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**Datasheet for the decision
of 5 June 2008**

Case Number: T 0857/06 - 3.3.04

Application Number: 90109337.7

Publication Number: 0398327

IPC: C12P 21/02

Language of the proceedings: EN

Title of invention:

Tumor necrosis factor binding protein II, its purification and antibodies thereto

Patentee:

YEDA RESEARCH AND DEVELOPMENT CO., LTD.

Opponent:

ABBOTT GmbH & Co. KG

Headword:

TNF binding protein II/YEDA

Relevant legal provisions:

EPC Art. 54(3), 83, 106(2), 112a(2)(b)
RPBA Art. 19(1)

Relevant legal provisions (EPC 1973):

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Keyword:

"Presence of assistant at deliberations (yes)"
"Appealability of interlocutory decision (yes)"
"Added subject-matter (no)"
"Sufficiency of disclosure (yes)"
"Novelty (yes)"

Decisions cited:

G 0001/88, R 0001/08, T 0762/90

European Court of Human Rights judgements *Borgers v. Belgium* of 30 October 1991, *Kress v. France* of 7 June 2001 and *Martinie v. France* of 12 April 2006, England and Wales Court of Appeal judgement *Parker v. The Law Society* of 4 December 1998

Catchword:

1. The discretion under Article 19(1), second sentence, RPBA may be exercised to allow the board's assistant to attend and to take part in the deliberations (see points 1 to 6).

2. A first interlocutory decision which does not allow a separate appeal can be appealed together with a second interlocutory decision which does not leave any substantive issues outstanding and which allows a separate appeal (see points 7 to 11).



Case Number: T 0857/06 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 5 June 2008

Appellant I: YEDA RESEARCH AND DEVELOPMENT CO., LTD.
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Appellant II: ABBOTT GmbH & Co. KG
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
3 May 2006 concerning maintenance of European
patent No. 0398327 in amended form.

Composition of the Board:

Chair: U. Kinkeldey
Members: R. Gramaglia
R. Moufang

Summary of Facts and Submissions

- I. Three oppositions had been filed against European patent No. 0 398 327, entitled "Tumor necrosis factor binding protein II, its purification and antibodies thereto". The oppositions by opponents 01 and 03 were withdrawn by letters of 27 and 26 January 1999 respectively.
- II. Oral proceedings before the opposition division were held on 1 July 2003 and 15 December 2005.

During the first of these oral proceedings, the opposition division decided that the subject-matter of the claims of the main request before it did not fulfil the requirements of Article 54(3) EPC 1973. No decision was yet taken on the claims of the auxiliary requests which contained disclaimers, since cases G 1/03 and G 2/03 were pending before the Enlarged Board of Appeal at the time. The minutes of these oral proceedings were issued on 2 October 2003 and included a part B entitled "MOTIVATION FOR THE DECISION" which dealt with said main request and stated that "no appeal possibility is given, because no final decision in the light of Article 102 EPC has been taken (Article 106(3) EPC)".

During the second oral proceedings held on 15 December 2005, the chairman of the opposition division *inter alia* stated that "the first and second oral proceedings are to be seen as one procedure the decisions of which being appealable in the usual manner" and that "the partial decision taken in the first oral proceedings of 01.07.2003 will be part of the final decision" (see page 2 of the minutes). At the end of the oral

proceedings, the chairman announced the opposition division's (interlocutory) decision according to which, on the basis of the proprietor's auxiliary request 4, the patent and the invention to which it related were found to meet the requirements of the EPC.

The written reasons of this (second) interlocutory decision were dispatched on 3 May 2006. They contain a page with the title "Cover sheet" stating that "[t]he present decision of the Opposition Division [...] has been taken on two independent days" and inter alia they repeat, under the heading "REASONS FOR THE DECISION, PART 1 (DAY 1, 01.07.03)", the reasons concerning the proprietor's main request already given as part of the minutes issued on 2 October 2003 in almost identical terms. Separate appeal was allowed according to Article 106(3) EPC 1973.

- III. The patent proprietor (appellant I) and opponent 02 (appellant II) lodged appeals against the interlocutory decision of the opposition division dated 3 May 2006.

- IV. With the grounds of appeal, appellant I filed a new main request containing 33 claims. Claims 1, 5 to 9 and 11 to 14 read as follows:

"1. A Tumor Necrosis Factor (TNF) Binding Protein II (TBP-II) in substantially purified form having the following features:

- (a) it inhibits the cytotoxic effect of TNF; and

- (b) it contains the following amino acid sequence:

Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr;

or salts, functional derivatives, precursors or active fractions thereof or mixtures of the foregoing, said salts, functional derivates [sic], precursors, active fractions or mixtures having the ability to inhibit the cytotoxic effect of TNF on cells.

