Application Data Sheet 37 CFR 1.76		Attorney Docket Number	33320.03087.US2E/3087K
	eet 37 CFK 1.76	Application Number	
Title of Invention	PH20 POLYPEPTIDE VA	RIANTS, FORMULATIONS AN	D USES THEREOF

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.

### **Inventor Information:**

Invent	or	1									
Legal	Nar	ne									
Prefix								Family Nam	ne		Suffix
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Resid	enc	e Inform	atio	on (Select One) 🛚 🖂	US Reside	US Residency 🔲 Non US Residency 🔲 Active US Milita				Active US Military	y Service
City	Sa	ın Diego		State/Province	CA		Countr	y of Residen	се	US	
Mailing Address of Inventor:											
Address 1 11530 Miro Circle											
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Invent Legal											
Prefix		Given N	ame	e	Middle Na	me		Family Nam	ne.		Suffix
	$\rightarrow$	Н.			Michael			Shepard			
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City		ringfield		1 1	OR		<del>-</del>	y of Residen		US	,
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Mailin	g A	ddress	of In	ventor:							
Addre	SS '	1		870 Mountaingate	Drive						
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City		Spri	ngfie	eld			State/Prov	ince	OR		
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Invent	or :	3									
Legal	Nar	ne									
Prefix     Given Name     Middle Name     Family Name     Suffix											
Qiping Zhao											
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Title of	f Invention		PH20 POLYPE	PTIDE	VARI	IANTS	, FORMI	JLATION	S AND	USE	S THEREOF		
Addres	ss 2												
City	San	Diego				St	ate/Prov	ince	(	CA			
Postal	Code	92	131			Coun	try	US					
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Invente	or 4												
Legal	Name			1				T					
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				James				Connor					
Residence Information (Select One) 🛛 US					eside	ncy [	☐ Non L	JS Reside	ency	$\Box$ _A	ctive US Milita	ry Se	rvice
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	City San Diego State/Province CA												
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All Inventors	s wust be Listea – A	ad Addition	al Inventor Information blo	CKS TOT EACH	inventor.								
Corre	sponden	ce Info	ormation:										
	either Custo ation see 3		umber or comp 1.33(a).	lete the	e Cor	respo	ndence	Informati	ion se	ction	below. For f	urthe	er:
Custor	ner Numbe	r	13565										
Email A	Address		stephanie.seid	man@d	denton	ns.com	1						
Email A	Address		mlaipsd@dente	ons.con	n								
Appli	cation Inf	ormat	ion:										
Title of	f the Inventi	ion	PH20 POLY	PEPTIC	DE VA	RIAN	TS, FOR	MULATIO	ONS A	ND U	SES THEREC	F	
Attorne	ey Docket N	lumbei	r 33320.0308	7.US2E	:/3087	'K	S	mall Ent	ity Sta	atus (	Claimed 🔲		
Applic	ation Type			risional		] Pro	visional						
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Please	Please Select One: ☐ Customer Number ☐ US Patent Practitioner ☐ Limited Recognition (37 CFR 11.9)												
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Stephanie   Registration Number: 33,77				70			Seidma	an					
			n Name	33,7		alla Ni		Fam: !!	. NI		Cee:		
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Darie	Frank J. Miskiel Registration Number: 53,332												
Regis	u auon <b>N</b> Ul	mber:		33,3	ა∠								

Filing Date (YYYY-MM-DD)

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	33320.03087.US2E/3087K
Application Data Shi	eet 37 CFR 1.76	Application Number	
Title of Invention	PH20 POLYPEPTIDE VA	ARIANTS, FORMULATIONS AN	D USES THEREOF

