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COTTAM, David William  
 TEVA UK Ltd  
 Field House  
 Station Approach  
 Harlow, Essex CM20 2FB  
 GB

80298 Munich  
 Germany  
 Tel. +49(0)89 2399-0 | Fax -4465

P.O. Box 5816  
 2280 HV Rijswijk  
 Netherlands  
 Tel. +31(0)70 340-2040 | Fax -3016

10958 Berlin  
 Germany  
 Tel. +49(0)30 25901-0 | Fax -840

**Empfangsbescheinigung<sup>2</sup> für  
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 nachgereichte Unterlagen zu  
 Patentanmeldungen / Patenten**

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**Eingereichte Unterlagen**

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Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet	Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen <sup>1</sup> Nature and date of items (optional) <sup>2</sup> Nature et date des pièces (facultatif) <sup>3</sup>
1. PCT/EP2015/060257	HAR056-PCT	Letter & PCT/RO/101 request & Annex and page 1 of the specification dated 13/05/2015
2.		
3.		
4.		
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EPA/ERO/008 1037.1 12.07



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COTTAM, David William  
TEVA UK Ltd  
Field House  
Station Approach  
Harlow, Essex CM20 2FB  
GB

80298 Munich  
Germany  
Tel. +49 (0)99 2380-0 | Fax +4405

P.O. Box 5818  
2280 HV Rijswijk  
Netherlands  
Tel. +31 (0)70 340-2040 | Fax -3016

10958 Berlin  
Germany  
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**Eingereichte Unterlagen**

**Items filed**

**Pièces produites**

Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet	Ihr Zeichen Your reference Votre référence	gültige Art und Datum der Unterlagen <sup>1</sup> Nature and date of items (optional) <sup>3</sup> Nature et date des pièces (facultatif) <sup>3</sup>
1. PCT/EP2015/060257	HAR056-PCT	Letter & PCT/PC/101 request & Annex end page 1 of the specification dated 13/05/2015
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The European Patent Office  
 D-80298 Munich  
 Germany

By Fax and confirmation

13 May 2015

Dear Sirs,

**Re: International Patent Application No. PCT/EP2015/060257  
 TEVA PHARMACEUTICALS EUROPE B.V.  
 Our ref: HAR056-PCT**

A PCT request for the above PCT application was filed on the 8 May 2015. The wrong Teva internal reference number was used on the PCT/RO/101 request and the PCT/RO/101 (Annex) forms. Please correct the file reference to **HAR056-A1-PCT**. For ease of reference please see the enclosed PCT/RO/101 request and the PCT/RO/101 (Annex) forms.

Please correct the title on the PCT/IB/101 request to read as **TREATMENT OF RESPIRATORY DISORDERS**.

The 'S' was missing from the word **DISORDERS** when the PCT/RO/101 request form was filed on the 8 May 2015 for ease of reference the first page of the specification is enclosed.

In the event of under payment or non-payment, please debit the require amount from our debit account, No 28050605 (TEVA UK LTD).

Yours faithfully

**COTTAM, David William**  
 Professional Representative

cc WIPO

**Return address**

- Head Office** Ridings Point, Whistler Drive, Castleford, West Yorkshire WF10 5HX..... | Tel. +44 (0)1977 628 500 | Fax. +44 (0)1977 628 799
- Eastbourne** Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG..... | Tel. +44 (0)1323 501111 | Fax. +44 (0)1323 512812
- Harlow** Field House, Station Approach, Harlow, Essex, CM20 2FB..... | Tel. +44 (0)20 7540 7000 | Fax. +44 (0)870 532 3334

**Registered Office** Ridings Point, Whistler Drive, Castleford, West Yorkshire WF10 5HX  
 Registered in England No. 302461 | VAT Reg. No. G.B. 675 2172 28 | Medical Information Unit | Tel. +44 (0)20 7540 7000

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## PCT REQUEST

Print Out (Original In Electronic Form)

