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Date: 26-08-2011

Reference	Application No./Patent No.
P1151EP00	05820913.1 - 1223 / 1831699

Applicant/Proprietor: Antibodyshop A/S

EPA/EPO/OEB Formblatt/Form/Formulaire : F2310, F2906O, Annex: list 5 pages, Getting to the EPO The Hague.

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Reference	Application No./Patent No.
OP004290EP1 OPPO 03	05820913.1 - 1223 / 1831699
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MJF5718/MNM/rg OPPO 01	05820913.1 - 1223 / 1831699
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I 8063/MH OPPO 04	05820913.1 - 1223 / 1831699
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1. A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being, wherein said method discriminates between a renal disorder and a condition that is not affecting the kidney, said method comprising the steps of

i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

ii) comparing said concentration with a predetermined cutoff value, said cutoff value being 250 ng/mL or a higher value, such as a value between 250 ng/mL and 525 ng/mL, chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cutoff value is indicative of a renal disorder.

Feature analysis

Claim 1 cites the following features (fx):

(f1) A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being,

(f2) wherein said method discriminates between a renal disorder and a condition that is not affecting the kidney, said method comprising the steps of

(f3) i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

(f4) ii) comparing said concentration with a predetermined cutoff value,

(f5) said cutoff value being 250 ng/mL or a higher value,

(f6) such as a value between 250 ng/mL and 525 ng/mL, (optional feature, so that claim 1 thus comprises 2 embodiments)

(f7) chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cutoff value is indicative of a renal disorder.

Documents used

The documents cited by the four Opponents have been given the following numbers, starting with the numeration employed by Opponent 1 (Abbott Laboratories), followed by Opponent 2 (Getica AB), Opponent 3 (Phadia AB) and Opponent 4 (Alere San Diego, Inc.) with the elimination of overlapping citations. Then follow documents (D54 to D60) cited by Applicant.

D1	**Mishra et al. 2004** "Neutrophil gelatinase-associated lipocalin: A novel early urinary biomarker for cisplatin nephrotoxicity". Am J Nephrol 24:307-315. Published online on May 12, 2004.
D2	**WO 2004/0888276** Published on October 14, 2004 Applicants: Children's Hospital Medical Center *and* The Trustees of Colombia University D (exam)
D3	**Mori et al. 2005** "Endocytic delivery of lipocalin-siderophore-iron complex rescues the kidney from ischemia-reperfusion injury". J Clin Invest 115(3):610-621, 2005.
D4	**US 2005/0272101** Published on December 8, 2005 Applicants: Devarajan, Prasad; Barasch, Jonathan M. see D17. D4 (exam)

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A5	D5	**Devarajan 2005** "Novel biomarkers for the early prediction of acute kidney injury". Cancer Ther 3:477-488. September 2005.
A6	D6	**Mehta et al. 2007** "Acute kidney injury network: report of an initiative to improve outcomes in acute kidney injury". Crit Care 11(2):R31. 1 March 2007. POST
A7	D7	**Uttenthal 2007** "NGAL: how useful is the new marker of kidney damage". Clinical Laboratory International (CLI), (www.cli-online.com). April 2007. POST
A8	D8	**Xu & Venge 2000** "Lipocalins as biochemical markers of disease". Biochim Biophys Acta 1482:298-307. D3(cont)
A9	D9	**Bangert et al. 2006a** "NGAL is significantly increased in urine and plasma in acute renal failure". Abstract 0023, ESICM, 19th annual congress – Barcelona, Spain – 24-27 September 2006. POST
A10	D10	**Bewick et al. 2004** "Statistics review 13: Receiver operating characteristic curves". Crit Care 8(6):508-512.
A11	D11	**Nielsen et al. 1999** "Rectal dialysate and fecal concentrations of neutrophil gelatinase-associated lipocalin, interleukin-8, and tumor necrosis factor-α in ulcerative colitis". Am J Gastroenterol 94(10):2923-2928.
A12	D12	**Dorland's** Illustrated Medical Dictionary, 29th Edition. W.B. Saunders Company, New York (2000).
A13	D13	**Wu et al. 1998** "Analytical and clinical evaluation of new diagnostic tests for myocardial damage". Clin Chim Acta 272:11-21.
A14	D14	**Forsblad et al. 2002** "Clinical manifestations of atherosclerosis in an elderly population are related to plasma neopterin, NGAL and endothelin-1, but not to *Chlamydia pneumoniae* serology". Int Angiol 21(2):173-179.
A15	D15	**US 2003/175686** error in D2 Published on September 18, 2003 Applicants: Rose, Steven L; Oh, Esther H; Walsh, Michael J.
A16	D16	**Mori et al.** "Endocytic delivery of lipocalin-siderophore-iron complex rescues the kidney from ischemia-reperfusion injury" J Clin Invest 115(3):620-621, March 2005 – **"Enlarged" version of Figure 1C, with logarithmic y-axis values and gridlines added.**
	D17	**WO 2005/121788** see D4 D4(cont) US2005/072101 Published on December 22, 2005 Applicants: Children's Hospital Medical Center *and* The Trustees of Colombia University
	D18	**Mishra et al. 2005** "Neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for acute injury after cardiac surgery". Lancet 365:1231-1238. 2 April 2005.
	D19	**Mishra et al. 2003** "Identification of neutrophil gelatinase-associated lipocalin as a novel early urinary biomarker for ischemic renal injury". J Am Soc Nephrol 14:2534-2543, 2003.

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D20	**Uttenthal 2005** "NGAL: a marker molecule for the distressed kidney". Renal Disease, Clinical Laboratory Investigation (CLI), (www.cli-online.com). November 2005.
D21	**Solberg 1994** Textbook of Clinical Chemistry. 2nd Edition, Chapter 13.
D22	**Xu et al. 1995** "Serum measurements of human neutrophil lipocalin (HNL) discriminate between acute bacterial and viral infections". Scand. J Clin Lab Invest 55:125-131.
D23	**Bangert et al. 2005** "Urinary NGAL is dramatically increased in acute renal failure". Abstract ESICM Congress submission 2005.
D24	**WO 2010/058378** Published on May 27, 2010 Applicant: PHADIA AB POST
D25	**NGAL ELISA Kit 036.** Download, BioPorto Diagnostics. POST
D26	**Bennett et al. 2008** "Urine NGAL predicts severity of acute kidney injury after cardiac surgery: A prospective study". Clin J Am Soc Nephrol 3:665-673, 2008. POST
D27	**BioPorto.** Announcement dated September 22, 2005. Danish
D28	**BioPorto.** Announcement dated September 22, 2005. English
D29	**Bangert et al. 2006b** "NGAL is significantly increased in urine and plasma in acute renal failure". Poster ESICM, 19th annual congress – Barcelona, Spain – 24-27 September 2006. ?
D30	**Kunis, Cheryl L.** Declaration and poster – 31.10.2004
D31	**Exhibit A** of Dr. Kunis' declaration: cover page of onsite program/meeting brochure of the American Society of Nephrology Renal Week 2004, October 27 – November 1, 2004, St. Louis Missouri.
D32	**Exhibit B** of Dr. Kunis' declaration: copy of page 334 and 335 of the onsite program of the American Society of Nephrology Renal Week 2004, October 27 – November 1, 2004, St. Louis Missouri, indicating poster presentation S-PO204 of 31 October 2004.
D33	**Exhibit C** of Dr. Kunis' declaration: photograph of the poster of Kunis et al., American Society of Nephrology Renal Week 2004, October 27 – November 1, 2004, St. Louis Missouri, *"Ngal (neutrophil gelatinase-associated lipocalin) as a marker for tubular damage in patients with Acute Tubular Necrosis (ATM)"* as presented during poster presentation SU-PO204.
D34	**Exhibit D** of Dr. Kunis' declaration: clean copy reproduction/image file of the poster of Kunis et al., American Society of Nephrology Renal Week 2004, October 27 – November 1, 2004, St. Louis, Missouri, *"Ngal (neutrophil gelatinase-associated lipocalin) as a marker for tubular damage in patients with Acute Tubular Necrosis (ATM)"* as presented during poster presentation SU-PO204.
D35	**Kunis et al.,** Poster abstract 3709 published on 31 October 2004.
D36	**Curriculum Vitae** of Dr. Cheryl L. Kunis
D37	**Kellum et al. 2002** "Developing a consensus classification system for acute renal failure". Curr Opin Crit Care 2002, 8:509-514, 2002.

