



(51) International Patent Classification:

A61K 47/48 (2006.01)

(21) International Application Number:

PCT/US2017/035461

(22) International Filing Date:

01 June 2017 (01.06.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/344,256	01 June 2016 (01.06.2016)	US
62/344,249	01 June 2016 (01.06.2016)	US
62/344,252	01 June 2016 (01.06.2016)	US

(71) Applicants: **BAXALTA INCORPORATED** [US/US];
1200 Lakeside Drive, Bannockburn, IL 60015 (US). **BAX-
ALTA GMBH** [CH/CH]; Zaehlerweg 4, 6300 Zug (CH).(72) Inventors: **FORNASINI, Gianfranco**; c/o Troutman San-
ders LLP, 875 Third Avenue, New York, NY 10022 (US). **SOUKHAREVA, Nadejda**; c/o Troutman Sanders LLP,
875 Third Avenue, New York, NY 10022 (US). **PHIL-
LIPS, Christopher**; c/o Troutman Sanders LLP, 875 Third
Avenue, New York, NY 10022 (US).(74) Agent: **SULLIVAN, Nicole, R.**; Troutman Sanders LLP,
875 Third Avenue, New York, NY 10022 (US).(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR,
KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG,
MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).(54) Title: FORMULATIONS OF POLYALKYLENE OXIDE-ASPARAGINASE AND METHODS OF MAKING AND USING
THE SAME

(57) Abstract: Aspects of the invention include polyalkylene oxide-asparaginase compositions. In some instances, the composition is a lyophilized storage stable composition. In some instances, the lyophilized compositions include one or more of a buffer, a salt, and a sugar. Aspects of the invention further include methods of making the compositions. The compositions find use in a variety of applications, e.g., in the treatment of a neoplastic condition in a subject.

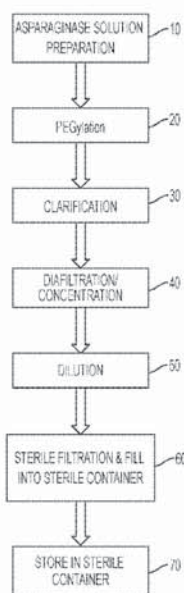


FIG. 1

Published:

- *without international search report and to be republished
upon receipt of that report (Rule 48.2(g))*

PCT

(PCT Rule 92*bis*.1 and
Administrative Instructions, Section 422)

SULLIVAN, Nicole, R.
Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (<i>day/month/year</i>) 28 November 2018 (28.11.2018)	
Applicant's or agent's file reference 250478.001426	IMPORTANT NOTIFICATION
International application No. PCT/US2017/035461	International filing date (<i>day/month/year</i>) 01 June 2017 (01.06.2017)

1. The following indications appeared on record concerning:		
☒ the applicant	☐ the inventor	☐ the agent
Name and Address BAXALTA GMBH Zaehlerweg 4 6300 Zug Switzerland		State of Nationality CH
		State of Residence CH
		Telephone No.
		Facsimile No.
		E-mail address

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☒ the person	☐ the name	☐ the address
☐ the nationality	☐ the residence	
Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address ☐ Notifications by e-mail authorized	

3. Further observations, if necessary: The person identified in Box 1 has been deleted from the records.

4. A copy of this notification has been sent to:		☐	the International Preliminary Examining Authority
☒	the receiving Office	☒	the designated Offices concerned
☐	the International Searching Authority	☐	the elected Offices concerned
☐	the Authority(ies) specified for supplementary search	☐	other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 70 10	Authorized officer Maru Yoshihiko e-mail pct.team8@wipo.int Telephone No. +41 22 338 74 08
--	--

PCT

(PCT Rule 92*bis*.1 and
Administrative Instructions, Section 422)

SULLIVAN, Nicole, R.
Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (<i>day/month/year</i>) 28 November 2018 (28.11.2018)	
Applicant's or agent's file reference 250478.001426	IMPORTANT NOTIFICATION
International application No. PCT/US2017/035461	International filing date (<i>day/month/year</i>) 01 June 2017 (01.06.2017)

1. The following indications appeared on record concerning:		
☒ the applicant	☐ the inventor	☐ the agent ☐ the common representative
Name and Address BAXALTA INCORPORATED 1200 Lakeside Drive Bannockburn, IL 60015 United States of America	State of Nationality	State of Residence
	US	US
	Telephone No.	
	Facsimile No.	
E-mail address		

