NOTIFICATION OF DECISION ON PROTEST OR DECLARATION THAT PROTEST CONSIDERED NOT TO HAVE BEEN MADE

(PCT Rule 40.2(c) and (e) and Administrative Instructions, Section 502)

Date of mailing
(day/month/year) 18.07.2012

Applicant's or agent's file reference
COTH-529-WO1

International application No.
PCT/US2011/034998

International filing date
(day/month/year) 03.05.2011

Applicant
BRISTOL-MYERS SQUIBB COMPANY

☒ The applicant is hereby notified that this International Searching Authority, after having examined the protest on the payment of the additional fees, has reached the decision indicated below.

1. ☐ The protest is found justified to the extent that:
   
   ☑ partial reimbursement in the amount of 1 (currency/amount) will be made in due course for the following reason(s): see separate sheet

2. ☐ The protest is found unjustified and the additional fees and, where applicable, any protest fee paid will not be refunded for the following reason(s):

3. ☐ The International Searching Authority declares that the protest is considered not to have been made since the applicant has not paid the protest fee within the limit referred to in the invitation (Form PCT/ISA/206) dated

ATTENTION

The applicant should notify the International Bureau promptly if he wishes a copy of the protest and the decision thereon to be sent to the designated Offices.

A copy of this notification has been sent to the International Bureau

Name and mailing address of the international searching authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Authorized Officer
Chavanne, Franz
Tel. +49 89 2399 - 8399

Form PCT/ISA/212 (April 2005)
Result of the prior review according to Rule 40.2(e) PCT, Int. Appl. PCT/US2011/034998

The International searching Authority (ISA) has issued in its letter of 06.10.2011 a formally acceptable invitation to pay additional fees with a motivation for the decision of lack of unity. The ISA indicated the presence of 25 inventions which were not linked by a single inventive concept since fibronectin type III tenth (10Fn3) domain modified to bind to a target molecule not bound by the wild-type 10Fn3 domain are known in the art (See e.g. WO 2009/133208; WO 2009/102421; WO 2008/066752). Consequently, the ISA indicated that claims 1-65 relate to 25 inventions.

In reply to the non-unity objections raised by the ISA, two additional search fees have been submitted under protest for further prosecution of inventions relating to SEQ ID No.4 and SEQ ID No.132, respectively. In the telefax of 28.11.2011, the Applicant submitted that the number of additional search fees required is excessive in view of the effort required to search in addition to the first invention, the inventions regarding SEQ ID No.4 and SEQ ID No.132. The Applicant further objected that the claimed subject-matter relates to a single general inventive concept since SEQ ID No.4 is the 10Fn3 domain of SEQ ID No.132, and that the prior art document WO 2009/133208 does not disclose the 10Fn3 domain of SEQ ID No.4

The prior art document WO 2009/133208 indeed does not describe the 10Fn3 domain of SEQ ID No.4. WO 2009/133208, like the other cited prior art documents WO 2009/102421 and WO 2008/066752 describe 10Fn3 domains modified to bind to a target molecule not bound by the wild-type 10Fn3 domain. The claimed subject-matter is not limited to the modified 10Fn3 domain of SEQ ID No.4 but encompass further modified 10Fn3 domains. The common concept underlying the claims is the provision of a modified fibronectin type III tenth domain which binds to a target molecule not bound by the wild-type 10Fn3 domain. The 10Fn3 domains described in the above mentioned prior art document have been modified to bind to a target molecule not bound by the wild-type 10Fn3 domain, such as e.g. human serum albumin. Hence, in view of the prior art, the claims do not relate to a single inventive concept. Each fibronectin type III tenth (10Fn3) domain modified to bind to a target molecule not bound by the wild-type 10Fn3 domain corresponds to a different invention. The present set of claims lacks unity under Rule 13.1 PCT.

The additional search effort required for each different specific invention is related not only to the specific modifications performed on the 10Fn3 domain but further
combined with the functional properties resulting from said modifications. The modifications shall result in target binding properties not shared by the wild-type 10Fn3 domain. The resulting search effort for each specific invention is, thus, so large that it justifies the amount of required search fees. The Review Panel comes therefore to the conclusion that the claims lack unity under Rule 13.1 PCT, and that the number of additional search fees required was not excessive.

