasons, point 14) or in a communication (see R 3/09 of 3 April 2009, Reasons, points 5.1 and 5.2). A party which wants a decision in its favour must play a full part in proceedings and submit arguments in support of its case on its own initiative and at the appropriate time (see R 2/08 of 11 September 2008, Reasons, points 8.5 and 9.10). It is part of the professional task of representatives to decide independently - that is, without assistance from the Board - how to pursue their cases (see T 0506/91 of 3 April 1992, Reasons, point 2.3 cited with approval in R 11/08 of 6 April 2009, Reasons, point 10)"
(translation by the board from the German text of the decision).

9.4.7 It follows from the above findings of the Enlarged Board of Appeal that, in view of the requirement of judicial impartiality in *inter partes* opposition appeal proceedings, in would be inappropriate for a board to interfere in these adversarial proceedings by advising one party how to conduct its case. Hence, in the present case the board would have been in breach of its duty of neutrality if, beyond the information provided in its communications of 25 October 2011 and 22 November 2011 for the guidance of both parties, it had given guidance on any further issue for the assistance of only one party. It was indeed the responsibility of the appellants or their representatives to determine the content of the patent in suit and to decide independently how to pursue their case, including what requests to submit in view of the

provisions of the EPC, the jurisprudence thereon and the content of the file.

9.4.8 Moreover, the board notes that the wording of Article 15(1) RPBA imposes no obligation on the board to send a communication if oral proceedings are to take place. This means that the board could even have sent no communication at all to the parties in advance of the oral proceedings and it could have still expected the parties to present their case in oral proceedings, taking into account merely the written and oral submissions presented by the parties to the proceedings.

9.4.9 Third, presenting 117 auxiliary requests on 7 February 2012, i.e. one month before the date of the oral proceedings, is certainly at odds with the principles of procedural economy and of good faith. Neither the respondent nor the board could have been expected to deal with such a large number of auxiliary requests in such a short time even if, as the appellants submitted, auxiliary requests 95 to 117 had previously been filed as auxiliary requests and were merely renumbered. The board is convinced that an adjournment of the oral proceedings would have already been necessary to give the respondent and the board sufficient time to deal adequately with the 94 new auxiliary requests filed in addition to said auxiliary requests 95 to 117, since neither the board nor the respondent could reasonably be expected to familiarise itself with each and every request of the bundle of 94 new auxiliary requests in the given time-frame.

9.4.10 In view of the above considerations with regard to the filing of the bundle of 94 new auxiliary requests, the

submission of auxiliary requests 5 and 6 could not be justified by the argument that claim 1 of auxiliary requests 5 and 6 had been on file as claim 1 of auxiliary requests 31 and 34 since 7 February 2012. As a consequence, submitting claim 1 of auxiliary requests 31 and 34 of 7 February 2012 as part of auxiliary requests 5 and 6 was a further amendment to the appellants' case at oral proceedings on 9 March 2012. Hence, neither the respondent nor the board could reasonably be expected to deal with this amendment to the appellants' case at that late stage of the proceedings without adjournment of the oral proceedings.

9.4.11 Finally, the change of category of the product claim 1 of the main request into a use claim in auxiliary requests 5 and 6 does not represent a direct reply to the discussion under Article 100(c) EPC 1973 in the light of decision G 2/10 which took place during the oral proceedings held on 7 to 9 March 2012 prior to the filing of auxiliary requests 5 and 6 since the change of category does not address any of the issues discussed in relation to the lack of basis in the parent application as filed for the subject-matter remaining after the introduction of the disclaimer.

9.4.12 For the above reasons alone, auxiliary requests 5 and 6 were not admitted into the appeal proceedings pursuant to Article 13(1) and (3) RPBA. In view of this finding, the board did not have to consider the addition of claim 2, which was identical to claim 2 of the auxiliary requests 1, 2, 3, 4 and 7 filed during oral proceedings.

9.5 *Auxiliary request 8*

The sole claim of auxiliary request 8 is identical to the sole claim of the ninth auxiliary request which formed the basis of the interlocutory decision maintaining the patent in amended form (see point II). Since the patent proprietors are the sole appellants against the interlocutory decision, in view of the principle of the prohibition of *reformatio in peius* as set out above (point 9.1.2), neither the board nor the non-appealing respondent could challenge the maintenance of the patent as amended in accordance with the interlocutory decision under appeal. Consequently, the board had no power to examine auxiliary request 8.