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D38	**Zweig & Campbell 1993.** "Receiver-Operating Characteristic (ROC) Plots: A Fundamental Evaluation Tool in Clinical Medicine". Clin Chem 39(4):561-577, 1993.
D39	**ISR/WO** for International application No. PCT/DK2005/000806 Applicant: AntibodyShop A/S
D40	**NGAL Rapid ELISA kit 037.** Revision NR2007-12-EN, BioPorto Diagnostics. POST
D41	**Axelsson et al. 1995** "Studies of the release and turnover of a human neutrophil lipocalin". Scand J Clin Lab Invest, 1995, 55:577-588, 1995
D42	**Parikh et al. 2005** "NGAL and IL-18: Novel early sequential predictive biomarkers of acute kidney injury after cardiac surgery". Abstract, contact view, November 11, 2005.
D43	**Friedl et al. 1999** "Neutrophil gelatinase-associated lipocalin in normal and neoplastic human tissues. Cell type-specific pattern of expression". Histochem J. 31:433-441, 1999.
D44	**ANTIBODYSHOP** O14a Product Specification "Anti-NGAL (human, neutrophil gelatinase-associated lipocalin) Mouse monoclonal antibody". Product No. HYB 211-01. March 31, 2009. POST
D45	**ANTIBODYSHOP** O14b Product Specification "Anti-NGAL (human, neutrophil gelatinase-associated lipocalin) Mouse monoclonal antibody, biotinylated". Product No. HYB 211-01 B. March 31, 2009. POST
D46	**ANTIBODYSHOP** O14c Product Specification "Anti-NGAL (human, neutrophil gelatinase-associated lipocalin) Mouse monoclonal antibody". Product No. HYB 211-02. April 14, 2009. POST
D47	**ANTIBODYSHOP** O14d Product Specification "Anti-NGAL (human, neutrophil gelatinase-associated lipocalin) Mouse monoclonal antibody, biotinylated". Product No. HYB 211-02 B. April 14, 2009. POST
D48	**ANTIBODYSHOP** O14e Product Specification "Anti-NGAL (human, neutrophil gelatinase-associated lipocalin) Mouse monoclonal antibody". Product No. HYB 211-05. April 14, 2009. POST
D49	**E-mail correspondence** – Trine Overgaard Østerbye, Jaya Mishra and Claus Morsø Schrøder dated March 25, 2004.
D50	**Kjeldsen et al. 1996** "Characterization of two ELISAs for NGAL, a newly described lipocalin in human neutrophils". J Immunol Methods 198:155-164, 1996.
D51	**Zappitelli et al. 2007** "Urine neutrophil gelatinase-associated lipocalin is an early marker of acute kidney injury in critically ill children: a prospective cohort study". Crit Care 11(4):R84, published 2 August 2007. POST
D52	**Merck Manual.** List of causes of Acute Tubulointerstitial Nephritis (ATN).
D53	**Merck Manual.** Longer List of causes of Acute Renal Failure (ARF).
D54	**Sack et al. 2000** "Diurnal changes in the pattern of the distribution of gelatinases and associated proteins in tear fluid. Evidence that the PMN cell is a major source of MMP activity in normal and pathological tear fluid". Cornea 19:(6) p S119, 2000.
D55	**Kristiansen et al. 2004** "A proteomic analysis of human bile". Mol Cell Proteomics 3:715-728, 2004

D56	**Westerlund et al. 1996** "Human neutrophil gelatinase and associated lipocalin in adult and localized juvenile periodontitis". J Dent Res 75:1553-1563, 1996.
D57	**Salom et al. 2010** "Aqueous humor neutrophil gelatinase-associated lipocalin levels in patients with idiopathic acute anterior uveitis". Mol Vision 16:1448-1452, 2010.
D58	**Wheeler et al. 2008** "Serum neutrophil gelatinase-associated lipocalin (NGAL) as a marker of acute kidney injury in critically ill children with septic shock". Crit Care Med 36(4):1297-1303, 2008.
D59	**Ohlsson et al. 2003** "Increased circulating levels of proteinase 3 in patients with anti-neutrophilic cytoplasmic autoantibodies-associated systemic vasculitis in remission". Clin Exp Immunol 131:528-535, 2003.
D60	**US 6,136,526** Published (during PCT as WO95/29404) on 02.11.1995 Inventor: Venge, Per.

Introduction

To facilitate the discussion of the cited prior art in relation to the Patent, Applicant hereunder introduces the central aspects of the invention disclosed in the Patent.

Applicant has discovered that NGAL may be used in a method of discriminating, in a human being, between a renal disorder and a non-renal disorder (i.e. a condition that does not affect the kidney), including non-renal disorders that may raise NGAL levels, and a method of distinguishing between severe and less severe renal disorders. In short, the methods enable the discrimination between renal and non-renal disorders and between severe and less-severe renal disorders. The invention is based on the finding of specific cutoff values; specifically cutoff values relating to the concentration of the protein NGAL.

The first cutoff value is set so that a value falling below it is not diagnostic of a renal disorder with a high degree of specificity because such a level can be found in healthy individuals or individuals suffering from inflammatory, infective, or cancerous disorders without the kidneys being affected. The second cutoff value is set so that a value falling below it is not diagnostic of a renal disorder that requires or will require treatment by dialysis. In other words, the present invention concerns the finding and application of cutoff values that not only distinguish between disease and non-disease states, but distinguish between types of disease and the severity of renal disorders. This can be illustrated as follows:

Provisional and Non-binding opinion of the Opposition Division

1 EP 1 831 699, having application number ep05820913.1 has been opposed by four opponents Abbott Labs.(**OI**), Getica AB (**OII**), Phadia AB (**OIII**) and Alere Inc. (**OIV**) requesting revocation of the granted patent on the grounds of Articles 100(a) (Articles 54 and 56), Article 100(b) and Article 100(c) EPC. The Proprietor has requested rejection of the opposition. All parties have requested oral proceedings.

2 In total, 60 documents have been submitted by the parties. The documents will be identified on the basis of the consolidated document list found on pages **2-6** of the Proprietors letter dated **23/12/2010**.

3 The granted claim **1** reads:-

"*A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being, wherein said method discriminates between a renal disorder and a condition that is not affecting the kidney, said method comprising the steps of*

i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

ii) comparing said concentration with a predetermined cut-off value, said cut-off value being 250 ng/mL or a higher value, such as a value between 250 ng/mL and 525 ng/mL, chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cut-off value is indicative of a renal disorder."