# **Domestic Benefit/National Stage Information:**

**Continuity Type** 

**Present Application No.** 

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

**Prior Application Number** 

This application		is a Divisiona	al of		17/327,5	68		2021-05-21		
Prior Application	No. 17/32	27,568 - Statu	s:		☐ Pate	nted 🛛 Pending		Abandoned	☐ Expired	
Application No.	Conti	nuity Type	Prior App	licat	tion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
17/327,568	is a Cor	itinuation of	16/912,59	0		2020-06-25		11,066,656	2021-07-20	
Prior Application	No. 16/91	2,590 - Statu	s:		☑ Pate	ented 🗌 Pending	, [	☐ Abandoned ☐ Expired		
16/912,590	is a Cor	itinuation of	15/226,489		2016-08-02		1	0,865,400	2020-12-15	
Prior Application	No. 15/22	26,489 - Statu	s:		☑ Pate	nted 🔲 Pending		Abandoned	Expired	
Application No.	Contir	nuity Type	Prior Appli	cati	on No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Divi	sional of	13/694,731			2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/69	94,731 - Statu	s:		☑ Pate	nted 🗌 Pending		Abandoned	Expired	
Application Numb	er	Continuity	Туре	Pri	or Appli	cation No.	Fil	ing Date (YY	YY-MM-DD)	
13/694,731		claims prior	ity to	61/	796,208		20	12-11-01		
Prior Application	No. 61/7	96,208- Statu	s:		Patente	d 🗌 Pending 🔲	Ab	andoned 🛚	Expired	
Application Numb	oplication Number Continuity Type			Pri	or Appli	ation No.	Fil	Filing Date (YYYY-MM-DD)		
13/694,731 claims priority to			ity to	61/631,313				11-12-30		
Prior Application No. 61/631,313 - Status:				Patente	d Pending	Ab	andoned 🛛	Expired		
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Application No.	Cont	inuity Type	Prior A	ppli No.	cation	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
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Application No.	also is a	Continuation	of <b>16/824,5</b>	No.	I	Filing Date (YYYY-MM-DD)		Patent Number 11,041,149	(YYYY-MM-DD) 2021-06-22	
Application No. 17/327,568	also is a	Continuation	of 16/824,5 s:	No. 72	☑ Pate	Filing Date (YYYY-MM-DD) 2020-03-19	 	Patent Number 11,041,149	(YYYY-MM-DD) 2021-06-22	
Application No.  17/327,568  Prior Application	also is a No. 16/82 Cont	Continuation o	of 16/824,5 s:	No. 72 ppli No.	☑ Pate	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date		Patent Number 11,041,149 Abandoned	(YYYY-MM-DD) 2021-06-22 Expired Issue Date	
Application No.  17/327,568  Prior Application  Application No.	also is a No. 16/82 Cont	Continuation of	of 16/824,5 s: Prior A 15/226,4	No. 72 ppli No.	☑ Pate	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date (YYYY-MM-DD) 2016-08-02		Patent Number 11,041,149 Abandoned Patent Number	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15	
Application No.  17/327,568  Prior Application Application No.  16/824,572	also is a No. 16/82 Cont is a Cor No. 15/22	Continuation of	16/824,5 s: Prior A 15/226,4 s:	No.	☑ Patection	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date (YYYY-MM-DD) 2016-08-02		Patent Number 11,041,149 Abandoned Patent Number 10,865,400	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15	
Application No.  17/327,568  Prior Application  Application No.  16/824,572  Prior Application	also is a No. 16/82 Cont is a Cor No. 15/22 Cont	Continuation of 24,489 - Statu	16/824,5 s: Prior A 15/226,4 s:	No. 72 Appli No. 89 Appli No.	☑ Patection	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date (YYYY-MM-DD) 2016-08-02 Pending Filing Date		Patent Number 11,041,149 Abandoned Patent Number 10,865,400 Abandone	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15  Expired  Issue Date	
Application No.  17/327,568  Prior Application Application No.  16/824,572  Prior Application Application No.	also is a No. 16/82 Cont is a Cor No. 15/22 Cont	Continuation of 26,489 - Statutinuity Type	16/824,5 s: Prior A 15/226,4 s: Prior A 13/694,7	No. 72 Appli No. 89 Appli No.	☑ Patented	Filing Date (YYYY-MM-DD)  2020-03-19  ented Pending  Filing Date (YYYY-MM-DD)  2016-08-02  Pending  Filing Date (YYYY-MM-DD)	3 🗆	Patent Number  11,041,149  Abandoned  Patent Number  10,865,400  Abandone  Patent Number  9,447,401	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15  ed Expired  Issue Date (YYYY-MM-DD)  2016-09-20	
Application No.  17/327,568  Prior Application Application No.  16/824,572  Prior Application Application No.  15/226,489	also is a No. 16/82 Cont is a Cor No. 15/22 Cont is a Divi No. 13/69	Continuation of 26,489 - Statutinuity Type	16/824,5 s: Prior A 15/226,4 s: Prior A 13/694,7	in No.  in Political No.  in Political No.  in Political No.  in Political No.  in No.	☐ Patented Cation	Filing Date (YYYY-MM-DD)  2020-03-19  ented Pending  Filing Date (YYYY-MM-DD)  2016-08-02  Pending  Filing Date (YYYY-MM-DD)  2012-12-28		Patent Number  11,041,149  Abandoned  Patent Number  10,865,400  Abandoned  Patent Number  9,447,401  Abandoned	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15  ed Expired  Issue Date (YYYY-MM-DD)  2016-09-20	
Application No.  17/327,568  Prior Application Application No.  16/824,572  Prior Application Application No.  15/226,489  Prior Application	also is a No. 16/82 Conf is a Cor No. 15/22 Conf is a Divi No. 13/69	Continuation of 24,572 - Statustinuation of 26,489 - Statustinuity Type sional of 24,731 - Status	16/824,5 s: Prior A 15/226,4 s: Prior A 13/694,7 s:	in No.  in Political No.	☐ Patented Cation	Filing Date (YYYY-MM-DD)  2020-03-19  ented Pending  Filing Date (YYYY-MM-DD)  2016-08-02  Pending  Filing Date (YYYY-MM-DD)  2012-12-28  ented Pending		Patent Number  11,041,149  Abandoned  Patent Number  10,865,400  Abandoned  Patent Number  9,447,401  Abandoned	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15 ed Expired  Issue Date (YYYY-MM-DD)  2016-09-20  Expired	
Application No.  17/327,568  Prior Application Application No.  16/824,572  Prior Application Application No.  15/226,489  Prior Application Application Numb	is a Conton Cont	Continuation of 24,572 - Statustinuation of 26,489 - Statustinuity Type sional of 24,731 - Status Continuity Type claims priority	16/824,5 s: Prior A 15/226,4 s: Prior A 13/694,7 s: /pe to	in No.  in Political No.	☐ Patented Cation ☐ ☐ ☐ Patented Cation ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date (YYYY-MM-DD) 2016-08-02 Pending Filing Date (YYYY-MM-DD) 2012-12-28 ented Pending eation Number		Patent Number 11,041,149 Abandoned Patent Number 10,865,400 Abandoned Patent Number 9,447,401 Abandoned Filing Date (Yang)	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15 ed Expired  Issue Date (YYYY-MM-DD)  2016-09-20  Expired	
Application No.  17/327,568  Prior Application Application No.  16/824,572  Prior Application Application No.  15/226,489  Prior Application Application Numbers	also is a No. 16/82 Cont is a Cor No. 15/22 Cont is a Divi No. 13/69 Per	Continuation of 24,572 - Statustinuation of 26,489 - Statustinuity Type sional of 24,731 - Status Continuity Type claims priority	16/824,5 s: Prior A 15/226,4 s: Prior A 13/694,7 s: /pe to s:	Appliance Applia	Patented cation  Patented cation  Patented 796,208  Patented	Filing Date (YYYY-MM-DD) 2020-03-19 ented Pending Filing Date (YYYY-MM-DD) 2016-08-02 Pending Filing Date (YYYY-MM-DD) 2012-12-28 ented Pending eation Number	] [	Patent Number  11,041,149  Abandoned  Patent Number  10,865,400  Abandoned  Patent Number  9,447,401  Abandoned  Filing Date (Y)  2012-11-01  Abandone	(YYYY-MM-DD)  2021-06-22  Expired  Issue Date (YYYY-MM-DD)  2020-12-15  ed Expired  Issue Date (YYYY-MM-DD)  2016-09-20  Expired  (YYYY-MM-DD)	