5. The TBP-II according to any one of claims 1 to 4, which contains the following amino acid sequence:
Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr

6. A process for the isolation of substantially purified TBP-II protein which comprises:
 - (a) recovering the crude protein fraction from a dialyzed concentrate of human urine;

 - (b) subjecting said crude protein fraction of step (a) to affinity chromatography on a column of immobilized TNF to obtain purified active fractions of TNF binding proteins defined by their ability to inhibit the cytotoxic effect of TNF;

 - (c) applying said purified active fractions of the TNF-binding proteins from step (b) to reversed-phase HPLC to obtain substantially purified active fractions of TNF binding proteins defined by their ability to inhibit the cytotoxic effect of TNF; and

- (d) recovering the substantially purified TBP-II protein of step (c), said protein having a molecular weight of about 30 kD on SDS-PAGE under reducing conditions, moving as a single peak in the fraction corresponding to about 31% acetonitrile on reversed phase HPLC and having the ability to inhibit the cytotoxic effect of TNF.
7. The TBP-II according to any one of claims 1 to 5 produced by the process of claim 6.
 8. The TBP-II of any one of claims 1 to 5 or 7 wherein the TBP-II is of human origin.
 9. The TBP-II of any one of claims 1 to 5 or 8 which is a recombinant protein.
 11. A DNA molecule comprising a nucleotide sequence coding for the TBP-II of any one of claims 1 to 5 or 7 to 10.
 12. A replicable expression vehicle comprising the DNA molecule of claim 11 and capable, in a transformant host cell, of expressing the TBP-II defined in any one of claims 1 to 5 or 7 to 10.
 13. A host cell selected from a prokaryotic and a eukaryotic cell transformed with the replicable expression vehicle of claim 12.
 14. A process for producing recombinant TBP-II comprising the steps of

- (a) culturing a transformed host cell according to claim 13 in a suitable culture medium;
and
- (b) isolating said TNF Binding Protein TBP-II."

Claims 2 to 4 are dependent on claim 1, and claim 10 is dependent on claim 9. Claims 15 to 33 relate to pharmaceutical compositions comprising TBP-II, uses of TBP-II, antibodies to TBP-II, pharmaceutical compositions containing said antibodies, in vitro immunoassays for TBP-II, and methods for the purification of TBP-II.

- V. Oral proceedings before the board took place on 5 June 2008. At the beginning of the proceedings, the chair announced that, in addition to the members of the board, the assistant to the board would be present during the proceedings, including the deliberations. Appellant I objected to the presence of the assistant during the deliberations. The board, in the absence of the assistant, deliberated on this objection and dismissed it. The assistant was present in the subsequent deliberations.
- VI. Appellant I requested that the decisions under appeal be set aside and that the patent be maintained in amended form on the basis of the new main request filed with the grounds of appeal dated 12 September 2006. Appellant II requested that the decision under appeal be set aside and that the patent be revoked.
- VII. The following documents are mentioned in the present decision:

B/I P 39 15 072.0 (first priority document of international application B/III)
B/III WO 90/13575 A1
D29 US 6,262,239 B1
D32 Porteu, F. et al., J. Biol. Chem., 1991, vol. 266, pages 18846-18853

VIII. The submissions made by appellant I in writing and during the oral proceedings, insofar as they are relevant for the present decision, can be summarised as follows:

- The claims complied with Article 123(2) EPC since the 10- and 11-amino-acid sequences depicted in claims 1 and 5 were disclosed at page 10, lines 53 and 55, of the application as filed. It would have been clear to the skilled person from this disclosure that these amino acid sequences characterised the TNF binding protein II (TBP-II).
- It would not prejudice the sufficiency of disclosure of a claimed invention if embodiments covered by the claims were disclosed only later. The TNF receptor was in any case not covered by the claims since it did not inhibit the cytotoxic effect of TNF. Furthermore, there was no evidence on file showing that the claimed subject-matter was not enabled.
- The claimed subject-matter was novel over document B/III under Article 54(3) EPC since the required certainty that the protein isolated in Example II of document B/I, the first priority document of

document B/III, was identical to the protein of the patent in suit was lacking.

IX. The submissions made by appellant II in writing and during the oral proceedings, insofar as they are relevant for the present decision, can be summarised as follows:

- The claims did not comply with Article 123(2) EPC since the 10- and 11-amino-acid sequences depicted in claims 1 and 5 had only been disclosed in the application as filed as parts of longer sequences.
- The claimed invention was not sufficiently disclosed under Article 83 EPC, because the patent did not enable either the 42 kDa TNF binding protein disclosed in document B/III or precursors of TBP-II like the TNF receptor or DNA encoding any of these proteins.
- Pursuant to Article 54(3) EPC, the claimed subject-matter lacked novelty over the 42 kDa TNF binding protein disclosed in document B/III and its priority document B/I.

Reasons for the decision

Presence of the assistant during deliberations of the board

1. At the beginning of the oral proceedings appellant I raised an objection to the announced presence of the board's assistant during the deliberations (see Section V above). Since the board has dismissed this objection,

it is necessary to summarise the reasons and the legal basis for allowing such presence, which has been the established practice of this board for many years.

2. In several EPC contracting states the judicial work of courts, in particular supreme courts and constitutional courts, is supported by assistants. In accordance with this practice, to which the European Court of Justice and the European Court of Human Rights (ECHR) also adhere, a limited number of assistants supports the EPO's boards of appeal. They are selected in a formal internal recruitment procedure for which only experienced examiners, i.e. permanent employees of the EPO, may apply. When serving as assistant, the examiner is seconded to Directorate-General 3 (Appeals) and subordinated exclusively to its competent organs. Normally an assistant is assigned to a specific board. As set out in the relevant standard vacancy note, the assistant's main duties may include the following:

- analysing contested decisions, relevant applications or patents, grounds for appeal and requests;
- analysing the state of the art and commenting on patentability;
- drafting comments and decisions;
- attending oral proceedings and board deliberations, taking minutes.