3.1 In order to form an opinion on the contested matter, the Opposition Division finds it necessary to set out in this annex how the subject matter of the claim has been construed as the precise interpretation of the claim has formed a key argument in the notices of opposition.

3.2 The phrase "*A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being, wherein said method discriminates between a renal disorder and a condition that is not affecting the kidney,"* is taken to mean that the human being under investigation is already unwell and the purpose of the method is to differentiate or identify the cause of the lack of well being. Thus a method which solely differentiates patients having a renal disorder from healthy patients is not considered to be a method directed to the same purpose as set out in claim **1**. Furthermore the Proprietor has argued that the phrase '*renal disorder*' includes such conditions as bacterial infections which affects the kidney so the claimed method includes discrimination

between e.g. septicemia and septicemia induced renal disorder. Such an interpretation is, at best, confusing. It is noted that in the patent itself in Table **2**, the term 'renal affection' is used rather than renal disorder. It is the opinion of the Division, that in order to construe the claim, renal disorder should be interpreted to mean damage to, or malfunctioning of the kidneys as the primary cause of patient distress. Thus e.g. septicemia induced renal disorder is not considered to fall under the term renal disorder as used in claim **1**.

3.3 The phrase "*..predetermined cutoff value..*" is construed to mean a value derived from experimentation, indicated in a document as a value, above or below which certain conclusions can be drawn with regard to the state of the patient. A value disclosed in a document which merely represents the result of a test cannot, itself, be regarded as a predetermined cutoff value. It may however provide some guidance to a person skilled in the art to come to a conclusion as to what value a cutoff value may have.

3.4 The phrase "*..such as a value between 250 ng/mL and 525 ng/mL,*" is not limiting upon the claim as it is merely a preferred feature.

3.5 The phrase "*..or a higher value,....chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney..*" defines the feature in terms of the result to be achieved and does not constitute a technical feature which can be used to distinguish the subject matter of the claim from the prior art.

3.6 Thus claim **1** recites a predetermined cutoff value of 250 ng/ml or higher which is indicative of a primary renal disorder. The same interpretation of the above phases, when used in other claims, has been applied.

Article 123(2) EPC

1 The originally filed claim **1** reads

"*A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being, wherein said method discriminates between a renal disorder and another condition that does not affect the kidney, said method comprising the steps of*

i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

ii) comparing said concentration with a predetermined cut-off value, said cut-off value being chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cut-off value is indicative of a renal disorder."

1.1 The granted claim **1**, with the differences emphasised, reads:-

"*A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being, wherein said method discriminates between a renal disorder and **a** condition that is not affecting the kidney, said method comprising the steps of*

i) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

*ii) comparing said concentration with a predetermined cut-off value, said cut-off value **being 250 ng/mL or a higher value, such as a value between 250 ng/mL and 525 ng/mL**, chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cut-off value is indicative of a renal disorder.*"

Support for the specific values added during the examination process was drawn from original claims **2** and **3**.

1.2 In the original claims **2** and **3**, the cutoff values exemplified are specifically linked to values derived from urine, plasma or serum. Both the opponents and proprietor have filed documents (**D8**, **D11**, **D41**, **D54-D56**) showing the presence of NGAL in body fluids other than urine, serum and plasma. Thus the skilled person would be aware of this fact. The granted claim **1** now teaches a cutoff value of 250 ng/ml for **any** bodily fluid which in the opinion of the Opposition Division represents teaching not found in the originally filed documents as no specific values where highlighted as being of general application to all bodily fluids.

1.3 The Proprietor has argued that "..when there is a generic disclosure of the invention together with a specific disclosure of an illustrative or preferred embodiment falling under the generic disclosure, the skilled person will normally imply that all the other embodiments comprised in the generic disclosure without being mentioned specifically also form part of the invention. The non-exemplified or non-preferred embodiments are thus implicitly disclosed as the logical complement of the exemplified or preferred embodiments." (**T1107/06** citing **T860/00**). The originally filed documents clearly link the values now present in the granted claim **1** to urine, serum and plasma (paras.[**0015**]-[**0021**]) and do not even mention other sources of bodily fluid. Given the disclosed linkage of the value to specific fluids, the lack of

reference to, or use of, other fluids known to contain NGAL in the description and examples and the differing nature and composition of fluids falling with the term used in the claim, the skilled person would not implicitly assume that the cutoff values disclosed in granted claim **1** would hold true for bodily fluids other than urine, serum and plasma. Furthermore, **T1107/06** and T**860/00** deal primarily with the question of disclaimers and compositions respectively, not bodily fluids.

2 The Opponents also raise objection to claim **13** which was amended during the examination process. It is the opinion of the Opposition Division that basis for the amendment is found at page **10** line **23** - page **11** line **7** of the originally filed documents. However, both the original and amended claim (which sought to change a negative formulation to a positive formulation) comprise a substantial lack of clarity with regard to the exact limits of protection claimed. Lack of clarity is, of course, not a ground of opposition.

3 In summary, it is the opinion of the Opposition Division that claim **1** of the granted patent and claims dependent thereon infringe Article 123(2) EPC.

Article 83

1 The opponents argue that the granted patent lacks disclosure as the method cannot be worked over the whole of the area of protection granted by the claims. In particular, it is argued that the cutoff figure of 250 ng/ml or higher does not permit the method to discriminate between renal and non-renal disorders as required. The figure of 250 ng/ml itself has not been demonstrated to achieve the intended purpose nor do higher values because as the cutoff value increases, the ability to discriminate between renal and non-renal disorders diminishes. In addition the opponents point out that the cutoff figure is said to be valid for all bodily fluids but, if valid, is only demonstrated for urine, plasma or serum. Furthermore, a single cutoff value is not possible as the nature of the test and the components of the test will effect the possible outcome in terms of values obtained.

1.1 As counter argument, the Proprietor states that the granted patent provides all the necessary technical steps required by the skilled person to carry out the method and that at least one example disclosing discrimination between renal and non-renal disorders is found in the description. To summarise the proprietors further arguments, the key teaching of the patent is that it has now been demonstrated that it is possible to determine and use a cutoff value >250 ng/ml which allows discrimination, not only between renal v non-renal conditions but also between renal disorders and renal disorders derived from

other causes. The exact optimum cutoff value to use may have to be determined statistically to balance specificity against sensitivity but this was an established technique. It was also necessary when calculating the cutoff value to take into account the state of the patient under investigation and the conditions between which are be discriminated e.g. renal disorder with v without sepsis or needing dialysis v not requiring dialysis.

2 The basic technical aspects of the method i.e. how to determine the concentration of NGAL, are clearly disclosed in the description. The wording of claim **1** is '..comprising..' so that other non-inventive and non-essential steps may also fall within the scope of the claim in order to achieve the goal. The questions relevant to Article 83 EPC concern the use and determination of the cutoff value. Is a single cutoff value of >250ng/ml capable of providing the discrimination over the whole scope of the claims? Would the skilled person, taking such a figure, be able to achieve the aim of the method or are further technical features, not falling within the knowledge and ability of the skilled person essential to the method?

2.1 It can be assumed that a skilled person would be well aware of cutoff or threshold values in clinical testing and would be familiar with the statistical intricacies and subtleties that arise when working with such values. Thus, if apparent anomalies in the data presented by the granted patent occur, it would not necessarily be an obstacle to carrying out the method as claimed, provided said apparent anomalies do not call in question the fundamental teaching of the patent that a single value of >250 ng/ml for the concentration of NGAL in any bodily fluid permits the claimed discrimination between conditions.