Application Data Sheet 37 CFR 1.76					torney D	ocket Number	33320.03087	.US2E/3087K	
Application Da	ila Sii	eet 37 CFK 1.7	•	Αp	plication	n Number			
Title of Invention		PH20 POLYPER	PTIDE V	ARIA	NTS, FC	RMULATIONS AN	ID USES THEF	REOF	
	I								
13/694,731		claims priority to			631,313		2011-12-30		
Prior Application I	No. 61/6	31,313 - Status:		Ш	Patented	☐ Pending	Abandone	d 🛛 Expired	
Application No.				Application Filing Date No. (YYYY-MM-DD)			Patent Number	Issue Date (YYYY-MM-DD)	
17/327,568 also is a Continuation of 15/226			15/226,	489		2016-08-02	10,865,400	2020-12-15	
Prior Application No. 15/226,489 - Status:				☑ Pate	ented  Pending	Abandoned	Expired		
Application No. Continuity Type Prior			Prior A	Appli No.	ication	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489 is a Divisional of 13/694			13/694,	731		2012-12-28	9,447,401	2016-09-20	
Prior Application No. 13/694,731 - Status:					☑ Pate	ented  Pending	☐ Abandoned ☐ Expired		
Application Numb	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	(YYY-MM-DD)	
13/694,731		claims priority to		61/	796,208		2012-11-01		
Prior Application I	No. 61/7	96,208 - Status:			Patented	□ Pending	Abandone	ed 🛭 Expired	
Application Numb	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	(YYY-MM-DD)	
13/694,731		claims priority to		61/	631,313		2011-12-30		
Prior Application I	No. 61/6	31,313 - Status:			Patented	I ☐ Pending	☐ Abandoned ☒ Expired		
Application No.	Co	ntinuity Type	Prior A	Appli No.	ication	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)	
17/327,568	also is	a Continuation of	13/694,	731		2012-12-28	9,447,401	2016-09-20	
Prior Application I	No. 13/6	94,731 - Status:			☑ Pate	ented  Pending	☐ Abandoned	☐ Expired	
Application Numb	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	(YYY-MM-DD)	
13/694,731		claims priority to		61/	796,208		2012-11-01		
Prior Application I	No. 61/7	96,208 - Status:			Patented	☐ Pending	Abandone	ed 🛚 Expired	
Application Number Continuity Type				Pri	or Applic	ation Number	Filing Date (YYYY-MM-DD)		
13/694,731		claims priority to		<b>61/631,313</b> 2011-12-30					
Prior Application I	No. 61/6	31,313 - Status:			Patented	□ Pending	☐ Abandone	ed 🛛 Expired	