Which of the above duties an assistant is actually entrusted with is a matter to be decided by the chairman and members of the board to which the assistant is assigned, and may vary individually and from board to board to some degree.

The practice of employing assistants in the boards of appeal has two main goals: on the one hand, by supporting the judicial work of the board in several ways, quality and efficiency gains may be achieved; on the other hand, the employment serves the professional development of the assistant by providing insight into the working methods and decision-making processes of the boards of appeal, thereby also benefiting the assistant's future working environment after expiry of the period of secondment.

3. According to Article 19(1), second sentence, of the Rules of Procedure of the Boards of Appeal (RPBA), only members of the board may participate in the deliberations; the chairman may, however, authorise other officers ("anderer Bediensteten", "d'autres agents") to attend. The same provision was already present in Article 13, second sentence, of the Rules of Procedure as originally adopted in 1980 (see OJ EPO 1980, 171).

- 3.1 The chairman's discretion to authorise persons other than the members of the board to attend the deliberations is thus limited in an important manner: only officers of the European Patent Office qualify as possible beneficiaries of the discretion. One of the reasons for this limitation appears to be that Article 20(1) of the Service Regulations for permanent employees of the EPO and Article 6(1) of the Conditions of employment for contract staff at the EPO impose a duty of confidentiality on officers of the EPO. They have to exercise the greatest discretion with regard to all facts and information coming to their knowledge in

the course of or in connection with the performance of their duties, and they may not in any manner whatsoever use or disclose to any unauthorised person any document or information not already made public. In view of this general duty of officers of the EPO, the limitation of the chairman's discretion to allow persons other than the members of the board to attend the deliberations guarantees compliance with the principle that deliberations are to be secret (Article 19(1), third sentence, RPBA).

- 3.2 Since the assistant to the board is an officer of the EPO, the wording of Article 19(1), second sentence, RPBA ostensibly provides an adequate legal basis for allowing him or her to attend the deliberations. Nevertheless, it may be argued that, in view of the different terms used in Article 19(1), second sentence, RPBA ("participate" and "attend"), a difference should be made between passive attendance of and active participation in the deliberations, and that the active participation of an assistant or of any person other than the members of the board should not be allowed. However, such an interpretation of Article 19(1), second sentence, RPBA is not compelling since the legislator may have used the term "attend" not in contradistinction to the term "participate", but simply as a broader term encompassing it, thus giving the chairman the power to authorise the attending of EPO officers in different forms, i.e. not only as silent observers, but also as actively assisting the board during deliberations by asking questions and expressing thoughts. The board furthermore notes that, since the secrecy of the deliberations prevents the parties or the public from knowing the course of the deliberations,

a distinction between allowable passive attendance and unallowable active participation would appear to be rather questionable since it is not only necessary that justice is done but also that it is seen to be done ("doctrine of appearances", see ECHR judgment in *Martinie v. France* of 12 April 2006, point 53). Thus, if, for the sake of argument, it were procedurally improper to allow the active participation of any person other than the members of the board of appeal in the deliberations, this would also be a strong argument against allowing their passive attendance.

4. The board therefore has to deal with the more fundamental issue of whether the exercise of discretion under Article 19(1), second sentence, RPBA in allowing assistants to attend the deliberations is in line with generally recognised principles in the administration of justice (cf. Article 125 EPC). It is appropriate to review some of the positions taken in this respect in the jurisdictions of the contracting states and in the practice of other European courts.
 - 4.1 Section 193(1) of the German Judicature Act (Gerichtsverfassungsgesetz = GVG) contains the following general provision:

"Bei der Beratung und Abstimmung dürfen außer den zur Entscheidung berufenen Richtern nur die bei demselben Gericht zu ihrer juristischen Ausbildung beschäftigten Personen und die dort beschäftigten wissenschaftlichen Hilfskräfte zugegen sein, soweit der Vorsitzend deren Anwesenheit gestattet."

(Translation: "Apart from the judges rendering the decision, only persons employed at the same court as part of their legal training and the judicial assistants employed there may be present during deliberation and voting if the chairman so allows.")

Section 193(2) GVG provides a further exception to the privacy of deliberations in favour of foreign judges, prosecutors and attorneys. Prior to a legislative amendment enacted in 1994, Section 193(1) GVG mentioned only the persons employed at the court for the purposes of their legal education. Thus, there was some dispute as to whether it also provided a sufficient basis for allowing the attendance of court assistants (see Wolf in: Münchener Kommentar zur Zivilprozessordnung, 1st ed., 1992, Vol. 3, Section 193 GVG, marg. no. 3-4; Gummer in: Zöllner, Zivilprozessordnung, 18th ed. 1993, Sec. 193 GVG, marg. no. 4). The legislator therefore chose to clarify the issue by explicitly including court assistants in the wording of Section 193(1) GVG. According to the relevant commentaries, attendance need not be restricted to a passive role. Rather, the persons mentioned in Section 193 GVG may be allowed to express their opinion and to ask questions (see Wolf in: Münchener Kommentar zur Zivilprozessordnung, 2nd ed. 2001, Vol. 3, Section 193 GVG, marg. no. 4; Gummer in: Zöllner, Zivilprozessordnung, 26th ed. 2007, Sec. 193, marg. no. 6; Hartmann in: Baumbach et al., Zivilprozessordnung mit Gerichtsverfassungsgesetz und anderen Nebengesetzen, 66th ed. 2008, Section 193, marg. no. 3).