2.2 The prime source for an examination of the sufficiency of the cutoff value of >250ng/ml is Table **2** of the granted patent. The table provides plasma and urine NGAL concentration data for 60 patients as well as indicating the clinical classification of the patients. The figures in the table represent maximum values but no information of the time course of the measurements is given. 35 patients are indicated as 'renal affection' and 25 as not. Applying the cutoff value of claim **1** to the latter group would in the case of plasma only correctly identify 9/25 patients and in the case of urine, 5/25 patients, giving specificity values of 36% and 20%. Furthermore four patients (45, 69, 83, 100), classed as no renal affection, provide values greater than 250ng/ml in plasma (indicating renal disorder) but lower than 250ng/ml in urine (indicating no renal disorder). The exact clinical condition of Patient 45 is unknown as no renal disorder is indicated nor does the patient appear to be suffering from sepsis,

cancer or hemodialysis. Of the 35 patients classified as having a renal affection, 1/35 (plasma) and 2/35 (urine) give values below the cutoff and thus would indicate non renal problems.

2.3 The description provides no basis, other then relying on statistical analysis which itself seems flawed, for the cutoff value in claim **1**. There is strong evidence in the patent itself (paras.[**0038**], [**0039**] that in order to achieve the stated aims of the claim, different cutoff values apply to plasma and urine. This evidence is further strengthened by **D7**, a post published review by one of the inventors, which suggests a cutoff value of >400ng/ml to discriminate ARD and indicates that at low concentrations of NGAL, the skill of the diagnostician, rather than the test result, is the key determinant. It is also noted that in the instructions for performing the NGAL Rapid ELISA KIT (**D25**), separate information with regard to expected values and ranges for urine, plasma and serum are provided rather than a single figure applicable to all bodily fluids as stated in the claim. The description provides no teaching of the validity of the cutoff value of claim **1** in bodily fluids other than urine, plasma and serum.

2.4 It is noted that the claim does not indicate at what point in time the samples must be taken for the cutoff to be valid. The teaching of the patent (para. [**0011**]) appears to suggest that the NGAL should be measured within 2-3 hrs of initiation of insult and figure **5** clearly shows the variation of NGAL concentration over a period of days. Using the criteria of claim **1**, a measurement taken at Day 1 leads to a different diagnostic conclusion than a measurement taken on Day 2.

2.5 Thus, in summary, the Opposition Division, for the reasons stated above, are of the opinion that the granted patent does not fulfill the requirements of Article 83 EPC as the invention cannot be put into practice over the whole of the area of protection.

Novelty

1 The opponents question the priority validity of the granted patent as it is argued that the feature of 250 ng/ml or higher and the use of a second cutoff value to discriminate the need for dialysis (granted claim **13**) has no basis in the priority documents. The granted patent draws on two documents for priority, **US2004/637503 (PR1)** having the date of **20.12.2004** and **US2005/719307** having the date of **21.09.2005**.

1.1 The most relevant passage in **PR1** is example **4**. Table **1** (identical to Table **1** of the granted patent) provides data from which the conclusion at page **12** lines **24-28** is drawn that a cutoff of about 1000 ng/ml defines the urinary NGAL concentration above which renal affection is indicative. The figure of 250 ng/ml is not mentioned. **PR2** is also based on the same example **4** as in **PR1** and discloses on page **7** and in the claims a cutoff value for urine of between 0.5µg (500ng) - 10µg/ml and between 300ng-900ng/ml for plasma or serum. The specific value of of 250 ng/ml or higher is not present. Furthermore **PR1** lacks any reference to dialysis and **PR2** limits the second cutoff value as indicative, or not, of acute tubular necrosis (ATN) or acute tubular-interstitial nephrpathy (ATIN), not dialysis. It is noted that the Proprietor has not provided counter argument.

1.2 Therefore, it is the opinion of the Opposition Division that the granted patent is not entitled to either **20.12.2004** or **21.09.2005** as the priority date. Consequently any document or disclosure in the public domain prior to **20.12.2005** forms part of the state of the art as defined by Article 54(2) EPC.

2 The opponents have raised a lack of novelty against claims **1-3** and **11** at least based upon documents **D2**, **D3**, **D18**, **D23**, **D33** and **D34**.

2.1 The granted claim **1** comprises 7 features:-

(a) A method of diagnosing, monitoring or determining the likelihood of a renal disorder in a human being,

(b) wherein said method discriminates between a renal disorder and a condition that is not affecting the kidney, said method comprising the steps of

(c) determining the concentration of human neutrophil gelatinase-associated lipocalin (NGAL) in a sample of bodily fluid from the human being,

(d) comparing said concentration with a predetermined cut-off value,

(e) said cut-off value being 250 ng/mL or a higher value,

(f) such as a value between 250 ng/mL and 525 ng/mL, (non-limiting feature)

(g) chosen to exclude lower concentrations of NGAL associated with conditions that are not affecting the kidney, wherein a concentration above the cut-off

value is indicative of a renal disorder.

2.2 **D23**, **D33** and **D34** are copies of posters exhibited at conferences in 2004 and 2005, prior to the filing date of the granted patent. **D23** was presented by the inventors of the granted patent and discloses the same technical information

in the form of Table **1** as filed in the granted patent. **D33** and **D34** presented data later used in **D3**. None of the posters are directed to feature (**b**) i.e. discriminating between a renal disorder and another condition present in the patient. The posters seek to identify a biomarker found in renal disorders but not found in healthy individuals. None of the posters disclose a cutoff value (as defined by the Opposition Division) of >250 ng/ml which permits such discrimination. **D23** merely gives ranges and median values of NGAL (Urine: 110-15700 ng/ml, 1000 ng/ml; Serum: 66-922 ng/ml, 147 ng/ml) and **D33**/**D34** disclose NGAL values of ATN v healthy patients (Urine: 557 ng/ml v 22 ng/ml; Serum: 146 ng/ml v 21 ng/ml). Thus **D23**, **D33** and **D34** do not disclose features (**b**) and (**d**)-(**g**).

2.3 **D2** was first considered during the examination process (as document **D1**). It is directed to using NGAL as a biomarker for renal tubular injury, not to discriminating between such injury and other conditions. It does not measure NGAL concentration nor compare said concentration to a predetermined cutoff value and draw conclusions therefrom. Para [**0098**] appears to teach a level of discrimination using NGAL between urinary tract infection/transplant rejection and renal injury following kidney transplantation. However the value disclosed is >100 ng/ml, not 250 ng/ml. Thus **D2** does not disclose features (**b**) and (**d**)-(**f**).

2.4 **D3** is directed to the use of NGAL:siderophore:Fe complexes as treatment for ischemia-reperfusion injury. Figures **1A** and **1B** (first disclosed in **D33**/**D34**) indicate levels of NGAL in urine or serum for conditions labelled 'Others' which comprise e.g. liver cirrhosis, hemochromatosis or pancreatic cancer are lower than renal disorders (chronic renal failure (CRF) ATN). Figures **1C** and **1D** show, in histogram form on a logarithmic scale, a comparison between normal patients and those with renal disorders. Data for ATN has been split to discriminate between ATN-nonsepsis and ATN-sepsis which is considered by the Opposition Division to be 'a condition that is not affecting the kidney' as defined above. Examination of the spread of data points covering CRF, ATN, ATN-non sepsis and ATN sepsis reveals considerable overlap of ranges which does not permit the identification of any value capable of the discrimination required by feature (**b**). The only figures specifically exemplified are those previously disclosed in **D33**/**D34** which relate to ATN v healthy patients. Thus **D3** does not disclose features (**b**) and (**d**)-(**f**).