Requests for referral to the Enlarged Board of Appeal

10. The appellants requested that several questions be referred to the Enlarged Board of Appeal (see point XL(a) and (e) above).

10.1 Under Article 112(1)(a) EPC 1973, a board of appeal, either of its own motion or upon request from a party, refers any questions of law to the Enlarged Board of Appeal in order to ensure uniform application of the law, or if an important point of law arises, if it considers that a decision is required for the above purposes.

10.2 The requirement "to ensure uniform application of the law" is fulfilled if in the particular case the board deems it necessary to deviate from the interpretation or explanation of the EPC contained in another decision of a board of appeal, or if there are diverging decisions of two boards (Moser, "Münchner

Gemeinschaftskommentar zum EPÜ", 1997, Art. 112, Note 19, Benkard, "Europäisches Patentübereinkommen", München 2012, Art. 112, Note 5). However, a referral under Article 112(1)(a) EPC 1973 is made only when the board considers that a decision of the Enlarged Board of Appeal is required. In this context Articles 20 and 21 RPBA also have to be taken into consideration. Under Article 21 RPBA a referral of questions to the Enlarged Board of Appeal must be made in cases where the board considers it necessary to deviate from an interpretation or explanation of the EPC contained in an earlier opinion or decision of the Enlarged Board of Appeal. However, if a board wishes to deviate from an earlier decision taken by a board of appeal, a referral is not compulsory, but the board must give the grounds for deviation unless such grounds are in accordance with an earlier opinion or decision of the Enlarged Board of Appeal (Article 20(1), first sentence, RPBA).

10.3 "An important point of law" within the meaning of Article 112(1)(a) EPC 1973 arises if that point is of fundamental importance in the sense that it is relevant to a substantial number of similar cases and is therefore of great interest not only to the parties in the appeal in question but also to the public at large (see for example T 271/85, OJ EPO 1988, 341, point 5 of the Reasons). A question regarded as an important point of law does not need to be referred to the Enlarged Board of Appeal if the question can be answered beyond all doubt by the board itself (see for example J 5/81, OJ EPO 1982, 155, T 198/88, OJ EPO 1991, 254, point 2.3 of the Reasons, J 22/95, OJ EPO 1998, 569, point 7.2 of the Reasons, "Case Law of the Boards of Appeal of the

European Patent Office", 6th edition 2010, VII.E.14.2 with further references).

10.4 *Request for referral to the Enlarged Board of Appeal filed by letter dated 6 April 2009 (see points X and XL(e) above)*

10.4.1 When invited by the board at the end of the oral proceedings on 9 March 2012 to itemise any further requests apart from claim requests, in particular requests for referral, the appellants maintained only their further request for referral to the Enlarged Board of Appeal filed by letter dated 6 April 2009 (see points X *and XL(e)* above). This request was reworded at the oral proceedings held on 13 and 14 October 2009 (see point XII above) without changing the substance of the point of law to be referred. The reworded version contains two questions, the first question being a slightly redrafted version of the question filed with the letter of 6 April 2009 and the second question concerning the issue of whether it is relevant that the subject-matter of the disclaimer was disclosed in the earlier application.

10.4.2 In fact these questions submitted by appellants have already been answered in decision G 2/10, which states that the principles which govern the assessment of added subject-matter apply also to claims containing a disclaimer and that the subject-matter remaining in a claim after the introduction of a disclaimer has to be assessed in this respect.

10.4.3 For the reasons above (see points 8.1 to 8.6), the board concludes that, in accordance with the principles

developed in decision G 2/10, the remaining subject-matter of claim 1 of the main request extends beyond the content of the parent application P4 and therefore the main request must fail on the ground for opposition under Article 100(c) EPC 1973.

10.4.4 The appellants, in their written submissions, essentially based their request for referral filed in the letter dated 6 April 2009 (see point X above) on the argument that deviating from the ruling of decision T 1139/00 would result in conflicting decisions at the level of the boards of appeal, which was not desirable, and that the ruling of decision T 1139/00 had been applied in national decisions such as the High Court's decision D40, which had been confirmed by the decision of the Court of Appeal D40a (in particular paragraphs 68 to 97).

