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Datasheet for the decision of 31 January 2012

Case Number: T 1911/08 - 3.3.01

Application Number: 02721105.1

Publication Number: 1379520

IPC: C07D 401/12, C07D 471/08, C07D 487/04, A61K 31/444, A61P 29/02

Language of the proceedings: EN

Title of invention:
N-substituted nonaryl-heterocyclic NMDA/NR2B antagonists

Patentee:
Merck Sharp & Dohme Corp.

Opponent:
JANSSEN PHARMACEUTICAL N.V.

Headword:
NMDA/NR2B Antagonists/MERCK SHARP & DOHME

Relevant legal provisions:
EPC Art. 123, 54

Keyword:
"Main request and auxiliary requests 1 and 2: amendments (not allowable), disclaimer not accidental anticipation"
"Auxiliary request 3: added matter (yes), no basis for "in humans"
"Auxiliary request 4: remittal after amendment"

Decisions cited:
G 0001/03, G 0002/10, G 0009/91, T 0134/01, T 0739/01, T 0580/01, T 0639/01, T 0241/95

Catchword:
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Case Number: T 1911/08 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 31 January 2012

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 23 July 2008 revoking European patent No. 1379520 pursuant to Article 101(2)(3)(b) EPC.

Composition of the Board:

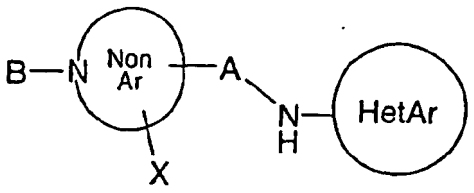
Chairman: P. Ranguis
Members: L. Seymour
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 379 520, which was filed as application number 02 721 105.1, based on international application WO 02/068409, was granted on the basis of fifty claims. Claim 1 was drafted as a "Swiss-type" use claim, and claims 2 to 47 were dependent claims. Claim 48 was in the "first medical use" format. Claim 49 was directed to pharmaceutical compositions and claim 50 to compounds; both these claims referred back to claim 48. Claim 48 contained disclaimers (i) to (iii), and claim 50 additional disclaimers (iv) and (v) each relating to various subgroups of compounds.

Independent claims 1 and 48 as granted read as follows (note: emphasis in claim 1 added by the board, and disclaimers omitted in claim 48 for the sake of conciseness):

"1. Use of a compound having the formula (I):



(I)

or pharmaceutically acceptable salts thereof, wherein NonAr is a nonaromatic 5-7 membered ring containing 1 or 2 nitrogen ring atoms or an aza bicyclo octane ring; HetAr is a 5 or 6 membered heteroaromatic ring containing 1-3 nitrogen ring atoms, or isoxazolyl, thiazolyl, thiadiazolyl, quinolinyl, quinazolinyl,

purinyl, pteridinyl, benzimidazolyl, pyrrolopyrimidinyl, or imidazopyridinyl;
HetAr is optionally substituted with 1 or 2 substituents, each substituent independently is C_{1-4}alkyl C_{1-4}alkoxy, C_{2-4}alkynyl, trifluoromethyl, hydroxy, hydroxyC_{1-4}alkyl, fluoro, chloro, bromo, iodo, cyano, methylsulfanyl, cyclopropylethynyl-, phenylethynyl-, heteroarylethynyl-, $-N(C_{0-4}alkyl)(C_{0-4}alkyl)$, nitro, $(C_{1-2}alkyl)(C_{1-2}alkyl)NCH_2-$, $(C_{1-2}alkyl)HNCH_2-$, $Si(CH_3)_3-C-$, or $NH_2C(O)-$;
A is $-C_{0-4}alkyl-$;
B is aryl$(CH_2)_{0-3}-O-C(O)-$, heteroaryl$(CH_2)_{1-3}-O-C(O)-$, indanyl$(CH_2)_{0-3}-O-C(O)-$, aryl$(CH_2)_{1-3}-C(O)-$, aryl-cyclopropyl-C(O)-, heteroaryl-cyclopropyl-C(O)-, heteroaryl$(CH_2)_{1-3}-C(O)-$, **aryl$(CH_2)_{1-3}-$, heteroaryl$(CH_2)_{1-3}-$**, aryl$(CH_2)_{1-3}-NH-C(O)-$, aryl$(CH_2)_{1-3}-NH-C(NCN)-$, aryl$(CH_2)_{1-3}-SO_2-$, heteroaryl$(CH_2)_{1-3}-SO_2-$, wherein any of the aryl or heteroaryl is optionally substituted by 1-5 substitutents, each substituent independently is C_{1-4}alkyl, C_{3-6}cycloalkyl, C_{1-4}alkoxy, trifluoromethyl, bromo, fluoro, or chloro; and
X is H, OH, F, C_{1-4}alkyl, C_{1-4}alkoxy, NH_2, or X taken with an adjacent bond is =O;
for the manufacture of a medicament for treating pain, migraine, depression, anxiety, schizophrenia, Parkinson's disease or stroke.