The Applicant has paid two additional search fees, for further prosecution of inventions relating to SEQ ID No.4 and SEQ ID No.132. SEQ ID No.4 is the 10Fn3 domain of SEQ ID No.132. Hence, SEQ ID No. 4 and 132 are part of the same invention. Two additional search fees have thus been paid for subject-matter relating to the same invention. One single additional search fee should have been paid for further prosecution of both SEQ ID No.4 and 132. The refund of one additional search fee is therefore ordered.
FAX TRANSMISSION

DATE: 28 November 2011 (28.11.2011)

CLIENT NO.: COTH-529-WO1

TO: Sandra Sonnenschmidt-Rogge
European Patent Office (ISA)
Anita Varma, Esq.

FROM: Guylaine Haché, Ph.D.
Julia J. Vierzen, Paralegal

PHONE: +1 (617) 951-7357

PAGES (Including Cover Sheet): 4  HARD COPY TO FOLLOW: X YES  NO

Title: SERUM ALBUMIN BINDING MOLECULES
International Filing Date: 3 May 2011 (3.05.2011)
Applicant: Bristol-Myers Squibb Company
Our Reference: COTH-529-WO1

Attached please find the Response to Invitation to Pay Additional Fees and, Where Applicable, Protest Fee and EPO Form 1037 (Acknowledgement of Receipt) for same, for the above-referenced application.

PLEASE ACKNOWLEDGE RECEIPT OF THIS FACSIMILE BY RETURN FACSIMILE TO +1 (617) 235-9492. THANK YOU.

If your receipt of this transmission is in error, please notify this firm immediately by collect call to sender at 001 (617) 951-7357 and send the original transmission to us by return mail at the address below.

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28585113_1
IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL SEARCHING AUTHORITY
UNDER THE PATENT COOPERATION TREATY

Applicant: BRISTOL-MYERS SQUIBB COMPANY
International Application No.: PCT/US2011/034998
International Filing Date: 3 May 2011 (3.05.2011)
Title: SERUM ALBUMIN BINDING MOLECULES

Via Facsimile (011 31-70-340-3016) & Courier
Authorized Officer: Sandra Sonnenschmidt-Rogge
European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
The Netherlands

RESPONSE TO INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

In Response to the Invitation to Pay Additional Fees dated 26 October 2011 (26.10.2011)
for the above-identified application, Applicant hereby requests the search of claims 1-65 (all
partially), in addition to Group 1 identified by the ISA, in so far as to encompass a fusion
polypeptide comprising an amino acid sequence identical or 70% identical to SEQ ID NO: 4.
Applicant also request the search of claims 1-65 (all partially) in so far as to encompass a fusion
polypeptide comprising an amino acid sequence identical to SEQ ID NO: 132.

Please charge two (2) additional search fees of €1,785.00 to Ropes & Gray LLP Deposit
Account No. 28300349.

In addition, pursuant to PCT Rule 40.2(c), Applicant hereby protests the payment of the
two (2) additional search fees and requests Deposit Account No. 28300349 be charged the
protest fee of €790.00.

This protest is based on the ground that the amount of the required additional search fees
is excessive in view of the effort required to search, in addition to Group 1, claims 1-65 (all
partially) in so far as to encompass a fusion polypeptide comprising an amino acid sequence
identical or 70% identical to SEQ ID NO: 4 and a fusion polypeptide comprising an amino acid
sequence identical to SEQ ID NO: 132. Applicant submits that SEQ ID NO: 4 is the HSA-
binding 10Fn3 domain component of the fusion polypeptide represented by SEQ ID NO: 132.
WO 2009/133208 does not disclose a 10Fn3 domain having the sequence of SEQ ID NO: 4.
Thus, the above-mentioned claims relate to a single general inventive concept under PCT Rule
13.1.
Agent's File Reference: COTH-529-WO1

It is believed that no other fee is due in connection with this paper. In the event any fee variance exists, please charge the fee to Deposit Account No. 28300349.

The authorized officer is invited to contact the undersigned by collect telephone call if further information is required.

Respectfully submitted,

[Signature]

Anita Varma
Agent for Applicant
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Dated: 28 November 2011 (28.11.2011)
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** Der Eingang der angegebenen Unterlagen wird bestätigt. Enthält diese Spalte keine Eintragungen, so wird lediglich bestätigt, daß eine Sendung zu dem angegebenen Anzeichen eingegangen ist.

² The receipt of the items indicated is confirmed. If this column does not contain any entries, it is only confirmed that an item has been received for the indicated file.

³ Le réception des pièces indiquées est confirmée. Faute de mention dans cette colonne, le présent accusé de réception se rapporte à une pièce quelconque envoyée sous la référence indiquée.