<b>0</b>	<b>For receiving Office use only</b>	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	
<b>0-4</b>	<b>Form PCT/RO/101 PCT Request</b>	
0-4-1	Prepared Using	PCT Online Filing Version 3.5.000.241e MT/FOP 20141031/0.20.5.20
0-5	<b>Petition</b> The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	European Patent Office (EPO) (RO/EP)
0-7	Applicant's or agent's file reference	HAR056-PCT
<b>I</b>	<b>Title of Invention</b>	<b>TREATMENT OF RESPIRATORY DISORDER</b>
<b>II</b>	<b>Applicant</b>	
II-1	This person is	Applicant only
II-2	Applicant for	All designated States
II-4	Name	TEVA PHARMACEUTICALS EUROPE B.V.
II-5	Address	Piet Heinkade 107 1019GM Amsterdam Netherlands
II-6	State of nationality	NL
II-7	State of residence	NL
<b>III-1</b>	<b>Applicant and/or inventor</b>	
III-1-1	This person is	Inventor only
III-1-3	Inventor for	All designated States
III-1-4	Name (LAST, First)	ULLMANN, Michiel
III-1-5	Address	Teva Pharmaceuticals Europe B.V. Piet Heinkade 107 1019GM Amsterdam Netherlands

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## PCT REQUEST

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IV-1	<b>Agent or common representative; or address for correspondence</b> The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	<b>Agent</b>
IV-1-1	Name (LAST, First)	COTTAM, David William
IV-1-2	Address	TEVA UK LTD Global IP Group Field House Station Approach Harlow Essex CM20 2FB United Kingdom
IV-1-3	Telephone No.	00 44 20 7540 7824
IV-1-4	Facsimile No.	00 44 20 7540 7029
IV-1-5	e-mail	david.cottam@tevaau.com
IV-1-5(a) )	E-mail authorization The receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority are authorized to use this e-mail address, if the Office or Authority so wishes, to send notifications issued in respect of this International application:	as advance copies followed by paper notifications
IV-1-6	Agent's registration No.	09229870
<b>V</b>	<b>DESIGNATIONS</b>	
V-1	The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.	
VI-1	<b>Priority claim of earlier national application</b>	
VI-1-1	Filing date	12 May 2014 (12.05.2014)
VI-1-2	Number	1408387.7
VI-1-3	Country	GB

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## PCT REQUEST

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VI-2	<b>Incorporation by reference :</b> where an element of the International application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this International application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(ii) were first received by the receiving Office, that element or parts, subject to confirmation under Rule 20.6, incorporated by reference in this International application for the purposes of Rule 20.6.		
VII-1	<b>International Searching Authority Chosen</b>	<b>European Patent Office (EPO) (ISA/EP)</b>	
VIII	<b>Declarations</b>	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	<b>Check list</b>	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	4	✓
IX-2	Description	6	✓
IX-3	Claims	1	✓
IX-4	Abstract	1	✓
IX-5	Drawings	0	-
IX-7	TOTAL	12	
	<b>Accompanying items</b>	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	-	✓
IX-19	Other	Pre-conversion archive	✓
IX-20	Figure of the drawings which should accompany the abstract		
IX-21	Language of filing of the International application	English	

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## PCT REQUEST

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X-1	Signature of applicant, agent or common representative	/COTTAM, David William/
X-1-1	Name (LAST, First)	COTTAM, David William
X-1-2	Name of signatory	COTTAM, David William
X-1-3	Capacity (if such capacity is not obvious from reading the request)	(Representative)

## FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	
10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	

## FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	
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### Treatment of respiratory disorders

The present invention relates to the treatment of respiratory disorders, and particularly to a fixed-dose composition comprising formoterol and budesonide for use in the treatment of chronic obstructive pulmonary disease (COPD).