...

48. A compound as defined in any one of claims 1 to 47 or a pharmaceutically acceptable salt thereof for use as a medicament provided that:
..."

II. An opposition was filed and revocation of the patent in its entirety requested pursuant to Articles 100(c), 100(b) and 100(a) EPC (lack of novelty and inventive step).

III. The following documents were cited *inter alia* during the opposition/appeal proceedings:

(1) US-A-3 184 462

(2) J Moragues et al., Il Farmaco ed. sci., 1980, 35(11), 951-964

(3) US-A-3 933 832

(4) I. Parrot et al., Synthesis, 1999, 1163-1168

(5) WO 97/43279

(6) WO 99/51589

(7) WO 84/01151

IV. The appeal lies from the decision of the opposition division revoking the patent under Article 101(2), (3)(b) EPC.

The decision was based on the claims as granted (main request), and a first auxiliary request incorporating amendments to claims 1, 48 and 50, filed during oral proceedings before the opposition division.

The opposition division considered the subject-matter of the main request to lack novelty over the disclosures of documents (5) to (7).

Concerning the first auxiliary request, the opposition division was of the opinion that, in contrast to the disclosures of documents (3) and (4), those of documents (1), (2) and (5) to (7) could not be considered to represent accidental anticipations according to the criteria set out in Enlarged Board of Appeal decision G 1/03. The disclaimers introduced into claims 1, 48 and 50 in order to restore novelty with respect to these documents were therefore considered to contravene Article 123(2) EPC.

V. The appellant (patentee) lodged an appeal against this decision. With the grounds of appeal, the appellant filed a main request, which was identical to the claim set of the auxiliary request forming the basis of the decision under appeal, and four auxiliary requests.

The claims of the main request differs from the claims as granted (cf. above point I) in the insertion of a number of additional disclaimers in claims 1, 48 and 50. The last of these disclaimers introduced into claim 48 reads as follows:

"(vi) when HetAr is pyridin-4y1 or pyrimidin-4-yl; HetAr is optionally substituted by one or two groups independently chosen from C_{1-4}alkyl, C_{1-4}alkoxy, trifluoromethyl, C_{2-4}alkynyl, F, Cl, Br, I, hydroxy, nitro, cyano, methylsulfanyl and -N(C_{0-4}alkyl)(C_{0-4}alkyl), provided no more than one trifluoromethyl group is present;

NonAr contains 1 nitrogen ring atom;
X is H, F, C_{1-4}alkoxy or C_{1-4}alkyl; and
B is aryl$(CH_2)_{0-3}$-O-C(O)- or heteroaryl$(CH_2)_{1-3}$-O-C(O)- optionally substituted on the aryl or heteroaryl with up to three, in the case of F also up to the maximum number of, substituents; then
A is not C_0alkyl;".

Auxiliary request 1 differs from the main request in that the first line of claim 1 has been amended to read: "Use of an NMDA NR2B antagonist which is a compound having the formula (I):".

Auxiliary request 2 differs from the main request in the deletion of "aryl$(CH_2)_{1-3}$-" and "heteroaryl$(CH_2)_{1-3}$-" from the definitions of B in claim 1 (cf. definitions highlighted in bold in claim 1 reproduced above under point I). As a result, most of the disclaimers became redundant and have been deleted, apart from disclaimer (vi) in claim 48.