On the basis of the above provision, it is, to the knowledge of the board, common practice in the senates of the German Federal Supreme Court to allow court assistants to attend the deliberations and, at the discretion of the presiding judge, to express their opinion before voting takes place. Future patent attorneys who are receiving part of their professional education in the German Federal Patent Court are also regularly allowed to actively attend the deliberations of the senate to which they are attached during their traineeship.

- 4.2 The French Code of Administrative Justice (Code de justice administrative), in its Article R731-4, contains an explicit provision enumerating those persons who may be allowed to attend the deliberations of the courts:

"Peuvent être autorisés à assister au délibéré, outre les membres de la juridiction **et leurs collaborateurs**, les juges, avocats stagiaires, professeurs des universités et maîtres de conférences accomplissant auprès de celle-ci un stage ou admis, à titre exceptionnel, à suivre ses travaux, qu'ils soient de nationalité française ou étrangère." (emphasis added)

(Translation: "Apart from the members of the court **and their assistants**, the following may be authorised to attend the deliberations: judges, trainee lawyers, university professors and lecturers on a placement at the court or exceptionally allowed to observe its workings, whether of French or other nationality." (emphasis added))

The French Code of Civil Procedure (Code de Procédure Civile = CPC) does not contain a similar provision and it has been held by French courts that, in view of the principles enshrined in Articles 447 CPC (entrusting the judges who have heard a case with the task of deliberating on it) and 448 CPC (secrecy of deliberations), the presence of the court's registrar during the deliberations constitutes a procedural violation (see the references given in JurisClasseur Procédure civile, Fasc. 504: JUGEMENTS, point 42, and Code de Procédure Civile, Litec, 20th ed. 2007, Art. 447, point 4). Nevertheless, in order to accommodate the needs of adequate professional education for judges and attorneys, certain exceptions are made, see in particular Article 1 of Act No. 77-749 of 8 July 1977 ("Les magistrats qui participent à une session de formation peuvent être autorisés à assister aux délibérés des juridictions de l'ordre judiciaire auprès desquelles ils font leur stage."; translation: "Magistrates taking part in training may be authorised to attend the deliberations of the judicial courts with which they are undertaking their placement.") and Article 19 of the Ordonnance of 22 December 1958 which allows that trainee magistrates may sit in on cases and participate in an advisory capacity in the deliberations of civil and criminal courts ("[les auditeurs de justice] peuvent siéger en surnombre et participer avec voix consultative aux délibérés des juridictions civiles et correctionnelles").

- 4.3 In its decision *Parker v. The Law Society* of 4 December 1998 ([1998] EWCA Civ 1915), the England and Wales Court of Appeal gave a negative answer to the question

whether a party is entitled to request the disclosure of a bench memorandum prepared by a judicial assistant. As the Court of Appeal explained, bench memoranda consist of a summary of facts, a history of the proceedings, an indication of the issues on the appeal and any opinion which the judicial assistant has on the merits of the appeal, and will often be supplemented by discussions between members of the court and the judicial assistant. The court described and endorsed the institution of judicial assistants with the following words:

"For approximately two years now the Court of Appeal has engaged judicial assistants to assist the court. They are employed in addition to the lawyers who are permanent members of the staff of the Court of Appeal. Judicial assistants are usually young lawyers of the highest calibre who have recently been accepted as members of chambers or recently admitted solicitors [...]. Their primary responsibility is to prepare bench memoranda and conduct research for members of this Court. Their duties overlap with those of the lawyers who are permanent members of the court staff.

The judicial assistants are of great benefit to the Court. They assist the Court to understand what are the issues on an appeal. [...] They save the time of members of the Court by drawing to their attention relevant authorities decided in this jurisdiction or abroad. [...]

It is intended that the relationship between members of the Court and judicial assistants should be as close as possible. This is not only

so that they can be of most help to the Court but also so that they can benefit from working for a short period of time in close proximity to members of the Court. The tasks judicial assistants perform are intended to enable members of the Court to perform their duties more effectively and to save the time of the Court."

4.4 In the European Court of Justice (ECJ), the judges are assisted by "référéndaires" (judicial assistants), who inter alia prepare drafts of judgments. Since, however, Article 27(1) and (2) of the Rules of Procedure of the ECJ provides that "the Court shall deliberate in closed session" and that "[o]nly those Judges who were present at the oral proceedings and the Assistant Rapporteur, if any, entrusted with the consideration of the case may take part in the deliberations", the référéndaires of the ECJ do not participate in the deliberations.

4.5 The European Court of Human Rights (ECHR) is assisted by legal secretaries who are attached to the registry (see Article 25 of the European Convention on Human Rights and Rule 18 of the ECHR Rules of Court). They prepare files and analytical notes for the judges and correspond with the parties on procedural matters, but are not assigned as legal secretaries to individual judges. Rule 22 of the ECHR Rules of Court provides that only the judges take part in the deliberations but that the Registrar or the designated substitute, as well as such other officials of the registry whose assistance is deemed necessary, may be present.