Application Data Sheet 37 CFR 1.76					Attorney	Docket Number	33320.03087.US2E/3087K			
Application Da	ata Sne	et 37 CFR	1.70	4	Application	on Number				
Title of Invention		PH20 POLY	PEPTIDE V	٩R	IANTS, F	ORMULATIONS A	ND	USES THEF	REOF	
Present Application	on No.	Continuity 7	<b>Туре</b>		Prior Ap	pplication Number		Filing Date	(YYYY-MM-DD)	
This application		also is a Divi	sional of		17/327,5	86	2021-05-21			
Prior Application I	No. 17/32	27,586 - Statu	ıs:		☐ Pate	nted 🛛 Pending	☐ Abandoned ☐ Expired			
Application No.	Contir	nuity Type	Prior Appli	cat	ation No. Filing Date (YYYY-MM-DD)			Patent Number	Issue Date (YYYY-MM-DD)	
17/327,586	is a Cor	ntinuation of	16/912,590			2020-06-25	1	1,066,656	2021-07-20	
Prior Application I	No. 16/91	2,590 - Statu	ıs:		☑ Pate	nted  Pending		Abandoned	☐ Expired	
Application No.	Contir	nuity Type	Prior Appli	cat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
16/912,590	is a Con	tinuation of	15/226,489			2016-08-02	10	),865,400	2020-12-15	
Prior Application I	No. 15/22	26,489 - Statu	s:		☑ Pate	nted  Pending		Abandoned [	Expired	
Application No.	Contin	nuity Type	Prior Appli	cat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Divi	sional of	13/694,731			2012-12-28	9	,447,401	2016-09-20	
Prior Application I	No. 13/69	94,731 - Statu	ıs:		☑ Pate	ented 🗌 Pending		Abandoned	☐ Expired	
<b>Application Numb</b>	er	Continuity	Туре	Pı	rior Appli	cation No.	Filing Date (YYYY-MM-DD)			
13/694,731		claims prior	ity to	61	1/796,208		201	2-11-01		
Prior Application I	No. 61/7	96,208- Statu	ıs:		] Patente	d 🗌 Pending 🔲	Aba	ndoned 🛚	Expired	
Application Numb	er	Continuity	Туре	Pı	rior Appli	cation No.	Fili	ng Date (YY)	(Y-MM-DD)	
13/694,731		claims prior	ity to	61	1/631,313		201	1-12-30		
Prior Application I	No. 61/63	31,313 - Statu	ıs:		] Patente	d 🗌 Pending 🔲	Aba	ndoned 🛚	Expired	
Application No.	Con	tinuity Type	<b>I</b>	pp No	lication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
17/327,586	also is	a Continuation	of <b>16/824</b> ,	572	2	2020-03-19	1	1,041,149	2021-06-22	
Prior Application I	No. 16/82	24,572 status	:		□ Pate	ented  Pending		Abandoned	Expired	
Application No.	Con	itinuity Type		pp No	lication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
16/824,572	is a Co	ntinuation of	15/226,	489	<del></del>	2016-08-02	10	0,865,400	2020-12-15	
Prior Application I	No. 15/22	26,489 - Statu	ıs:		☑ Pate	ented  Pending		Abandoned	☐ Expired	
Application No.	Con	tinuity Type		pp No	lication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	risional of	13/694,	731	1	2012-12-28	9	,447,401	2016-09-20	
Prior Application I	No. 13/69	94,731 - Statu	ıs:		☑ Pate	ented  Pending		Abandoned	☐ Expired	
Application Numb	er	Continuity	Туре	Р	rior Appl	ication No.	Fili	ng Date (YY	YY-MM-DD)	
13/694,731		claims prio	rity to	6	1/796,208	1	201	2-11-01		
Prior Application I	No. 61/7	96,208- Statu	ıs:		] Patente	ed Pending	Aba	andoned 🛛	Expired	
Application Number Continuity Type				Р	rior Appl	ication No.	Fili	ng Date (YY	YY-MM-DD)	
13/694,731 claims priority to				61/631,313				2011-12-30		
Prior Application I	No. 61/63	31,313 - Statu	ıs:	☐ Patented ☐ Pending ☐ Abandoned ☒ Expired				Expired		