Auxiliary request 3 differs from auxiliary request 2 in the deletion of claims 49 and 50, and the amendment of claim 48 to read as follows (emphasis added):

"48. A compound as defined in any one of claims 1 to 47 or a pharmaceutically acceptable salt thereof for use as a medicament **in humans**."

Auxiliary request 4 differs from auxiliary request 3 in the deletion of claim 48.

VI. With its letter of response, the respondent (opponent) filed counterarguments.

VII. In reply to a communication sent as annex to the summons to oral proceedings, the appellant filed, with letter of 22 December 2011, a replacement page 145 for auxiliary request 2, incorporating a minor amendment to claim 50.

VIII. Oral proceedings were held before the board on 31 January 2012. Following a request by the board, the appellant submitted a complete set of claims for auxiliary request 4.

IX. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

As regards the issue of the disclaimers introduced into the main request and auxiliary requests 1 and 2, the appellant argued that, in order to decide whether a document was an accidental anticipation in the sense of decision G 1/03, it was first necessary to focus on the general inventive concept lying behind the invention. In the present case, the invention related to the provision of NMDA NR2B receptor antagonists. When seeking new pharmaceutical compounds to treat a particular disease, the skilled person, that is, the medicinal chemist, almost always would focus on the biological pathway by which that disease was understood to occur. Modern medicine placed considerable importance on understanding the biology of a disease, since this allowed the development of optimised treatments with a minimum of side effects. Thus, the search for drug candidates normally involved high-throughput screening to identify compounds that modulated specific receptors. Consequently, when making

the invention, the skilled person would only take into account compounds interacting with the same receptor, and would never consider using compounds that interacted with an unrelated receptor as a starting point for developing further NMDA NR2B antagonists. The pathway by which compounds acted thus provided the boundary between accidental and non-accidental anticipations. This view was also consistent with EPO practice of taking into account mechanistic considerations when determining the closest prior art, and in granting patents based on *in vitro* data. Since none of documents (1) to (7) dealt with compounds acting on NMDA NR2B receptors, they were to be regarded as being accidental anticipations in the sense of decision G 1/03, and their disclosures could be disclaimed from the present use or compound claims. Although G 1/03 was silent on the topic of disclaimers in use claims, there was no reason as to why the same logic should not apply as for compound claims.

In relation to document (6), the appellant argued that this was indeed an accidental anticipation. This document principally related to pesticides and fungicides, and only contained a passing references to uses in veterinary compositions. Thus, even were document (6) to be considered as disclosing veterinary drugs, this disclosure was very remote from the invention of the patent in suit, which principally related to the treatment of diseases relevant to humans. The reference to favourable toxicity in warm-blooded species clearly referred to the fact that residues resulting from pesticidal and fungicidal use would not be toxic when consumed. This did not amount to a disclosure of relevance to pharmaceutical applications.

The appellant further argued that it would be too sweeping to hold that a prior art document was non-accidental merely because it related to the technical field of pharmaceuticals, as implied by decision T 134/01. Much narrower definitions of what was to be considered to be non-accidental prior art were to be found in a number of other decisions, such as, T 739/01, T 580/01 and T 639/01, wherein the prior art related to the treatment of the same illness as the patent or application in suit.

As regards the basis in the application as originally filed for the feature "in humans" introduced into claim 48 of auxiliary request 3, the appellant conceded that this was not to be found *expressis verbis* in the application as originally filed. However, the appellant argued that "in humans" could be seen as an implicit feature, since the nature of the diseases to be treated in the patent in suit, in particular, schizophrenia and Parkinson's disease, were clearly human-specific. Moreover, the appellant submitted that the EPC itself provided a basis for this amendment, since Article 53(c) EPC specifically referred to "methods for treatment of the human or animal body". Therefore, the appellant was of the opinion that it was entitled to draft its "first medical use" claim in accordance to Article 54(4) EPC as relating to only part of the subject-matter set out in Article 53(c) EPC.