10.4.5 The present board notes that, in its decision G 2/10, (points 3 and 4 of the Reasons), the Enlarged Board of Appeal explicitly dealt with decision T 1139/00 and national decisions referring to decision T 1139/00.

In point 3 of the Reasons for decision G 2/10, the Enlarged Board dealt with the question whether decision G 1/03 decided the issue of disclaimers for subject-matter disclosed in the application as filed. The Enlarged Board arrived at the conclusion that decision G 1/03 related only to "… *the situation in which neither the disclaimer nor the subject-matter excluded by it have a basis in the application as filed*" (see in particular point 3.3 of the Reasons). In point 3.8 of the Reasons, the Enlarged Board held that national decisions had taken the same stance and read decision

G 1/03 in the same way, and it referred to the decision "Napp Pharmaceutical Holdings Ltd v. Ratiopharm GmbH and Sandoz Ltd", Court of Appeal (England and Wales), [2009] EWCA Civ 252, point 82 et seq. of the Reasons, with reference to T 1139/00, and to the decision "Mundipharma Pharmaceuticals B.V. v. Sandoz B.V.", District Court of The Hague of 7 April 2010, case no. 340373/09-2029, point 4.11 et seq. of the Reasons, i.e. in the present case documents D40a and D78a respectively.

In point 4.4.2 of the Reasons for decision G 2/10, the Enlarged Board explicitly referred to points 2.6.2 and 2.6.5 of the Reasons for decision G 1/03 and discussed the meaning of the statements made in those parts of decision G 1/03.

Further on the Enlarged Board concluded that the gist of the questions referred to it in cases G 1/03 and G 2/03 (OJ EPO 2004, 448) was to establish whether and, if so, under which circumstances undisclosed disclaimers could be considered allowable at all, as a matter of principle, despite the absence of a basis in the application as filed. The Enlarged Board also took the view that the wording which the Enlarged Board had chosen in the starting line of answer 2 of the decision G 1/03, reading "a disclaimer may be allowable", indicated that with the criteria set up in answer 2 the Enlarged Board did indeed not intend to give a complete definition of when a disclaimer violated Article 123(2) EPC and when it did not. According to the Enlarged Board it was in this sense that the teaching of decision G 1/03 had also been interpreted first in decision T 1139/00 and then in the above-cited national

decisions, also with respect to disclaimers for disclosed subject-matter.

10.4.6 It follows from the reasons given in decision G 2/10 that the Enlarged Board has already discussed the reasoning of decision T 1139/00 in the context of the allowability of disclaimers. Hence the board sees no reason to raise this issue again by allowing the appellants' request for a referral to the Enlarged Board of Appeal.

10.4.7 For the above reasons, the board does not see any necessity to refer the appellants' questions filed by letter dated 6 April 2009 to the Enlarged Board of Appeal.

10.5 *Referral suggestion 1 filed during the oral proceedings of 7 March 2012 (see point XL(a)(i) above)*

The board considers that according to the EPC there is no difference in quality between structural and functional features. In this respect, the board accepts the appellants' submissions during the oral proceedings held on 7 to 9 March 2012 reflected in point LIII(a) above. Thus, the principles developed in decision G 2/10 are also to be applied in the assessment of added subject-matter in claims comprising structural and functional features. Therefore, the board does not see any need to refer the appellants' questions to the Enlarged Board of Appeal under Article 112(1)(a) EPC 1973.

10.6 *Referral suggestion 2 filed during the oral proceedings of 7 March 2012 (see point XL(a)(ii) above)*

The board has no doubt that, as far as the change in the composition of the board is concerned, the indication of the reason "complexity of the case" in the order of 3 May 2011 (EPO Form 3303.15) was sufficient information for the parties and that there was no obligation for the board to give detailed reasoning for its enlargement by the addition of two further members (see point 4 above). It is also clear for the board that there is no obligation to explain what aspects were decisive for the alleged "change of position" in relation to the relevance of a decision of the Enlarged Board of Appeal or a pending referral question allegedly taken earlier in these proceedings by the three-member board, because the five-member board is not bound by any position expressed by the board in its three-member composition. Such a position is not a decision but only an opinion (see also point 4.1). Analogous reasons apply to the intention to refer a fundamental point of law to the Enlarged Board of Appeal by the three-member board expressed at the end of the oral proceedings dated 19 October 2010 (see point XXI above). Thus, the board considers that there is no need to refer the questions under point 1 of the suggestion for referral 2 to the Enlarged Board of Appeal under Article 112(1)(a) EPC 1973.