2.5 **D18** discloses features (**a**)-(**c**) and (**g**) as it recites the use of NGAL as a biomarker able to discriminate which patients (children) who have under gone a cardiopulmonary bypass procedure also show renal injury. 71 patients took place in the trial of which 20 developed renal injury as assessed by a 50%

creatinine increase. NGAL concentration was tested in urine and serum. Figures **1-3** show various representations of the data as NGAL concentration v time or as a scatterplot of NGAL concentration at 2hrs after surgery. **D18** establishes a cutoff value of 50 ng/ml in urine or serum which at 2hrs post surgery can discriminate between renal injury and non-renal injury. This value is described as 'arbitrary' as it is calculated from actual data and represents observation rather than being 'predetermined' and the data subsequently compared to it. Table **2** discloses sensitivity and specificity data for cutoff values in the range 25-100 ng/ml at 2hr and 4hr post surgery. In no case, in any form or at any point post surgery, is the figure of 250 ng/ml or higher shown to be capable of discrimination as required by claim **1**. In fact the figure of 250 ng/ml is only reached on two occasions during testing for up to 120 hrs post surgery. Therefore features (**d**) and (**e**) are not disclosed in **D18.**

2.6 In summary, for the above reasons, it is the opinion of the Opposition Division that the priority dates of the granted patent are invalid and that the subject matter of claims **1-17** of the granted patent is novel.

Inventive Step

1 The opponents raise objection against claims **1-17** for lack of inventive step. Documents **D1-D4**, **D18** and **D20** have been offered as closest prior art in combination with a wide variety of further documents.

1.1 It is the opinion of the Opposition Division that **D18** is the closest prior as it is directed to the same problem, i.e. discriminating between renal injury and non-renal injury and has the most features in common with the granted patent - see para.**2.5** above. **D4** is a patent application clearly based upon the disclosure of **D18** as the figures and worked example are identical to that found in **D18**. **D4** does not provide any additional features over **D18**. It is noted that a family member of **D4**, **WO 2005/121788**, (cited as **D17** in opposition) was raised during the examination procedure with regard to novelty by virtue of Article 54(3) EPC.

1.2 **D1** is directed to identifying a biomarker of cisplatin (a common chemotherapeutic agent) nephrotoxicity, not to discriminating between renal injury and non-renal injury. It identifies urine NGAL levels of 20-80 ng/ml as indicative of nephrotoxicity. There is no disclosure of a predetermined cutoff value nor is the figure of 250 ng/ml anywhere present in the document. **D2** and **D3** do not show as many features as **D18** - see paras **2.3** and **2.4** above.

1.3 **D20** is a review article about NGAL as a marker for renal injury authored by one of the inventors. The review looks at the role of NGAL in inflammation/ infection, cancer (neoplasia) and kidney cells. With regard to inflammation/ infection (**front** page, **mid**.col. **3**rd para.), there is a warning concerning how sepsis should be considered in the light of possible sepsis induced kidney damage. **Back** page, **left** col. para.**3** states

"*It is apparent that a variety of independent pathologies are associated with raised levels of urinary or plasma NGAL. Therefore the finding of a raised value cannot be diagnostic of any of these pathologies. Other information concerning the patient must be taken into account to assess the significance of the result.*"

D20 does not suggest or provide any guidance to the skilled person to use a cutoff value nor indicate at what level any cutoff value may have. Therefore **D20**, if any, leads away from the subject matter of the granted patent.

2 The technical problem addressed is to provide an improved method of using NGAL to discriminate between renal injury and non-renal injury. The difference is the use of a cutoff value of >250 ng/ml. As demonstrated in **D18** which discloses a cutoff at 50 ng/ml and shown in other documents such as **D1-D4**, **D23**, **D33**/**D34**, levels of NGAL in urine, serum or plasma levels of <250 ng/ml were known to be associated with renal disorders. The figure of >250 ng/ml is an arbitrary choice by the proprietor based on solutions derived from a set of experimental figures, calculated using standard statistical techniques which balance sensitivity against specificity. Such a choice is not considered to be inventive (**T939**/**02**). Furthermore the only identifiable technical effect of the difference is to increase the specificity but dramatically reduce the sensitivity of the use of NGAL for discriminating between renal and non-renal disorders. This can be predicted from figures **2** and **3** and Table **2** of **D18**. No unexpected technical advantage has been demonstrated to accompany this worsening of the prior art. In such circumstances, an inventive step cannot be recognised (**T119**/**82**).

Conclusion

1 The granted patent infringes Article 123(2) EPC, does not meet the requirements of Article 83 EPC, the priority dates are invalid, claims **1-17** can be considered to be novel as required by Article 54 EPC but lack an inventive step required by Article 56 EPC.

2 After having fully taken into consideration the grounds of opposition and the submissions advanced by the parties, the Opposition Division considers that the questions at issue have been clarified to such an extent that a decision could now be reached without Oral Proceedings.

2.1 Considering that the aims in the interest of both the public and the parties to the proceedings are to bring the proceedings to a conclusion as rapidly as possible, and to avoid unnecessary costs, both parties are invited to declare within the given time limit whether, in view of the provisional conclusion set forth above, the requests for Oral Proceedings are maintained.

Europäisches Patentamt
European Patent Office
Office européen des brevets

Wichtige Hinweise zur mündlichen Verhandlung

Das Europäische Patentamt verfügt über keine eigenen Dolmetscher. Diese müssen im Bedarfsfall von außerhalb, teilweise sogar aus anderen Ländern, beigezogen werden, was mit einem hohen Aufwand an Kosten und organisatorischen Vorbereitungen verbunden ist. Muss ein Verhandlungstermin kurzfristig abberaumt werden, können Kosten für bestellte Dolmetscher nicht mehr vermieden werden.

Es wird daher gebeten, eine Simultanübersetzung nur bei wirklichem Bedarf in Anspruch zu nehmen. Es wäre wünschenswert, wenn sich die Beteiligten (zweckmäßigerweise gleichzeitig mit der Terminabstimmung) auf die Benutzung einer Amtssprache einigen könnten. Bei Verständigungsschwierigkeiten sind die Mitglieder der Einspruchsabteilung bereit zu helfen.

Die von den Verfahrensbeteiligten bevorzugte (abgestimmte) Verhandlungssprache und ggf. eine notwendige Simultanübersetzung sind dem Amt möglichst vor der in Regel 4(1) EPÜ angegebenen Frist mitzuteilen.

☐ Verfahrenssprache ist **Deutsch**

Von der/dem/den Einsprechenden wurde

☐ Englisch

☐ Französisch benutzt.

Es wird um eilige Mitteilung - möglichst per Telefax an den zuständigen Formalprüfer - gebeten,

möglichst bis

Datum **06.12.2011**

1. welche Sprache(n) Sie in der mündlichen Verhandlung verwenden (**Sprechen**)
2. aus welcher Sprache Sie eine Simultanübersetzung benötigen (**Hören**).

Important information concerning oral proceedings

The European Patent Office has no interpreters of its own. When interpreters are needed they have to be brought in from outside, sometimes even from other countries, which is costly and involves considerable organisation. If oral proceedings have to be cancelled at short notice, the cost of interpreters already engaged still has to be borne.