X. The arguments of the respondent, insofar as they are relevant to the present decision, can be summarised as follows:

Several objections were raised by the respondent with respect to the disclaimers introduced into the main request and auxiliary requests 1 and 2, namely, regarding the questions of whether they related to accidental disclosures, whether they were correctly worded, and whether the requirements of clarity were fulfilled, in the sense of Enlarged Board of Appeal decision G 1/03. In addition, the respondent argued that the subject-matter remaining in the claim after the introduction of the disclaimers was not directly and unambiguously disclosed in the application as originally filed, as required by Enlarged Board of Appeal decision G 2/10.

With respect to disclaimer (vi), the respondent argued that it was not allowable in view of decision G 1/03, since document (6) belonged to the same technical field as claims 48 to 50, namely to the field of medicaments.

Turning to auxiliary request 3, the respondent submitted that the feature "in humans" contravened Article 123(2) EPC since it was not directly and unambiguously derivable from the application as originally filed. The assumption of specificity to humans could only apply to some of the diseases listed, if at all.

Regarding auxiliary request 4, the respondent stated that it did not have any objections under Articles 123, 84, 83 and 54 EPC. Moreover, the respondent agreed with the appellant at oral proceedings that this request should be remitted to the opposition division for further prosecution.

XI. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the first to third auxiliary requests filed with the statement of grounds of appeal, each consisting of claim pages 129 to 144 as granted and amended claim pages 128 and 145, apart from the second auxiliary request, in which page 145 has been replaced by page 145 filed with letter of 22 December 2011; or on the basis of the fourth auxiliary request received during oral proceedings. The appellant further requested remittal of the case to the opposition division for further prosecution.

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

XII. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Structure of requests*

The structure of the independent claims in the main request (MR) and auxiliary requests (AR) on file, can be summarised in tabular form as follows (cf. above point V):

	Swiss-type claim 1	1st medical use claim 48	composition claim 49*	compound claim 50*
MR	disclaimers (i), (ii)	disclaimers (i)-(vi)	disclaimers (i)-(vi)	disclaimers (i)-(viii)
AR 1	"	"	"	"
AR 2	no disclaimer	disclaimer (vi)	disclaimer (vi)	disclaimer (vi)
AR 3	no disclaimer	no disclaimer	claim deleted	claim deleted
AR 4	no disclaimer	claim deleted	claim deleted	claim deleted

* note: claims 49 and 50 refer back to claim 48 and therefore also comprise the disclaimers defined in the latter.

Thus, it can be seen that, in each of the requests on file, claim 1 is formulated as a "second (further) medical use" or "Swiss-type" claim.

In addition, the main request and auxiliary requests 1 to 3 each contain a claim 48 in the format of a "first medical use" claim, as provided for in Article 54(4) EPC 2000. Under the transitional provisions for EPC 2000, Articles 53(c) and 54(4) EPC 2000 are applicable to European patents, such as the patent in suit, which were already granted at the time of its entry into force; in contrast, Article 54(5) EPC 2000 does not apply (see OJ EPO 2007, special edition no. 1, 197, Article 1, points 1 and 3).

3. *Main request and auxiliary requests 1 and 2 - Allowability of disclaimers under Article 123(2) EPC*

3.1 Numerous objections were raised by the respondent concerning the disclaimers in the main request and

auxiliary requests 1 and 2 (cf. above point X). However, in the analysis below, the board will restrict itself to the issue of whether disclaimer (vi), which is present in claims 48 to 50 of each of the requests under consideration here (cf. first three rows of table above), can be viewed as relating to an accidental anticipation in the sense of Enlarged Board of Appeal decision G 1/03 (OJ EPO 2004, 413).

3.2 Disclaimer (vi), as reproduced above under point V, was introduced in response to a novelty objection raised under Article 54(2) EPC with respect to document (6).

It is not in dispute that this disclaimer relates to an "undisclosed disclaimer" in the sense of decision G 1/03 (cf. Reasons, point 2, first paragraph), that is, it does not have a basis in the application as filed. However, the parties disagree on whether document (6) can be viewed as being an "accidental anticipation" and, accordingly, as providing the basis for an allowable disclaimer under Article 123(2) EPC, as set out in decision G 1/03 (see Headnote II.1, and Reasons 2.2).