Since the questions under point 2 of the suggested referral have been made conditional to the questions under point 1, they need not be considered in view of the above findings of the board.

10.7 In view of the above, all requests for referral of questions to the Enlarged Board of Appeal under Article 112(1)(a) EPC 1973 must be rejected.

Objections under Article 112a and Rule 106 EPC

11. *Objection 1 (point XL(d)(i) above)*

11.1 The appellants essentially argued that the present appeal proceedings were unfair in view of Article 125 EPC 1973 and Article 6(1) of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 (ECHR) and of Article 113(1) EPC 1973. This could be derived from decision G 3/08 of 12 May 2010, OJ EPO 2011, 10, point 7.2.1 of the Reasons and the four opinions from legal experts filed by letters dated 1 and 5 March 2012 (D103, D104, D105, and D106, see points XXXVI and XXXVIII above). Thus their right to be heard under Article 113(1) EPC 1973 had not been observed because the appellants' questions concerning the relationship between decision G 2/10 and the still open fundamental legal question, initially indicated by the three-member board, had not been answered by the present five-member board. In the appellants' view, they should have been fully informed about this fundamental legal issue and should have been given proper time to react. Therefore, the board should have given proper and adequate notice as to what the fundamental legal issue referred to by the three-member board and reaffirmed by the five-member board was and of the board's changed position regarding the relevance and applicability of decision G 2/10. Thus there would be a breach of the appellants' right to be heard under Article 113(1) EPC 1973 if a decision was taken on the

appellants' claim requests before the board gave guidance on these matters.

11.2 In its decision G 4/95 (see point 10 of the Reasons) the Enlarged Board of Appeal held:

"*In the context of* inter partes *proceedings it is a generally recognised principle of procedural law that each party to such proceedings should have a proper opportunity to reply to the case which is presented by an opposing party. This principle is reflected in Article 113(1) EPC, which emphasises that a party should not be taken by surprise by grounds or evidence which are used as the basis of an adverse decision.*"

11.3 Further, according to the established jurisprudence of the Enlarged Board of Appeal, Article 113(1) EPC 1973 is complied with if the party concerned has an adequate opportunity to present its point of view to the board before a decision is taken, if the board considers the arguments presented by the party, and if the decision is based on a line of reasoning that can be said to have been in the proceedings, either as a result of having been submitted by a party or raised by the board (see decisions R 1/08, points 3 and 3.1 of the Reasons, R 2/08, point 8.2 of the Reasons, and the summary of prior jurisprudence in R 12/09 of 15 January 2010, point 11 of the Reasons; see also "Case Law of the Boards of Appeal of the European Patent Office", 6th edition 2010, VI.B.1, first and second paragraphs).

11.4 However, as is clear from the established jurisprudence of the Enlarged Board of Appeal, the parties to *inter partes* proceedings are not entitled to advance

indications of the reason or reasons for a decision before it is taken (see point 7.1 above). In fact a party must know the arguments advanced by the other party or parties and must have an opportunity to comment thereon before a decision is taken (see also R 12/09 of 15 January 2010, point 13 of the Reasons, and R 15/10, point 11 of the Reasons). However, a party has no right to be told in advance in detail how the board of appeal will decide on the arguments put forward by the parties.

11.5 As far as the appellants' argument regarding Article 6(1) ECHR is concerned, it is established jurisprudence that the boards of appeal and the Enlarged Board of Appeal respectively act as judicial bodies, which were established by law, and apply general principles of procedural law (see decision G 3/08 of 12 May 2010, point 7.2.1 of the Reasons, and decision G 2/08 of 15 June 2009, point 3.1 of the Reasons with reference to decisions G 1/86, G 9/91 and G 10/91, G 1/99, G 5/91, G 1/05, J 15/04 and T 954/98). One of these principles is laid down in Article 6(1) ECHR, relying on principles of law common to the member states of the European Patent Organisation and applying to all EPO departments of the said organisation, which requires inter alia in "*… the determination of his civil rights and obligations … everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law*".