4.6 It emerges from the above review that, notwithstanding a certain bandwidth of positions not uncommon in

comparative legal analysis, the active involvement of assistants in preparing the ground for judicial decisions appears to be widely accepted. Furthermore, the rule that only the competent judges should be present during the deliberations is not generally adhered to without exceptions. In some jurisdictions (e.g. Germany), statutory provisions even explicitly allow the attendance of judicial assistants.

5. It is the board's conviction that the primary objective of a court should be to produce the best and most informed decisions. If, in order to reach this objective, the court considers it helpful to allow the attendance of an assistant in the court deliberations, it is appropriate to do so, within the limits of the relevant statutory provisions applicable in its jurisdiction. Notwithstanding the close collaboration of a board's assistant with the members of the board, there is no delegation of responsibility in respect of genuine judicial activity. With or without the attendance of an assistant, the board members always retain the decision-making prerogative expressed in the act of voting, and there can be no reasonable doubt about who is in charge.

- 5.1 The board is aware of the ECHR case law according to which the presence of persons such as the Advocate General (in proceedings before the Belgian Court of Cassation) or the Government Commissioner (in proceedings before the French Conseil d'Etat) during court deliberations violated the right to a fair trial enshrined in Article 6 of the European Convention on Human Rights (see *Borgers v. Belgium* of 30 October 1991, *Kress v. France* of 7 June 2001, *Martinie v. France* of

12 April 2006). However, this case law is based on the premise that these officers make submissions in the oral proceedings recommending a certain decision and thereby become, objectively speaking, the ally or opponent of one of the parties, so that their presence at the deliberations affords them, if only to outward appearances, an additional opportunity to bolster their submissions in private, without fear of contradiction (see *Kress v. France*, points 81 and 82). Such a situation in which the principle of equality of arms may be jeopardised is not comparable with the participation of assistants in court deliberations. The above-mentioned ECHR case law thus has no bearing on the issue at stake in the present case.

- 5.2 The board is also aware of the provision of Article 112a(2)(b) EPC, according to which it is a fundamental deficiency if the board includes a person not appointed as a member of the boards of appeal. However, this provision cannot sensibly be interpreted as applying to the involvement of an assistant in the preparation of decisions by a board acting in the correct composition of three (or five) appointed board of appeal members. Rather, a board can only be regarded as "including a person" if the person is acting as a member of the board, not if the person visibly fulfils a different function, such as that of an assistant.

This understanding of Article 112a(2)(b) EPC is supported by the extraordinary nature of the petition for review. As emphasised in the *travaux préparatoires* for the EPC 2000, setting aside a decision of a board of appeal should be possible only if it suffers from a fundamental defect, so that maintaining it without

further review would be intolerable (see CA/PL 17/00 of 27 March 2000, point 6; MR/2/00 of 13 October 2000, Explanatory Remarks to Article 112a EPC, point 11; see also decision R 1/08 of 15 July 2008, point 2.1 of the reasons). Since the involvement of assistants reflects long-standing practice of many boards of appeal and is a well-known institution in several contracting states and other European courts (see above point 4), it is simply not conceivable that the legislator intended to curtail this involvement by means of a provision introduced as a redress against intolerable fundamental procedural defects. The *travaux préparatoires* (see in particular MR/24/00, points 269 to 273, and MR/21/00) do not contain any intimation in that direction.

6. The board concludes that discretion under Article 19(1), second sentence, RPBA is properly exercised if the board's assistant is allowed to attend and to take part in the deliberations.

Extent and admissibility of appellant I's appeal

7. Both appellants have filed their appeals against the interlocutory decision of the opposition division dated 3 May 2006. However, as follows from section II above, the opposition division took two interlocutory decisions in the present case. The first decision, which concerned the refusal of appellant I's then main request, was pronounced in the oral proceedings of 1 July 2003, and written reasons for it were dispatched on 2 October 2003 as part of the minutes. In the second interlocutory decision, pronounced during the oral proceedings of 15 December 2005 and dispatched in written form on 3 May 2006, the patent in amended form

- on the basis of appellant I's then auxiliary request 4 was found to meet the requirements of the EPC.
8. The opposition division made an attempt to incorporate the content of its first interlocutory decision into its second interlocutory decision by stating during the oral proceedings of 15 December 2005 that "the first and second oral proceedings are to be seen as one procedure the decisions of which being appealable in the usual manner" and that "the partial decision taken in the first oral proceedings of 01.07.2003 will be part of the final decision" (see page 2 of the minutes), and by repeating the reasons for refusing appellant I's then main request in the written reasons of the second interlocutory decision. Since, however, matter already decided cannot be decided again by the same instance, the second interlocutory decision could no longer validly concern the refusal of appellant I's then main request. That means that in order to challenge this refusal, appellant I had to appeal not only the second but also the first interlocutory decision.
 9. In its notice of appeal, appellant I stated that it was lodging its appeal against the "decision of the Opposition Division dated 3 May 2006", and thus did not explicitly challenge the first interlocutory decision. However, it has to be taken into account that the above-described attempt of the opposition division to incorporate the content of its first interlocutory decision into its second interlocutory decision was procedurally incorrect and objectively misleading since appellant I could infer from it that it needed only to appeal the second interlocutory decision in order to challenge the conclusions of the first interlocutory

decision as well. According to the principle of the protection of legitimate expectations, a party must not suffer a disadvantage as a result of having relied on a misleading communication or statement in a decision. On the contrary, if his actions were based on such a misleading statement, he is to be treated as if he has satisfied the relevant legal requirements. The board thus concludes that appellant I's appeal has to be considered as also encompassing a challenge of the first interlocutory decision.