Therefore, in the present instance, it has to be decided whether document (6) is an accidental anticipation as defined in decision G 1/03, that is, whether "it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention" (see Headnote II.1).

3.3 The patent in suit relates heterocyclic compounds of general formula (I) (see above point I) that are effective as NMDA NR2B antagonists, and accordingly are

disclosed as being useful in the treatment of a number of diseases associated with this pharmacological activity, namely, pain, migraine, depression, anxiety, schizophrenia, Parkinson's disease, and stroke (see paragraphs [0001] and [0100]).

Document (6) also relates to heterocyclic compounds of overlapping general formula (I), and a number of the specific compounds listed in Table 1 fall within this area of overlap. The compounds according to document (6) are disclosed as being well tolerated by plants and having favourable toxicity to warm-blooded species, and being highly suitable for controlling animal pests, for controlling endoparasites and ectoparasites in the field of veterinary medicine, and for controlling harmful fungi (see page 1, last complete paragraph). Further details of the use in the field of veterinary medicine are disclosed on pages 37 and 38 (see page 37, paragraphs 4 and 5, and paragraph bridging pages 37 and 38), including the possibility of oral administration to animals.

3.4 The appellant argued that the biological pathway by which compounds acted should constitute the boundary between accidental and non-accidental anticipation, since, in modern mechanism-based research, the skilled person, that is, the medicinal chemist, would only take into account compounds interacting with the same receptor as a starting point for drug development.

The board cannot agree with this analysis for the following reason:

The ultimate aim of the pharmaceutical industry is the development of drugs capable of treating specific diseases. Therefore, in the present instance, where the patent in suit relates to the field of pharmaceuticals, the skilled person cannot merely be defined as being a medicinal chemist, but rather as being made up of a team covering the full range of disciplines required for drug discovery and development. High-throughput screening may be an important and integral part of this process. However, it will be equally important to establish whether candidate drug compounds have potentially favourable properties with respect to safety, toxicity, pharmacokinetics and metabolism. Therefore, the disclosure in document (6) that specific structures under consideration have favourable toxicity properties and are suitable for oral administration to animals would be considered to be valuable information to be taken it into consideration by the skilled person when making the present invention.

The board therefore agrees with the conclusion reached in T 134/01 (see Reasons point 2.3), namely, that a further document belonging to the field of pharmaceuticals is not to be considered as being an accidental anticipation within the meaning of the decision G 1/03, that is, even if it does not relate to the same illness or biological pathway as the patent or application in suit.

In decisions T 739/01, T 580/01 and T 639/01, the relevant prior art documents related to the treatment of the same illness as the patent or application in suit and were considered to be non-accidental anticipations (Reasons points 3.5, 2.4 and 3.2,

respectively). However, it does not follow that, had they related to a different illness, they would have been regarded as being accidental. Indeed, decisions T 739/01 (Reasons, points 3.4, 3.5) and T 580/01 (Reasons, points 2.3, 2.4) emphasise that "the patent in suit relates to the technical field of medicaments", as does the relevant prior art.

3.5 The further arguments advanced by the appellant are also not considered to be persuasive:

It is true that, for the purpose of patent protection of a medical application of a substance, a pharmacological effect observed *in vitro* may be accepted as sufficient evidence of a therapeutic application. However, this is only true if this observed effect directly and unambiguously reflects such a therapeutic application (cf. e.g. T 241/95, OJ EPO 2001, 103, Reasons point 4.1.2). Indeed, as is further stated in decision T 241/95, "the discovery that a substance selectively binds a receptor ... still needs to find a practical application in the form of a defined, real treatment of any pathological condition in order ... to be considered as an invention eligible for patent protection" (see Headnote I).

Moreover, the appellant's narrow problem-based approach to defining accidental disclosure focuses on an analysis of the problem to be solved. However, this was specifically rejected in decision G 1/03 (see Reasons 2.2.2): "Even less decisive, as an isolated element, is the lack of a common problem, since the more advanced a technology is, the more the problem may be formulated specifically for an invention in the field. Indeed, one

and the same product may have to fulfil many requirements in order to have balanced properties which make it an industrially interesting product. Correspondingly, many problems related to different properties of the product may be defined for its further development. When looking specifically at improving one property, the person skilled in the art cannot ignore other well-known requirements. Therefore, a "different problem" may not yet be a problem in a different technical field."