11.6 It is established jurisprudence that, for *inter partes* proceedings before a board of appeal to be fair, the board must be neutral (see for example decisions R 12/09 of 15 January 2010, point 13 of the Reasons,

and T 253/95, point 3 of the Reasons). Therefore, the purpose of oral proceedings in such adversarial proceedings is to hear the parties before making a decision, without assisting one party to the prejudice of another, which would be a breach of the board's duty of impartiality (see points 9.4.6 and 9.4.7 above).

11.7 The board also gave careful consideration to the legal experts' opinions filed by the appellants. However, these opinions could not convince the board to deviate from the settled jurisprudence of the Enlarged Board of Appeal and the boards of appeal as set out above.

11.8 In the light of the above jurisprudence, the appellants' right to be heard under Article 113(1) EPC 1973 had been observed. In the present case, by its respective communications of 25 October 2011 and 22 November 2011, the board clearly informed the parties to the proceedings that the five-member board was not pursuing the issue of a referral as indicated by the three-member board in the earlier oral proceedings (see points 9.4.3 and 9.4.4 above) and it clarified that the main issue to be discussed during the oral proceedings of 7 to 9 March 2012 was the new decision G 2/10 in relation to the assessment of added subject-matter (see points 9.4.3 to 9.4.5 above). Hence the procedural situation should have been clear to the appellants, as it evidently was to the respondent. The board would have been in breach of its duty of neutrality if, beyond the information provided in its communications of 25 October 2011 and 22 November 2011 for the guidance of both parties, it had given the appellants guidance on presenting their case in oral proceedings (see points 9.4.6 to 9.4.8 above).

11.9 Finally, the present five-member board is not bound by any position expressed by the board in its three-member composition (see points 4.1 and 10.6 above). Thus, it cannot be argued that there was a change in the board's position regarding the relevance and applicability of decision G 2/10, as alleged by the appellants. This could also be inferred from the communication pursuant to Article 15(1) RPBA dated 22 November 2011, in which the board further clarified that the issue of referral to the Enlarged Board of Appeal was also fully open and that, consequently, the board in its new composition did not intend to refer questions to the Enlarged Board of Appeal at that stage of the proceedings (see point 9.4.4 above).

11.10 In view of the above reasons, the board dismissed objection 1.

12. *Objection 2 (point XL(d)(ii) above)*

12.1 The appellants essentially argued that their right to be heard under Article 113(1) EPC 1973 had not been observed because, although the board had to decide whether the remaining subject-matter in claim 1 of the main request was explicitly or implicitly disclosed to the skilled person in the art, the board cut off all the evidence offered by the appellants, since it had not admitted document D100 or the requests under Article 117(1)(e) EPC into the proceedings and, applying decision G 4/95, did not allow Mr Lamprecht to make oral submissions as an accompanying person of the appellants at the oral proceedings of 7 to 9 March 2012.

12.2 It is clear from the provisions of Article 13 RPBA that, in spite of the principle of the right to be heard under Article 113(1) EPC 1973, a party does not have the right to have evidence which he filed or offered during appeal proceedings, in particular during *inter partes* proceedings, admitted into these proceedings (see also point 5.1 above). The board gave detailed reasons why document D100 and the requests under Article 117(1)(e) EPC were not admitted into the appeal proceedings (see points 5.2, 5.3 and 5.4 above, respectively).

12.3 The Enlarged Board of Appeal held in decision G 4/95 that oral submissions by an accompanying person in opposition appeal proceedings cannot be made as a matter of right, but only with the permission of and at the discretion of the board (point 9 of the Reasons). As set out above (point 6 above), the criteria as developed in said decision have not been met in the present case and therefore Mr Lamprecht was not allowed to make oral submissions as an accompanying person of the appellants at the oral proceedings of 7 to 9 March 2012.

12.4 Finally, in the board's view, decision G 7/93 (OJ EPO 1994, 775) is not relevant to the present case because it concerns the exercise by the examining division of its discretion under Rule 86(3) EPC 1973 following issue of a communication under Rule 51(6) EPC 1973.