Application Data Sheet 37 CFR 1.76					ttorney	Docket Number		33320.03087.US2E/3087K		
Application Da	ala Sile	el 31 CFK	1.70	Α	pplication	on Number				
Title of Invention		PH20 POLY	PEPTIDE V	ARI	ANTS, F	ORMULATIONS A	NP	D USES THEF	REOF	
Application No.	Con	tinuity Type	Prior A	\ppl	ication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
17/327,586	is a Cor	ntinuation of	15/226,	489	ı	2016-08-02		10,865,400	2020-12-15	
Prior Application	No. 15/22	6,489 - Statu	s:		□ Patented □ Pending			☐ Abandoned ☐ Expired		
Application No.	Application No. Continuity Type Prior A			Nppl No.	ication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	isional of	13/694,	731		2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/69	4,731 - Statu	s:		☑ Pat	ented 🗌 Pending		Abandoned	Expired	
Application Numb	er	Continuity	Туре	Pr	rior Appl	ication No.	Fi	iling Date (YY	YY-MM-DD)	
13/694,731		claims prio	rity to	61	/796,208		20	012-11-01		
Prior Application	No. 61/79	96,208- Statu	s:		Patente	ed 🗌 Pending 🗌	A	bandoned 🛚	Expired	
Application Numb	er	Continuity	Туре	Pr	rior Appl	ication No.	Fi	iling Date (YY	YY-MM-DD)	
13/694,731		claims prio	rity to	61	/631,313	1	20	011-12-30		
Prior Application	No. 61/63	1,313 - Statu	s:		] Patente	ed 🗌 Pending 🗌	] A	bandoned 🛚	Expired	
Application No. Continuity Type Prior Applic				lica	ication No. Filing Date (YYYY-MM-DD)			Patent Number	Issue Date (YYYY-MM-DD)	
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Prior Application	No. 61/63	1,313 - Statu	s:		Patente	d 🗌 Pending		Abandone	ed 🛛 Expired	
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Present Application No.	Contin	uity Type	Prior Appli	icati	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
This application	is a Di	visional of	16/912,590			2020-06-25	$\perp$	11,066,656	2021-07-20	
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Prior Application	No. 15/22	6,489 - Statu	s:		□ Pate	ented  Pending		Abandoned	☐ Expired	
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15/226,489	is a Divi	sional of	13/694,731			2012-12-28		9,447,401	2016-09-20	
Prior Application No. 13/694,731 - Status:		s:		□ Pate	ented 🗌 Pending	ַ⊑	Abandoned	☐ Expired		
Application No.	Conti	nuity Type	Prior Ap Nun			Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	

		4 = 4	At	torney D	Docket Number		33320.03087.US2E/3087K			
Application Da	ata She	eet 37 CFR	1.76	Aı	plicatio	n Number				
Title of Invention	l	PH20 POLYF	PEPTIDE V	ARIA	NTS, FO	DRMULATIONS A	١N	D USES THE	REOF	
16/912,590	also is a	a Divisional of	13/694,73	1		2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Status	, , , , , , , , , , , , , , , , , , ,	-	□ Pate		ı ı [	☐ Abandoned ☐ Expired		
Application Numb		Continuity 1		Pri		cation No.		Filing Date (YYYY-MM-DD)		
13/694,731		claims priorit		61/796.208				 012-11-01	,	
Prior Application	No. 61/7		<u>.                                      </u>		Patented	d ☐ Pending ☐	Α	bandoned 🛛	Expired	
Application Number Continuity Type				Pri	or Applic	cation No.	F	iling Date (YY	YY-MM-DD)	
13/694,731 claims priority to				61/	631,313		2	011-12-30		
Prior Application	No. 61/6	31,313 - Status	):		Patented	d Pending 🗌	Α	bandoned 🛚	Expired	
Present Continuity Type Prior Application No. Filing Date Patent Issue Date										
Application No.						(YYYY-MM-DD)	١	Number	(YYYY-MM-DD)	
This application is a Divisional of 16/824,57				2	•	2020-03-19		11,041,149	2021-06-22	
Prior Application No. 16/824,572 - Status:					☑ Pate	ented  Pending	, [	Abandoned	Expired	
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16/824,572	is a Co	ntinuation of	15/226,48	9 2016-08-02			10,865,400	2020-12-15		
Prior Application	No. 15/2	26,489 - Status	:	☐ Pending			☐ Abandone	ed 🗌 Expired		
Application No.	Cont	inuity Type	Prior App	olicat	tion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	risional of	13/694,73	<b>1</b> 2012-12-28				9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Status	:	☐ Patented ☐ Pending			, [	Abandoned	Expired	
Application No.	Cont	inuity Type	Prior App	olicat	lication No. Filing Date (YYYY-MM-DD			Patent Number	Issue Date (YYYY-MM-DD)	
16/824,572	also is a	a Divisional of	13/694,73				9,447,401 2016-09-20			
Prior Application	No. 13/6	94,731 - Status	:		☑ Pate	ented 🔲 Pending				
Application Numb	er	Continuity Typ	ре	Pri	or Applic	ation Number		Filing Date (	YYYY-MM-DD)	
13/694,731		claims priority t	.0	61/	796,208			2012-11-01		
Prior Application	No. 61/7	96,208 - Status	:		Patented	I ☐ Pending		☐ Abandone	ed 🛛 Expired	
Application Numb	er	Continuity Typ	ре	Pri	or Applic	ation Number		Filing Date (	YYYY-MM-DD)	
13/694,731		claims priority t	ю.	61/	631,313			2011-12-30		
Prior Application	No. 61/6	31,313 - Status	:		Patented	I ☐ Pending		☐ Abandone	ed 🛛 Expired	
							Issue Date (YYYY-MM-DD)			
This application	is a Co	ntinuation of	15/226,48	9		2016-08-02		10,865,400	2020-12-15	
Prior Application	No. 15/2	26,489 - Status	:	$\boxtimes$	Patented	l ☐ Pending		Abandone	ed 🗌 Expired	
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15/226,489 is a Divisional of 13/694,73						2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/6		⊠ Pate	ı ented	ı ſ	Abandoned	Expired			