10. According to Article 106(2) EPC (corresponding to Article 106(3) EPC 1973), a decision which does not terminate proceedings as regards one of the parties can only be appealed together with the final decision, unless the decision allows a separate appeal. In the present case, the first interlocutory decision did not allow a separate appeal (see section II above) while the second interlocutory decision did. However, no final decision has yet been taken by the opposition division. It could therefore be argued that in the absence of such a final decision only the second interlocutory decision could be appealed whereas an appeal against the first interlocutory decision was not (yet) admissible.

11. Notwithstanding its apparent formal logic, the above line of argument cannot be sustained since it would lead to a nonsensical procedural situation where the board, while prevented from dealing with appellant I's main request (basically corresponding to the subject of the first interlocutory decision), had to decide on lower-ranking requests (corresponding to the subject of the second interlocutory decision). The board therefore

considers that the provision of Article 106(2) EPC has to be construed in a purposive manner and that at least in a case such as the present, where the second interlocutory decision does not leave any substantive issues outstanding and, in accordance with established practice, is intended to form the complete basis for the maintenance of the patent in amended form after the fulfilment of purely formal requirements such as the payment of the printing fee and the filing of translations of the claims (see G 1/88, OJ EPO 1989, 189, point 7 of the reasons), the first interlocutory decision must be appealable together with the second. This view is supported by (interlocutory) decision T 762/90 of 23 January 1991, [1991] EPOR 213, in which it was held on the facts of the case that the non-admission of the separate appeal in a first interlocutory decision related only to the limited period of time until the arrival of the second interlocutory decision.

The board thus concludes that in the present case both interlocutory decisions could be appealed together, a result which also corresponds to the clear intention of the opposition division as expressed during the second oral proceedings (see section II above).

Main request

Interpretation of claim 1

12. To arrive at a conclusion on whether claim 1 of the main request fulfils the requirements of Articles 123(2), 54(3) and 83 EPC, the board considers it necessary to define the proper interpretation of the

- wording of claim 1 with a view to assessing what the subject-matter of the claim is.
13. Claim 1 consists of two parts, a first part referring to "[a] Tumor Necrosis Factor (TNF) Binding Protein II (TBP-II) in substantially purified form having the following features: (a) it inhibits the cytotoxic effect of TNF; and (b) it contains the following amino acid sequence: Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr", and a second part which reads: "or salts, functional derivatives, precursors or active fractions thereof or mixtures of the foregoing, said salts, functional derivatives [sic], precursors, active fractions or mixtures having the ability to inhibit the cytotoxic effect of TNF on cells".
 14. With respect to the first part of claim 1, the question arises as to the meaning which should be given to the term "Tumor Necrosis Factor (TNF) Binding Protein II (TBP-II)", as this term had no acknowledged meaning in the art at the filing date of the patent in suit. The board takes the position that the presence of this term in the claim cannot simply be ignored, as if the claim merely referred to a "protein" in general, but that said term must be given the technical meaning that a skilled person would obtain from reading the description of the patent in suit.
 - 14.1 At the beginning of the description of the patent in suit, page 3, lines 3 to 4, it is stated that the invention relates to "a novel protein designated Tumor Necrosis Factor (TNF) Binding Protein II (hereinafter TBP-II)", and line 6 refers to "a process for the purification of said TBP-II". Further down the same

page, it is reported that the prior art described the isolation from human urine of a first TNF Binding Protein called TBP-I, which was shown to be able to antagonize the effects of TNF. In lines 48 to 51, it is further stated that when attempting an alternative approach for the purification of TBP-I, the inventors applied urinary proteins or fractions thereof on a column of immobilized TNF. After elution, "most of the protein in the eluate migrated as a single broad band with apparent molecular size of 30,000 +/-2,000" in SDS PAGE analysis (lines 51 to 52). But "[w]hen applied to further fractionation by reversed-phase HPLC, the proteins eluting from the TNF column showed the presence of two active components: one, TBP-I, eluting as expected at 27% acetonitrile and, in addition, a second TNF-binding protein, eluting at a somewhat higher acetonitrile concentration (31%). This TNF-binding protein is new and is herein called TBP-II".

From this part of the disclosure of the patent in suit, a skilled reader would thus understand that it is the particular protein obtained by the inventors after the described reversed-phase HPLC which is to be understood by the term "TBP-II".

- 14.2 Further information about the protein "TBP-II" is provided on page 4 of the patent in suit. In line 26 of that page it is stated that Figure 3 "depicts the sequences of several tryptic peptides of TBP-II", making it clear that TBP-II comprises the sequences depicted in said Figure. Lines 46 to 49 of the same page state that "[t]he TBP-II of the invention was isolated from human urine. The substantially purified protein, which is substantially free of proteinaceous

impurities, has a molecular weight of about 30 kDa when analyzed by SDS PAGE under reducing conditions and it moves as a single peak on reversed-phase HPLC. Its activity is determined by its ability to inhibit the cytotoxic effect of TNF- α on murine A9 cells". Lines 50 to 55 then state that "TBP-II is further characterized by the following sequence obtained by N-terminal sequence analysis of the protein: Ala-Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu-Tyr-Tyr-Asp-Gln-Thr-Ala-Gln-Met-Cys-Cys-".