Please therefore make use of simultaneous interpreting facilities only where strictly necessary. If possible the parties should agree on an official language for the proceedings, preferably at the time when they arrange a date. The members of the Opposition Division will be willing to help should any communication problems arise.

The EPO should be told if possible before the period mentioned in Rule 4 (1) EPC which language the parties prefer (agree on) and whether simultaneous interpreting facilities are required.

☒ Language of the proceedings is **English**

The language used by the opponent/s was X English

☐ German

☐ French.

Please inform us urgently - where possible by fax addressed to the formalities officer concerned -

if possible by

Date **06.12.2011**

1. which language(s) you intend to use during the oral proceedings (**Speaking**)
2. from which language you need simultaneous interpretation (**Listening**).

Très important Procédure orale

L'Office européen des brevets ne dispose pas de son propre service d'interprètes. Aussi faut-il appel le cas échéant à des interprètes de l'extérieur, qui viennent même parfois de l'étranger, ce qui occasionne de frais élevés et demande un grand travail d'organisation. Si la date d'une procédure orale doit être annulée au dernier moment, il n'est plus possible d'éviter les frais d'interprètes.

Les parties à une procédure sont donc priées de ne demander une traduction simultanée qu'en cas de réel besoin. Il serait souhaitable qu'elles puissent se mettre d'accord en même temps qu'elles conviennent de la date sur l'utilisation d'une langue officielle comme langue des débats. Si les parties éprouvent des difficultés de compréhension lors des débats, les membres de la division d'opposition sont disposés à leur prêter leur assistance.

L'Office doit être avisé si possible avant le début du délai mentionné dans la règle 4(1) CBE de la langue préférée par les parties pour le déroulement des débat (et sur laquelle elles se sont préalablement mises d'accord) et de la nécessité éventuelle d'une traduction simultanée.

☐ La langue de la procédure est le **français**

La langue utilisée par l'opposant/les opposants était

☐ l'allemand

☐ l'anglais.

Prière d'indiquer d'urgence à l'agent des formalités compétent si possible par téléfax

si possible jusqu'au

Date **06.12.2011**

1. quelle(s) langue(s) vous utiliserez au cours de la procédure orale (**pour parler**)
2. à partir de quelle langue vous aurez besoin d'une traduction simultanée (**pour écouter**).

Sollten Sie Ihren Antrag auf mündliche Verhandlung zurückziehen oder zum anberaumten Verhandlungstermin nicht erscheinen wollen bzw. aus wichtigem Grund daran gehindert sein, werden Sie gebeten,

- **unverzüglich das Amt - möglichst per Telefax - davon zu benachrichtigen, wobei das Schriftstück mit einem deutlichen Vermerk "Dringend, mündliche Verhandlung am ..." oder sinngemäß gekennzeichnet sein sollte;**
- **in dringenden Fällen** (weniger als 1 Monat vor dem Verhandlungstermin) zusätzlich **auch dem/die anderen Verfahrensbeteiligten** bzw. ihre(n) Vertreter auf schnellstem Weg **direkt zu unterrichten.**

In jedem solchen Fall obliegt der Einspruchsabteilung die Entscheidung, ob die Verhandlung durchgeführt oder abberaumt wird. Es wird jedoch darauf hingewiesen, dass einem Verfahrensbeteiligten, der eine nicht rechtzeitige oder unterbliebene Benachrichtigung zu verantworten hat, die dadurch den anderen Beteiligten verursachten Kosten auferlegt werden können (Art. 104 EPÜ).

Hinweis auf Regel 4 EPÜ

Regel 4
Sprache im mündlichen Verfahren

(1) Jeder an einem mündlichen Verfahren vor dem Europäischen Patentamt Beteiligte kann sich anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen, sofern er dies dem Europäischen Patentamt spätestens einen Monat vor dem angesetzten Termin mitgeteilt hat oder selbst für die Übersetzung in die Verfahrenssprache sorgt. Jeder Beteiligte kann sich einer Amtssprache eines Vertragsstaats bedienen, sofern er selbst für die Übersetzung in die Verfahrenssprache sorgt. Von diesen Vorschriften kann das Europäische Patentamt Ausnahmen zulassen.

Should you decide to withdraw your request for oral proceedings or not wish to attend on the date set, or if for some special reason you are unable to do so, you are requested

- **to notify the EPO immediately, where possible by fax, marking the document clearly with the words "Urgent, oral proceedings on ..." or similar;**
- **in urgent cases** (less than one month before the date set for the proceedings), additionally to **notify the other party/parties** and/or their representative(s) **direct as rapidly as possible.**

In all such cases the Opposition Division will decide whether the proceedings are to go ahead or be cancelled. You should however note that costs incurred by the other parties may be charged to a party who either fails to notify them or does not do so in good time (Article 104 EPC).

Attention is drawn to Rule 4 EPC

Rule 4
Language in oral proceedings

(1) Any party to oral proceedings before the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings, if such party gives notice to the European Patent Office at least one month before the date of such oral proceedings or provides for interpretation into the language of the proceedings. Any party may use an official language of a Contracting State, if he provides for interpretation into the language of the proceedings. The European Patent Office may permit derogations from these provisions.

Si vous retirez votre requête tendant à recourir à la procédure orale ou si vous ne souhaitez pas vous présenter à la date fixée pour la procédure orale ou ne pouvez vous y présenter pour une raison sérieuse, veuillez

- **en faire avis sans retard à l'Office, si possible par téléfax, en partant sur votre communication clairement la mention "Urgent, procédure orale le ..." ou une indication similaire;**
- **dans les cas urgents** (moins d'un mois avant la date fixée pour la procédure orale) **en faire avis également directement** pas la voie la plus rapide à **l'autre/aux autres partie(s)** ou bien à son/leurs mandataire(s).

Il appartient alors à la division d'opposition de décider si la procédure orale aura lieu ou non. Il est néanmoins souligné que les frais causés aux autres parties par une partie qui est responsable de l'omission d'un tel avis ou de ce que cet avis n'a pas été fait en temps utile peuvent être mis à la charge de cette partie (art. 104 CBE).

Rappel de la Règle 4 CBE

Règle 4
Langues admissibles lors de la procédure orale

(1) Toute partie à une procédure orale devant l'Office européen des brevets peut utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure, à condition soit d'en aviser l'Office européen des brevets un mois au moins avant la date de la procédure orale, soit d'assurer l'interprétation dans la langue de la procédure. Toute partie peut utiliser une langue officielle de l'un des Etats contractants à condition d'assurer l'interprétation dans la langue de la procédure. L'Office européen des brevets peut autoriser des dérogations aux présentes dispositions.

(2) Die Bediensteten des Europäischen Patentamts können sich im mündlichen Verfahren anstelle der Verfahrenssprache einer anderen Amtssprache des Europäischen Patentamts bedienen.

(2) In the course of oral proceedings, employees of the European Patent Office may use an official language of the European Patent Office other than the language of the proceedings.

(2) Au cours de la procédure orale, les agents de l'Office européen des brevets peuvent utiliser une langue officielle de l'Office européen des brevets autre que la langue de la procédure.