Finally, the appellant questioned the relevance of the disclosure of document (6) to pharmaceutical applications. As outlined above under point 3.3, the use in the field of veterinary medicine is disclosed in this document as one of three fields of application. Moreover, a whole section is devoted to dosages and formulations suitable for this use (pages 37 and 38), and an example is included relating to antiparasitic use (see Example N). Therefore, it cannot be accepted that the disclosure of a veterinary use only qualifies as "a passing reference". Moreover, since document (6) envisages oral administration to animals, there seems no basis for the contention of the appellant that the reference to a favourable toxicity in warm-blooded species was not of relevance to pharmaceutical applications. Finally, as discussed further under point 4 below, the diseases claimed in the patent in suit cannot be seen as being exclusively human-specific. Moreover, animal models are frequently used in research into human diseases. Therefore, information derived from the former is also of relevance to the latter.

3.6 Accordingly, the main request and auxiliary requests 1 and 2 must be rejected, since the incorporation of disclaimer (vi) into the respective claims 48 to 50 contravenes the provisions of Article 123(2) EPC.

4. *Auxiliary request 3 - Article 123(2) EPC*

Auxiliary request 3 does not contain any disclaimers. However, the feature "in humans" has been introduced into claim 48 (cf. Table under above point 2).

The appellant conceded that this feature was not to be found *expressis verbis* in the application as originally filed.

Contrary to the appellant's submissions, said feature cannot be derived as an implicit feature of the diseases listed in the patent in suit, namely, "pain, migraine, depression, anxiety, schizophrenia, Parkinson's disease or stroke". Regardless of whether some of these diseases may be human-specific, it is evident that this is not the case for the list as a whole, since, for example, animals can clearly experience pain or anxiety. This list cannot therefore be interpreted as necessarily and unambiguously implying a use in humans as opposed to animals.

Moreover, Article 53(c) EPC refers to "the human or animal body" as a single concept. Therefore, the board fails to see how this Article can provide a basis for making a distinction between the two. Moreover, under Article 123(2) EPC, the relevant criterion to be applied is whether there is a direct and unambiguous disclosure in the application as originally filed for

the amendment made. The appellant has failed to demonstrate that this is the case.

Hence, the subject-matter of claim 48 according to auxiliary request 3 contravenes the requirements of Article 123(2) EPC.

5. *Auxiliary request 4*

The respondent did not raise any objections with respect to auxiliary request 4 under Articles 123, 84, 83 and 54 EPC, and the board sees no reason to differ.

In particular, the claims of this request find their basis in claims 1 to 47, 51 and 52 as originally filed, and claim 1 has been restricted with respect to claim 1 of the granted version through the deletion of "aryl$(CH_2)_{1-3}$-" and "heteroaryl$(CH_2)_{1-3}$-" from the definitions of B. The amended request therefore meets the requirements of Article 123(2) and (3) EPC.

Moreover, said restriction in claim 1 establishes novelty with respect to the prior art, since none of the cited documents discloses structures of present formula (I) in combination with the claimed diseases.

6. *Remittal*

The board has come to the conclusion that the subject-matter of auxiliary request 4 fulfils the requirements of Articles 123, 84, 83 and 54 EPC. However, the opposition division has not yet taken a decision on the question of inventive step, which was raised as a

ground of opposition pursuant to Article 100(a) EPC (see point II above).

Given that the purpose of the appeal proceedings *inter partes* is mainly to give the losing party the possibility of challenging the decision of the opposition division on its merits (see G 9/91, OJ EPO 1993, 408, point 18), the board finds it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the first instance for further prosecution, in agreement with both parties (see points X, last paragraph, and point XI above).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the fourth auxiliary request received during oral proceedings of 31 January 2012.

The Registrar: The Chairman:

M. Schalow P. Ranguis