At the top of page 5 (lines 1 to 7), it is reported that a heterogeneity of N-terminal sequences could be observed in the sample of TBP-II. Lines 8 to 25 refer to a process for isolating TBP-II from human fluid (e.g. urine) and state that TBP-II may also be prepared by genetic engineering techniques. The purification of TBP-II from urine is described in detail in Example I of the description of the patent in suit (page 8, line 44, to page 11, line 22).

- 14.3 The description thus teaches that "TBP-II" is the protein which was isolated by the inventors from human urine, which has a molecular weight of about 30 kDa, which contains the 30-amino-acid sequence shown at the bottom of page 4, with a heterogeneity at the N-terminus, and which can also be produced recombinantly.

There is no disclosure in the description of the patent in suit which could be interpreted such that a sequence of only 10 or 11 amino acids together with the inhibitory activity of the cytotoxic effect of TNF would be sufficient to characterise the protein termed "TBP-II".

14.4 The board therefore considers that in the light of the teaching of the description, the first part of claim 1 cannot be interpreted in such a way that **any** protein which inhibits the cytotoxic effect of TNF and contains the amino acid sequence Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr is considered as a TBP-II according to the claim, irrespective of the rest of its sequence. Consequently, the first part of claim 1 is directed to the particular 30 kDa TBP-II protein defined in the description of the patent in suit.

15. With respect to the interpretation of the second part of claim 1, the board considers that the definitions of the terms "functional derivatives", "precursors" and "active fractions" provided in the description of the patent in suit have to be taken into account.

15.1 Concerning the term "functional derivatives", the board takes the position that in the light of the definition given at page 7, lines 27 to 33, of the patent in suit, the skilled person would interpret this term as only relating to derivatives prepared from the functional groups which occur as side chains on the amino acid residues or the N- or C-terminal groups.

15.2 The term "precursors" would be interpreted by the skilled person on the basis of the definition of this term as given at page 7, line 34, of the patent in suit, i.e. as "compounds formed prior to, and converted into, TBP-II in the animal or human body". This implies for instance that proteins which are larger in size than TBP-II but which are not formed prior to, **and** not

converted into, TBP-II **in the animal or human body** would not be considered as "precursors".

15.3 By the same token, a skilled person would interpret the term "active fractions" on the basis of the definition given at page 7, lines 35 to 39, of the patent in suit as relating to "any fragment or precursors of the polypeptide chain of the protein molecule", i.e. of TBP-II, "alone or together with associated molecules or residues linked thereto, e.g. sugar or phosphate residues, or aggregates of the protein molecule or the sugar residues by themselves".

16. The reasons for the decision given in the following are based on the above technical analysis of claim 1.

Added subject-matter - Article 123(2) EPC

17. Appellant II argued that the claims did not comply with Article 123(2) EPC since the 10-amino-acid sequence recited in claim 1 and the 11-amino-acid sequence recited in dependent claim 5 had not individually been disclosed in the application as filed. The passages at page 3, line 58, and page 4, line 2, if properly read in their context, disclosed amino acid sequences five and four amino acids shorter than the 30-amino-acid sequence depicted in the preceding lines 52 to 53 of page 3, i.e. sequences of 25 and 26 amino acids, not just the 10- and 11-amino-acid sequences which had incidentally been written out in the text. Similarly, the passage at page 10, lines 52 to 55, disclosed sequences 3 and 2 amino acids shorter than the 21-amino-acid sequence depicted in the preceding lines 50 to 51, i.e. sequences of 18 and 19 amino acids.

18. The board agrees with appellant II in that the cited passages of the application as filed have to be read in their context, and therefore do not disclose the 10- and 11-amino-acid sequences in individualised form. However, the board cannot follow appellant II's conclusion with respect to Article 123(2) EPC. Claims 1 and 5 refer to the term "TBP-II", which defines the 30 kDa protein disclosed in the application as filed (see points 14 to 14.4 above). On the basis of the disclosure of the application as filed, in particular page 3, line 50, to page 4, line 2, and page 10, lines 50 to 55, there would be no doubt for the skilled person that this protein *inter alia* **contains** the 10- or 11-amino-acid sequences in question. Therefore, the presence of these sequences in claims 1 and 5 does not add any information to what the skilled person would understand by a protein termed "TBP-II" as disclosed in the application as filed. Consequently, the claimed subject-matter does not extend beyond the content of the application as filed, and the requirements of Article 123(2) EPC are thus fulfilled.

Sufficiency of disclosure - Article 83 EPC

19. Appellant II argued that the claimed invention was not sufficiently disclosed, because two proteins encompassed by the claims had not been made available by the disclosure of the patent in suit. The first of these proteins was the full-length TNF receptor as disclosed in post-published document D29. In document D32, which was also post-published, the 30 kDa TBP-II protein of the patent in suit had been shown to be the result of molecular shedding of said TNF receptor, and

this receptor would thus qualify as a precursor of TBP-II. The second protein concerned was the 42 kDa TNF-binding protein disclosed in documents B/I and B/III, which protein was also not enabled by the disclosure of the patent in suit.