(3) In der Beweisaufnahme können sich die zu vernehmenden Beteiligten, Zeugen oder Sachverständigen, die sich in einer Amtssprache des Europäischen Patentamts oder eines Vertragsstaats nicht hinlänglich ausdrücken können, einer anderen Sprache bedienen. Erfolgt die Beweisaufnahme auf Antrag eines Beteiligten, so werden die Beteiligten, Zeugen oder Sachverständigen mit Erklärungen, die sie in einer anderen Sprache als in einer Amtssprache des Europäischen Patentamts abgeben, nur gehört, sofern dieser Beteiligte selbst für die Übersetzung in die Verfahrenssprache sorgt. Das Europäische Patentamt kann jedoch die Übersetzung in eine seiner anderen Amtssprachen zulassen.

(3) Where evidence is taken, any party, witness or expert to be heard who is unable to express himself adequately in an official language of the European Patent Office or of a Contracting State may use another language. Where evidence is taken upon request of a party, parties, witnesses or experts expressing themselves in a language other than an official language of the European Patent Office shall be heard only if that party provides for interpretation into the language of the proceedings. The European Patent Office may, however, permit interpretation into one of its other official languages.

(3) Lors de l'instruction, les parties, témoins ou experts appelés à être entendus, qui ne possèdent pas une maîtrise suffisante d'une langue officielle de l'Office européen des brevets ou d'un Etat contractant, peuvent utiliser une autre langue. Si la mesure d'instruction est ordonnée sur requête d'une partie, les parties, témoins ou experts qui s'expriment dans une langue autre qu'une langue officielle de l'Office européen des brevets ne sont entendus que si cette partie assure l'interprétation dans la langue de la procédure. L'Office européen des brevets peut toutefois autoriser l'interprétation dans l'une de ses autres langues officielles.

(4) Mit Einverständnis aller Beteiligten und des Europäischen Patentamts kann jede Sprache verwendet werden.

(4) If the parties and the European Patent Office agree, any language may be used.

(4) Sous réserve de l'accord des parties et de l'Office européen des brevets, toute langue peut être utilisée.

(5) Das Europäische Patentamt übernimmt, soweit erforderlich, auf seine Kosten die Übersetzung in die Verfahrenssprache und gegebenenfalls in seine anderen Amtssprachen, sofern ein Beteiligter nicht selbst für die Übersetzung zu sorgen hat.

(5) The European Patent Office shall, if necessary, provide at its own expense interpretation into the language of the proceedings, or, where appropriate, into its other official languages, unless such interpretation is the responsibility of one of the parties.

(5) L'Office européen des brevets assure à ses frais, en tant que de besoin, l'interprétation dans la langue de la procédure, ou, le cas échéant, dans ses autres langues officielles, à moins que cette interprétation ne doive être assurée par l'une des parties.

(6) Erklärungen von Bediensteten des Europäischen Patentamts, Beteiligten, Zeugen und Sachverständigen, die in einer Amtssprache des Europäischen Patentamts abgegeben werden, werden in dieser Sprache in die Niederschrift aufgenommen. Erklärungen in einer anderen Sprache werden in der Amtssprache aufgenommen, in die sie übersetzt worden sind. Änderungen einer europäischen Patentanmeldung oder eines europäischen Patents werden in der Verfahrenssprache in die Niederschrift aufgenommen.

(6) Statements by employees of the European Patent Office, parties, witnesses or experts, made in an official language of the European Patent Office, shall be entered in the minutes in that language. Statements made in any other language shall be entered in the official language into which they are translated. Amendments to a European patent application or European patent shall be entered in the minutes in the language of the proceedings.

(6) Les interventions des agents de l'Office européen des brevets, des parties, témoins et experts faites dans une langue officielle de l'Office européen des brevets sont consignées au procès-verbal dans cette langue. Les interventions faites dans une autre langue sont consignées dans la langue officielle dans laquelle elles sont traduites. Les modifications apportées à une demande de brevet européen ou à un brevet européen sont consignées au procès verbal dans la langue de la procédure.

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European Patent Office
Office européen des brevets

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Huenges, Martin
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Elisenhof
Elisenstrasse 3
80335 München
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For any questions about this communication:
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Weinachter, Robert
ext.2245

Date
26-08-2011

Reference	Application No./Patent No.
I 8063/MH OPPO 04	05820913.1 - 1223 / 1831699
Applicant/Proprietor	
Antibodyshop A/S	

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will be public, will take place before the opposition division

on 07.02.12 at 09.30 hrs in Room 1.1 at the EPO Rijswijk, Patentlaan 2, NL-2280 HV Rijswijk (ZH)

and 08.02.2012.- 2 days in total-

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC).

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The final date for making written submissions and/or amendments (R. 116 EPC) is 07.12.11.

You are requested to report in good time beforehand to the porter in the EPO foyer. Room _____ is available as waiting room.

1st Examiner:
Routledge B

2nd Examiner:
Rosin O

Chairman:
Gunster M

For the Opposition Division

Annexes:
Confirmation of receipt (Form 2936)
Rule 4 EPC (EPC Form 2043)
Communication (EPO Form 2906)

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Getting to the EPO The Hague

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to EPO postal service: 22.08.11

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DANEMARK

For any questions about this communication:
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Weinachter, Robert
ext.2245

Date 26-08-2011

Reference	Application No./Patent No.
OP004290EP1 OPPO 03	05820913.1 - 1223 / 1831699
Applicant/Proprietor: Antibodyshop A/S	

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1264 Copenhagen K
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For any questions about this communication:
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Weinachter, Robert
ext.2245

Date: 26-08-2011

Reference	Application No./Patent No.
P1151EP00	05820913.1 - 1223 / 1831699

Applicant/Proprietor: Antibodyshop A/S

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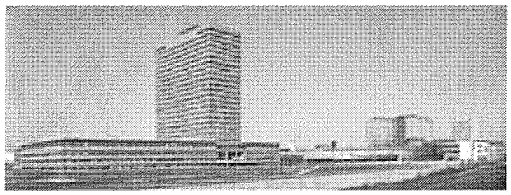
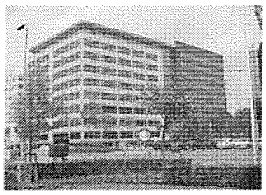
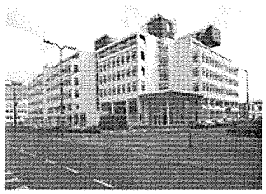
European Patent Office - The Hague - Getting there



Tower, Hinge and Shell Buildings



Le Croisé Building



Rijsvoort Building

Visitors address:

Patentlaan 2
2288 EE Rijswijk
The Netherlands

Using local public transport

From The Hague Central Station (Den Haag CS), Hollands Spoor (Den Haag HS), Town Centre and Rijswijk train station, take the 17 tram (heading for Wateringseveld) to Patentlaan.

From Scheveningen, take the 1 tram (stops at Central Station (CS), Town Centre and Hollands Spoor (HS), to Vlietbrug. From here it is a 10-minute walk (up the stairs, along the footpath on the motorway bridge, down the steps and round the building (Tinbergenstraat, Koopmansstraat) to the main entrance at the front.

By train (Train information: www.ns.nl)

From Rotterdam Central Station (CS), take the "stoptrein" (heading for Den Haag) to Rijswijk. From there, take 17 tram (heading for Statenkwartier) to Patentlaan.