Application Data Sho  Title of Invention  Application Number	Г		Application			US2E/3087K		
Title of Invention	Г							
					•	L		
Application Number			ARIANTS, FOR	RMULATIONS AN	ID USES THEF	REOF		
	Continuity Ty	уре	Prior Applicat	ion Number	Filing Date (\	YYY-MM-DD)		
13/694,731	claims priority	v to	61/796,208		2012-11-01			
Prior Application No. 61/7	96,208 - Statu	ıs:	☐ Patented	Pending	Abandone	d 🛛 Expired		
Application Number	Continuity Ty	уре	Prior Applicat	ion Number	Filing Date (\	YYY-MM-DD)		
13/694,731	claims priority	r to	61/631,313		2011-12-30			
Prior Application No. 61/6	31,313 - Statu	ıs:	☐ Patented	Pending	Abandone	d 🛛 Expired		
Present Application No.  Continuity Type Prior Application No.  Patent Number (YYYY-MM-DD)  Issue Date (YYYY-MM-DD)								
This application also is	a Divisional of	13/694,	731	2012-12-28	9,447,401	2016-09-20		
Prior Application No. 13/6	ıs:	⊠ Pate	ented 🗌 Pending	g 🔲 Abandone	ed  Expired			
Application Number	Continuity	Туре	Prior Applic	ation No.	Filing Date (\	YYY-MM-DD)		
13/694,731	rity to	61/796,208		2012-11-01				
Prior Application No. 61/7	796,208- Statu	ıs:	☐ Patented	d 🗌 Pending 🗌	Abandoned 🛛 Expired			
Application Number	Continuity	Туре	Prior Applic	ation No.	Filing Date (\	YYY-MM-DD)		
13/694,731	claims prio	rity to	61/631,313		2011-12-30			
Prior Application No. 61/6	31,313 - Statu	ıs:	☐ Patented ☐ Pending ☐ Abandoned ☒ Expired					
Foreign Priority Info	rmation:							
This section allows for the applic Providing this information in the a								
Application Number C	Country	Filing Date DD)	(YYYY-MM-	Priority Cla		ccess Code f applicable)		
				☐ Yes ☐	] No			
Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:  If checked, this application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.								
Authorization or Opt-Out of Authorization to Permit Access:								
When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).  Should applicant choose not to provide an authorization identified in subsection 1 below, applicant must opt-out of the authorization by checking the corresponding box A or B or both in subsection 2 below.  NOTE: This section of the Application Data Sheet is ONLY reviewed and processed with the INITIAL filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.								

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

				(for applications filed after 9/10/201					
	Application Data She	27 CED 4 76	Attorney Docket Number	33320.03087.US2E/3087K					
1	Application Data She	et 37 CFR 1.76	Application Number						
-	Title of Invention	PH20 POLYPEPTIDE VA	ARIANTS, FORMULATIONS AN	ID USES THEREOF					
t l k c c	A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h) (1).  B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the EPO access to the bibliographic data and search results from the								
	CFR 1.14(h)(2). The applicant is reminded tha	it the EPO's Rule 141(1) EPC	tion claiming priority to the instant p  C (European Patent Convention) rec in a European patent application th	quires applicants to submit a copy					
2	2. Opt-Out of Authorization	s to Permit Access by a Fo	oreign Intellectual Property Office	(s)					
	A. Applicant <u>DOES NOT</u> authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.								
[	B. Applicant <u>DOES NOT</u> authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.								
	NOTE: Once the application naccordance with 37 CFR 1.		e publicly available, the USPTO may	y provide access to the application					