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☒ the person	☐ the name	☐ the address
☐ the nationality	☐ the residence	
Name and Address SERVIER IP UK LIMITED Sefton House Sefton Park, Bells Hill Stoke Poges Slough, SL2 4JS United Kingdom	State of Nationality	State of Residence
	GB	GB
	Telephone No.	
	Facsimile No.	
E-mail address ☐ Notifications by e-mail authorized		

3. Further observations, if necessary:
--

4. A copy of this notification has been sent to:		☐	the International Preliminary Examining Authority
☒	the receiving Office	☒	the designated Offices concerned
☐	the International Searching Authority	☐	the elected Offices concerned
☐	the Authority(ies) specified for supplementary search	☐	other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 70 10	Authorized officer Maru Yoshihiko e-mail pct.team8@wipo.int Telephone No. +41 22 338 74 08
--	--

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

SULLIVAN, Nicole, R.
Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (day/month/year) 27 November 2018 (27.11.2018)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 250478.001426	
International application No. PCT/US2017/035461	International filing date (day/month/year) 01 June 2017 (01.06.2017)

1. The following indications appeared on record concerning:		
☐ the applicant	☒ the inventor	☐ the agent
☐ the common representative		
Name and Address FORNASINI, Gianfranco c/o Troutman Sanders LLP 875 Third Avenue New York, NY 10022 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☐ the person	☐ the name	☒ the address
☐ the nationality		
☐ the residence		
Name and Address FORNASINI, Gianfranco 8501 Old Seven Locks Road Bethesda, MD 20817 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address ☐ Notifications by e-mail authorized	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
☒ the receiving Office	☐ the International Preliminary Examining Authority	
☐ the International Searching Authority	☒ the designated Offices concerned	
☐ the Authority(ies) specified for supplementary search	☐ the elected Offices concerned	
	☐ other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Maru Yoshihiko e-mail pct.team8@wipo.int Telephone No. +41 22 338 74 08
Facsimile No. +41 22 338 70 10	

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

SULLIVAN, Nicole, R.
Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (day/month/year) 27 November 2018 (27.11.2018)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 250478.001426	
International application No. PCT/US2017/035461	International filing date (day/month/year) 01 June 2017 (01.06.2017)

1. The following indications appeared on record concerning:		
☐ the applicant	☒ the inventor	☐ the agent
☐ the common representative		
Name and Address PHILLIPS, Christopher c/o Troutman Sanders LLP 875 Third Avenue New York, NY 10022 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☐ the person	☐ the name	☒ the address
☐ the nationality		
☐ the residence		
Name and Address PHILLIPS, Christopher 5823 Ridgeview Drive Doylestown, PA 18902 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address ☐ Notifications by e-mail authorized	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
☒ the receiving Office	☐ the International Preliminary Examining Authority	
☐ the International Searching Authority	☒ the designated Offices concerned	
☐ the Authority(ies) specified for supplementary search	☐ the elected Offices concerned	
	☐ other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Maru Yoshihiko e-mail pct.team8@wipo.int Telephone No. +41 22 338 74 08
Facsimile No. +41 22 338 70 10	

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

SULLIVAN, Nicole, R.
Troutman Sanders LLP
875 Third Avenue
New York, NY 10022
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (day/month/year) 27 November 2018 (27.11.2018)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 250478.001426	
International application No. PCT/US2017/035461	International filing date (day/month/year) 01 June 2017 (01.06.2017)

1. The following indications appeared on record concerning:		
☐ the applicant	☒ the inventor	☐ the agent
☐ the common representative		
Name and Address SOUKHAREVA, Nadejda c/o Troutman Sanders LLP 875 Third Avenue New York, NY 10022 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☐ the person	☐ the name	☒ the address
☐ the nationality		
☐ the residence		
Name and Address SOUKHAREVA, Nadejda 7421 Mahaska Drive Derwood, MD 20855 United States of America	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	E-mail address ☐ Notifications by e-mail authorized	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
☒ the receiving Office	☐ the International Preliminary Examining Authority	
☐ the International Searching Authority	☒ the designated Offices concerned	
☐ the Authority(ies) specified for supplementary search	☐ the elected Offices concerned	
	☐ other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Maru Yoshihiko e-mail pct.team8@wipo.int Telephone No. +41 22 338 74 08
Facsimile No. +41 22 338 70 10	