By car: (Route planner: www.viamichelin.com)

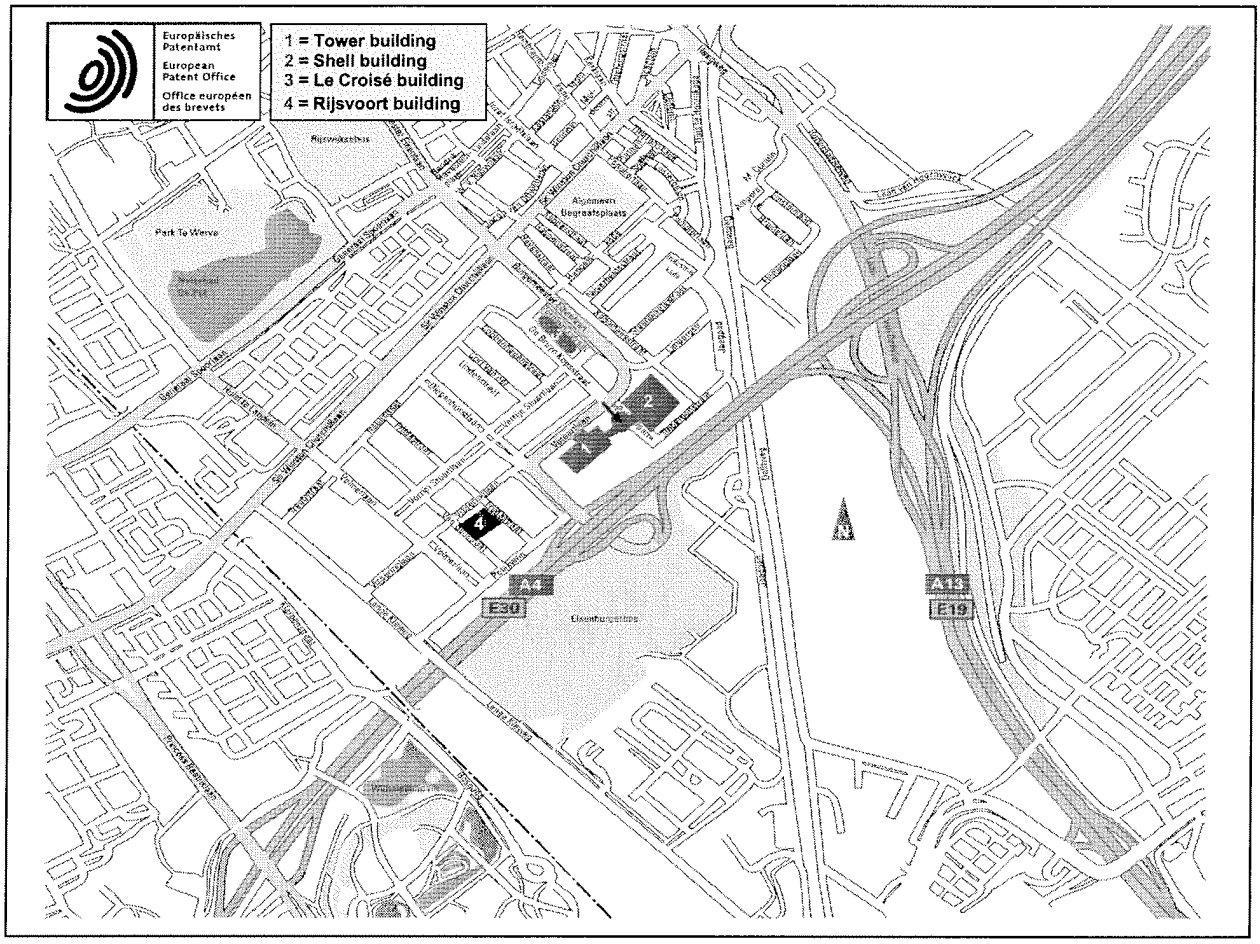
On the A13 from Rotterdam:
Follow the signs for Rijswijk, Den Haag. Approaching The Hague, this motorway becomes the E30. Follow the signs for Rijswijk, Den Haag Zuid, Hoek van Holland (A4/N4), i.e. DO NOT take the exit for Rijswijk Centrum. On the A4/N4, take the Plaspoelpolder exit (white sign with black lettering, exit Nr. 10). To get to Plaspoelpolder, turn right at the first set of traffic lights. The main building on your right is the EPO. At the next traffic lights, turn right into Veraartlaan.

On the A4 from Amsterdam or the A12 from Utrecht:
Follow the signs for Rijswijk, Den Haag Zuid, Hoek van Holland (A4/N4). On theA4/N4, take the Plaspoelpolder exit (white sign with black lettering, exit Nr. 10). From here, follow the directions given above.

Parking: Limited number of parking spaces (Tinbergenstraat entrance).

By air:

From Schiphol airport, Amsterdam, take the direct train to The Hague Central Station (Den Haag CS) or Holland Spoor (Den Haag HS). Change to the 17 tram (heading for Wateringseveld) to Patentlaan.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For any questions about this communication:
Tel.:+31 (0)70 340 45 00
Weinachter, Robert
ext.2245

Date: 26-08-2011

Reference	Application No./Patent No.
MJF5718/MNM/rg OPPO 01	05820913.1 - 1223 / 1831699
Applicant/Proprietor: Antibodyshop A/S	

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Chairman:
Gunster M

For the Opposition Division

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Schweiger, Georg
Patentanwälte
Reitstötter, Kinzebach & Partner (GbR)
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81679 München
ALLEMAGNE

For any questions about this communication:
Tel.:+31 (0)70 340 45 00
Weinachter, Robert
ext.2245

Date: 26-08-2011

Reference	Application No./Patent No.
M/51140-OPPO OPPO 02	05820913.1 - 1223 / 1831699
Applicant/Proprietor: Antibodyshop A/S	

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European Patent Office
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European Patent Office
Postbus 5818
2280 HV Rijswijk
NETHERLANDS
Tel: +31 70 340 2040
Fax: +31 70 340 3016

Application No.: 05 820 913.1

Patent No.: EP-B-1 831 699

Preparation for oral proceedings - Instructions to Support Service

Oral proceedings are to be held in connection with the above patent application

1. The matters to be discussed are set out in the annex (Form 2906)

2. Dispatch the summons using Form 2008/2310 and Form 2906 for the parties to attend on:

Day 07.12.2011 Time 09:30

+ 09.12.2011
- no room available
- changed to
07 + 08.02.12

ROOMS

1.1.1

Room booked

ORAL 01, 02, 03 and 05 coded

Date Initials

2.1 If no room is available, notify the division on Form 2088

R. Weinachter
Tel. (070) 3402245
The Hague

2.2 Parties' submissions in preparation for the oral proceedings, if any, should be made no later than

2 ~~1~~ month(s) → 07/12/2011 -

16.08.11

before the date of the oral proceedings
(transfer to Form 2008.1 / 2310.1)

2.3 Encode ORAL(04) → ✓

coded

Date Initials

2.4 Dispatch Form ~~2008.7~~ / 2310.7 to division → ✓

Date Initials

3. ☐ Arrange for the following special equipment to be provided in the conference room:

Date Initials

4. Request language service to provide simultaneous interpretation facilities as necessary

Date Initials

5. Return the dossier to primary examiner with Form 2041 (15 days before the oral proceedings)

Date Initials

6. Check that summons has been received (Form 2936 / advice of delivery)

7. 15 days before the oral proceedings:
- dispatch the dossier to the primary examiner and
- dispatch Form 2041 with copies for the other members of the examining division.

Date 1/8/11

Gunster, Marco
Chairman

Rosin, Oliver
2nd examiner

Routledge, Brian
1st examiner

Legal member

Enclosure(s):