# **Applicant Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.								
Applicant 1								
f the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.								
Assignee Assignee	☐ Legal Representative	und	er 35 U.S.C	. 117	☐ Joint Inventor			
Person to whom the property of the property	ne inventor is obligated to assigr	1	☐ Perso	n who shows :	sufficient proprietary interest			
If applicant is the legal	representative, indicate the aut	horit	y to file the	patent applica	ition, the inventor is:			
☐ Deceased	☐ Legally in	сара	acitated					
Name of the Decease	d or Legally Incapacitated Inven	tor:						
If the Applicant is an	Organization check here.			$\boxtimes$				
Organization Name:	HALOZYME, INC.							
Mailing Address Info	rmation For Applicant:							
Address 1	11388 Sorrento Valley Road							
Address 2								
City San Diego State/Province CA								
Country US Postal Code 92121								
Phone Number Fax Number								

Application Data Sh	oot 27 CED 1 76	Attorney Docket Number	33320.03087.US2E/3087K
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention PH20 POLYPEPTIDE VA		ARIANTS, FORMULATIONS AN	D USES THEREOF

Email Address		
If needed, Additional A	pplicant Data n	may be added within this form.

# Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications							
Signature	/Stephanie Seidman/			Date (YYYY-MM-DD)	2022-12-19		
First Name	Stephanie Last Name Seidman			Registration Number	33,779		
Additional Signatures may be added within this form.							

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Application Number: 18068418

Reviewed by: cSmvAsj2Eeg/p9KRnlQ7Xvx6SK8jnDazOz1UmNPrTuL7Ou65e6sKHw==

Note: This validation report concerns the sequence listing filed 12-19-2022 19:09:12 and indicates that NO errors were found by the USPTO during validation of the sequence listing. This validation report should not be construed as meaning that the sequence listing complies with all of the requirements of 37 CFR §§ 1.821-1.825, 37 CFR §§ 1.831-1.835 and 1.839, WIPO Standard ST.25, or WIPO Standard ST.26.

For any sequence listing related questions or concerns, the Applicant is invited to contact the USPTO Sequence Listing Help Desk at 571-272-2510 or SequenceHelpDesk@USPTO.GOV.

Timestamp: [year=2022; month=12; day=20; hr=10; min=42; sec=27; ms=880]

#### Validated By CRFValidator v 1.5.0

Application No: 18068418 Version No: 1.1

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Total Warnings: 5

Total Errors: 0

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Actual SeqID Count: 927

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Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Wei *et al.* Art Unit : Not yet assigned Serial No. : 18/068,418 Examiner : Not yet assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

THEREOF

#### Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

#### Dear Sir:

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee is not required. If a fee for filing these papers is required, the Commissioner is authorized to charge the fee to Deposit Account No. 50-0911.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98. Forms PTO-1449 (25 pages) and copies of the cited non-U.S. patent documents listed thereon are provided herewith in connection with the above-captioned application. The documents cited comprise the references cited in the application and incorporated by reference, and any additional information of which those associated with the prosecution are aware.

In accordance with 37 C.F.R. § 1.98(d), copies of the references listed on the Forms PTO-1449 that are marked with a double asterisk (\*\*) are not provided herewith as they have been previously provided in connection with U.S. Patent Application Serial No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which is relied upon for an earlier filing date in accordance with 35 U.S.C. § 120.

The documents cited on the Forms PTO-1449 are in the English Language with the exception of the items noted below. Item GB (CN 102065886A) is in the Chinese Language and an English Language equivalent is listed (Item GR). Item GI (JP 2007-153797) is in the Japanese Language and an English Language Abstract is listed (Item IM). Item GJ (KR 10-2020-0017538) is in the Korean Language and an English Language equivalent is listed (Item GG). Hence, in

#### CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on March 16, 2023.

/Anh Nguyen /
Anh Nguyen

Inventor(s) : Wei et al. Attorney Docket No.: 33320.03087.US2E/3087K

Serial No. : 18/068,418 Information Disclosure Statement

Filed: December 19, 2022

accordance with the requirements of 37 C.F.R. § 1.98, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S. Applications that have one or more common inventors and/or an owner in common.