- 5 COPD is a leading cause of death worldwide. Global trends indicate that case frequency will continue to rise and by 2030 COPD will become the fourth leading cause of death worldwide. COPD is considered a preventable and treatable disease and is characterised by persistent airflow limitation that is not fully reversible. The limitation is usually progressive, and primarily associated with an abnormal inflammatory response in the lungs to noxious particles or gases.
- 10 COPD is a heterogeneous long-term disease comprising chronic bronchitis, emphysema and also involving the small airways. The pathological changes occurring in patients with COPD are predominantly localised to the airways, lung parenchyma and pulmonary vasculature. Phenotypically, these changes reduce the healthy ability of the lungs to absorb and expel gases.
- 15 Bronchitis is characterised by long-term inflammation of the bronchi. Common symptoms may include wheezing, shortness of breath, cough and expectoration of sputum, all of which are highly uncomfortable and detrimental to the patient's quality of life. Emphysema is also related to long-term bronchial inflammation, wherein the inflammatory response results in a breakdown of lung tissue and progressive narrowing of the airways. In time, the lung tissue loses its natural elasticity and becomes enlarged. As such, the efficacy with which gases are exchanged is reduced and respired air is often
- 20 trapped within the lung. This results in localised hypoxia, and reduces the volume of oxygen being delivered into the patient's bloodstream, per inhalation. Patients therefore experience shortness of breath and instances of breathing difficulty.
- 25 Patients living with COPD experience a variety, if not all, of these symptoms on a daily basis. Their severity will be determined by a range of factors but most commonly will be correlated to the progression of the disease. These symptoms, independent of their severity, are indicative of stable COPD and this disease state is maintained and managed through the administration of a variety of drugs. The treatments are variable, but often include inhaled bronchodilators, anticholinergic agents, long-acting and short-acting  $\beta_2$ -agonists and corticosteroids. The medicaments are often administered as a single therapy or as combination treatments of corticosteroids and long-acting  $\beta_2$ -agonists.
- 30 Stable COPD may be indefinitely maintained, however the disease also manifests itself in an acute form, known in the art as an exacerbation. An exacerbation of COPD is an acute event characterised by a worsening of the patient's respiratory symptoms that is beyond the baseline day-to-day variations and can often lead to a change in medication. Exacerbations may be subcategorised as being mild,



HAR056-PCT

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**PCT (ANNEX - FEE CALCULATION SHEET)**

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0	For receiving Office use only		
0-1	International Application No.		
0-2	Date stamp of the receiving Office		
0-4	Form PCT/RO/101 (Annex) PCT Fee Calculation Sheet		
0-4-1	Prepared Using	PCT Online Filing Version 3.5.000.241a MT/FOP 20141031/0.20.5.20	
0-8	Applicant's or agent's file reference		HAR056-PCT
2	Applicant		TEVA PHARMACEUTICALS EUROPE B.V.
12	Calculation of prescribed fees		
12-1	Transmittal fee	T	⇒
12-2-1	Search fee	S	⇒
12-2-2	International search to be carried out by	EP	
12-3	International filing fee (first 30 sheets)	I1	1273
12-4	Remaining sheets	0	
12-5	Additional amount	(X) 0	
12-6	Total additional amount	I2	0
12-7	I1 + I2 =	I	1273
12-12	Electronic Filing reduction (Image)	R	-191
12-13	Total international filing fee (i-R)	I	⇒
12-14	Fee for priority document		
	Number of priority documents requested	0	
12-15	Fee per document	(X) 50	
12-16	Total priority document fee:	P	⇒
12-17	Fee for restoration of priority rights	RP	
	Number of requests for restoration of priority rights	0	
	Total amount of fees for restoration of priority rights		
12-18	<b>TOTAL FEES PAYABLE</b> (T+S+I+P+RP)		⇒
			3087

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**PCT (ANNEX - FEE CALCULATION SHEET)**

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12-21	Mode of payment	Authorization to charge current account
12-22	Current account instructions	
	The receiving Office	European Patent Office (EPO) (RO/EP)
12-22-1	Authorization to charge the total fees indicated above	✓
12-22-2	Authorization to charge any deficiency or credit any overpayment in the total fees indicated above	✓
12-22-3	Authorization to charge the fee for priority document	✓
12-23	Current account No.	28050605
12-24	Date	08 May 2015 (08.05.2015)
12-25	Name and signature	TEVA UK LTD,  /COTTAM, David W/illiam/