12.5 In view of the reasons above, the board dismissed objection 2.

13. *Objection 3 (point XL(d)(iii) above)*

13.1 The appellants raised the objection that the present appeal proceedings did not comply with the principle of the right to be heard under Article 113(1) EPC 1973, first because the board had not indicated any grounds and/or evidence on the basis of which it intended to determine whether the subject-matter of claim 1 of the main request was, be it explicitly or implicitly, directly and unambiguously disclosed in the parent application (P4) to the skilled person using common general knowledge, and secondly because it did not give the parties concerned an opportunity to present their comments thereon.

13.2 The established jurisprudence of the Enlarged Board of Appeal and the boards of appeal on the principle of the right to be heard under Article 113(1) EPC 1973 and of fair *inter partes* proceedings is set out above under points 11.2 to 11.5.

13.3 In support of objection 3 and their argument that the present appeal proceedings did not comply with Article 6(1) ECHR, the appellants further referred to the decision "Lawrence v The General Medical Council", High Court (England and Wales), [2012] EWHC 464 (Admin) (D107), in particular paragraphs 229 and 231 (see point XL(d)(iii) above).

Decision D107 is a national decision and the present board is not bound by it. This has also been submitted by the respondent. The board agrees with the appellants that legal evaluation by courts of member states could of course be relevant. However, this is not the case

for decision D107 of the High Court in an appeal against a decision of a Fitness to Practice Panel of the General Medical Council. The passages of said decision cited by the appellants in support of their arguments dealing with Article 6(1) ECHR (paragraphs 229 and 231, see point XL(d)(iii)) do not refer to Article 6(1) ECHR, but are concerned with implications of the "rules of natural justice". Thus, the board could not discern any relevance of said decision to the present case and consequently saw no reason to deviate from the established jurisprudence of the Enlarged Board of Appeal on the matter at issue.

13.4 The appellants also referred to decision T 951/92. However this decision is not relevant to the present case because it concerns the right to be heard under Article 113(1) EPC 1973 in first-instance *ex parte* proceedings.

13.5 The present board is convinced that both parties concerned had an adequate opportunity to present their point of view to the board before a decision was taken, as can be seen from the submissions of the parties (see points LIII and LIV above) and the reasoning set out in the present decision. In particular, the appellants' arguments regarding the ground for opposition under Article 100(c) EPC 1973 raised against the subject-matter of claim 1 according to their main request in the light of the jurisprudence of the technical boards of appeal and of the Enlarged Board of Appeal (particularly, decision G 2/10) and their submissions on the disclosure of the parent application P4 were discussed at length in the oral proceedings of 7 to 9 March 2012 and have been dealt with by the board in

the present decision (see point 8 above, especially points 8.7.1 to 8.7.7). As explained above (points 7.1 and 9.4.7), the board is not obliged under Article 113(1) EPC 1973 to indicate the reason(s) for its decision before it is taken. In its assessment of whether the subject-matter of claim 1 of the main request was, be it explicitly or implicitly, directly and unambiguously disclosed in the parent application (P4) to the skilled person using common general knowledge, the board did not take into account any evidence within the meaning of Article 117(1) EPC (see points 8.5 and 8.6). In particular, the expertise of the board is not to be considered as evidence within the meaning of said provision.

13.6 In view of the above, it was sufficient for compliance with the principle of the right to be heard under Article 113(1) EPC 1973 in the present case that the parties had a proper opportunity to comment on Article 100(c) EPC 1973 in the light of decision G 2/10. The appellants also had the opportunity to reply to the objections and arguments presented by the respondent.

13.7 Consequently, objection 3 was dismissed.

Conclusion with regard to the patent in suit

14. The main request is not allowable and all auxiliary requests 1, 1a, 2, 2a, and 3 to 7 were not admitted into the appeal proceedings. Auxiliary request 8 could not be challenged in view of the principle of the prohibition of *reformatio in peius*. Therefore, the appeal has to be dismissed. Consequently, the interlocutory decision under appeal maintaining the

patent in amended form on the basis of the ninth auxiliary request filed during the oral proceedings before the opposition division which took place on 21 April 2008 becomes final.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The requests for referral of questions to the Enlarged Board of Appeal are rejected.

The Registrar The Chairman

N. Maslin U. Oswald