20. Based on the technical analysis of the subject-matter claimed (see points 12 to 16 above), the board cannot agree with appellant II's assumption that the TNF receptor as disclosed in document D29 and the 42 kDa TNF-binding protein disclosed in documents B/I and B/III are encompassed by claim 1 or any of the other claims.
 - 20.1 With respect to the TNF receptor, the board finds that appellant I's argument that this receptor does not inhibit the cytotoxic effect of TNF, but would in fact trigger the effect of TNF, is convincing, given that there is no evidence on file showing that the TNF receptor protein could, under certain circumstances, also inhibit the cytotoxic effect of TNF. Since claim 1 requires that any precursors according to the claim must have the ability to inhibit the cytotoxic effect of TNF on cells, it does not encompass the TNF receptor protein.
 - 20.2 As concerns the 42 kDa protein isolated from urine of febrile patients, as described in Example II of document B/III and its priority document B/I, it is undisputed between the parties that this protein has an amino acid chain longer than that of the 30 kDa TBP-II protein of the patent in suit. Consequently, said 42 kDa protein is neither the "TBP-II" protein according to the first part of claim 1 (see points 14.1 to 14.4

above) nor a "functional derivative" of TBP-II in the sense of page 7, lines 27 to 33, of the patent in suit (see point 15.1 above). Furthermore, no arguments or evidence have been submitted by any of the parties showing that the 42 kDa protein is formed prior to, and converted into, the 30 kDa TBP-II protein in the animal or human body, and would therefore qualify as a "precursor" of TBP-II as defined in the patent in suit (see point 15.2 above). Due to its longer amino acid sequence, the 42 kDa protein can also not be a "fragment" of the 30 kDa TBP-II protein. Since, however, the term "active fractions" of TBP-II requires the presence of a fragment or a precursor of the polypeptide chain of TBP-II, or of aggregates of TBP-II or the sugar residues by themselves (see point 15.3 above), the 42 kDa protein is not covered by said term.

- 20.3 The board thus concludes that neither the TNF receptor as disclosed in document D29 nor the 42 kDa protein as disclosed in documents B/I and B/III is encompassed by the claims and that, for that reason alone, appellant II's objection concerning a lack of enablement under Article 83 EPC in relation to these proteins must fail.
21. Appellant II furthermore argued that the patent in suit did not enable DNA encoding the 30 kDa TBP-II protein or any of its precursors. In particular, the teaching of the patent in suit that "cells producing TBP-II" (page 5, line 30) or "cells which express TBP-II" (page 5, line 47) should be used to isolate mRNA, which could then be converted into cDNA, was misleading and pointed the skilled reader in a completely wrong

- direction. As TBP-II was the result of a proteolytic process, no such cells actually existed.
22. Appellant I submitted that the cell line U937 mentioned in the patent produced TBP-II and could thus have been used by the skilled person to isolate mRNA and obtain cDNA suitable for cloning TBP-II. Moreover, the patent in suit suggested the genomic cloning of DNA encoding TBP-II, which did not require a TBP-II-producing cell line.
23. According to established case law of the boards of appeal, an objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts. In order to establish insufficiency, the burden of proof is upon an opponent to establish on the balance of probabilities that a skilled reader of the patent in suit, using his or her common general knowledge, would be unable to carry out the claimed invention (see for instance "Case Law of the Boards of Appeal of the European Patent Office", 5th edition, 2006, Chapter II.A.7).
24. In the present case, no verifiable facts have been submitted showing that the genomic cloning of DNA encoding TBP-II, as suggested in the patent in suit (see page 5, lines 28 and 40 to 43, and page 6, lines 24 to 26), would not have been possible for a skilled person at the claimed priority date. As the necessary techniques were commonly known at the time, the board takes the position that it was possible for a skilled person to obtain DNA encoding TBP-II by genomic cloning. Therefore, it can be left undecided whether, based on the disclosure of the patent in suit together with

common general knowledge, a skilled person would also have been able to identify the cell line U937 as a TBP-II-producing cell line in order to obtain TBP-II encoding cDNA without undue burden and without inventive effort.

25. In view of the above, the board concludes that the claimed invention has to be regarded as sufficiently disclosed.

Novelty - Article 54 EPC

26. Appellant II argued that the claimed subject-matter lacked novelty under Article 54(3) EPC in view of the disclosure of the 42 kDa TNF-binding protein in document B/III and its first priority document B/I. Given however the board's finding that the 42 kDa TNF-binding protein of document B/III is not encompassed by any of the claims (see points 19 to 19.3 above), this disclosure cannot be prejudicial to the novelty of the claimed subject-matter.

27. The board concludes that the claimed subject-matter is novel over the prior art.

Inventive step - Article 56 EPC

28. Appellant II has not made any submissions to the effect that the claimed subject-matter lacks an inventive step under Article 56 EPC. The board cannot see any facts that would support a finding that the claimed subject-matter was obvious to a person skilled in view of the prior art. Therefore, the board is satisfied that the

claimed invention meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decisions under appeal are set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of claims 1 to 33 of the new main request filed with the grounds of appeal of appellant I and a description yet to be adapted.

The Registrar:

The Chair:

R. Schumacher

U. Kinkeldey