Examiner's	U.S.S.N.	Filing Date	Publ. No.	Publ. Date	Docket
Initials					No.
	16/930,766	07/16/2020	2020/0368330	11/26/2020	3066D
	17/062,425	10/02/2020	2021/0023184	01/28/2021	3051M
	17/327,568	05/21/2021	2021/0284985	09/16/2021	3087E
	17/327,586	05/21/2021	2021/0277376	09/09/2021	3087F
	17/850,903	06/27/2022	2022/0372151	11/24/2022	3122B
	18/064,886	12/12/2022	n.a.	n.a.	3087G
	18/066,960	12/15/2022	n.a.	n.a.	3087H
	18/068,218	12/19/2022	n.a.	n.a.	3087I
	18/068,327	12/19/2022	n.a.	n.a.	3087J
	18/068,443	12/19/2022	n.a.	n.a.	3087L
	18/069,651	12/21/2022	n.a.	n.a.	3087M

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §§ 1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

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email: stephanie.seidman@dentons.com

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attomey Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
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List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned

U.S. Patent Documents							
Examiner	Desig.	Document	Publication		1		Filing Date
Initial	ID	Number	Date	Patentee	Class	Subclass	1f Appropriate 02/17/1969
	AA	3,536,809	10/27/1970	Applezweig	424	28	
	AB	3,598,123	08/10/1971	Zaffaroni	128	268	04/01/1969
	AC	3,630,200	12/28/1971	Higuchi	128	260	06/09/1969
	AD	3,710,795	01/16/1973	Higuchi et al.	128	260	09/29/1970
	AE	3,845,770	11/05/1974	Theeuwes et al.	128	260	06/05/1972
	AF	3,916,899	11/04/1975	Theeuwes et al.	128	260	02/07/1974
	AG	4,002,531	01/11/1977	Royer	195	68	01/22/1976
	AH	4,008,719	02/22/1977	Theeuwes et al.	128	260	02/02/1976
	AI	4,044,126	08/23/1977	Cook et al.	514	180	07/09/1976
	AJ	4,179,337	12/18/1979	Davis et al.	435	181	07/28/1977
	AK	4,364,923	12/21/1982	Cook et al.	424	46	04/30/1981
	AL	4,414,209	11/08/1983	Cook et al.	514	180	06/13/1977
	AM	4,769,027	09/06/1988	Baker et al.	424	493	02/24/1987
	AN	4,952,496	08/28/1990	Studier et al.	435	91	12/29/1986
	AO	4,980,286	12/25/1990	Morgan et al.	435	371	01/03/1989
	AP	5,033,252	07/23/1991	Carter	53	425	07/30/1990
	AQ	5,052,558	10/01/1991	Carter	206	439	07/27/1990
	AR	5,059,595	10/22/1991	Le Grazie	424	468	03/20/1990
	AS	5,073,543	12/17/1991	Marshall et al.	514	21	07/21/1988
	AT	5,120,548	06/09/1992	McClelland et al.	424	473	11/07/1989
	AU	5,122,614	06/16/1992	Zalipsky	548	520	04/19/1990
	AV	5,323,907	06/28/1994	Kalvelage	206	531	03/15/1993
	AW	5,324,844	06/28/1994	Zalipsky	548	520	01/08/1992
	AX	5,446,090	08/29/1995	Harris	525	54.1	11/12/1993
	AY	5,591,767	01/07/1997	Mohr et al.	514	413	06/06/1995
	AZ	5,612,460	03/18/1997	Zalipsky	530	391.9	02/17/1994
	BA	5,639,476	06/17/1997	Oshlack et al.	424	468	06/02/1995
	BB	5,643,575	07/01/1997	Martinez et al.	424	194.1	10/27/1993
	ВС	5,672,662	09/30/1997	Harris et al.	525	408	10/02/1995
	BD	5,674,533	10/07/1997	Santus et al.	424	493	05/26/1995
	BE	5,721,348	02/24/1998	Primakoff et al.	536	22.1	10/21/1991
	BF	5,733,566	03/31/1998	Lewis	424	426	10/30/1995
	BG	5,766,581	06/16/1998	Bartley et al.	424	85.1	03/30/1995
	BH	5,795,569	08/18/1998	Bartley et al.	424	85.1	10/12/1994
	BI	5,808,096	09/15/1998	Zalipsky	548	520	01/21/1997
	BJ	5,854,046	12/29/1998	Au-Young et al.	435	201	01/20/1998
	BK	5,900,461	05/04/1999	Harris	525	54.11	02/23/1998
	DIX						<u> </u>

	Examiner Signature	Date Considered		
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Į	conformance and not considered. Include copy of this form with next communication to applicant.			

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418	
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List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned	

				ent Documents			1
Examiner Initial	Desig. ID	Document	Publication Date	Detentes	Class	Subclass	Filing Date If Appropriate
шшаг	BL	Number 5,919,455	07/06/1999	Patentee Greenwald et al.	424	178.1	03/20/1997
	BM	5,932,462	08/03/1999	Harris et al.	435	188	05/17/1995
		5,958,750	09/28/1999		435	201	07/03/1996
	BN	5,985,263	11/16/1999	Au-Young et al.  Lee et al.	433	85.2	12/19/1997
	BO					54.2	
	BP	5,990,237	11/23/1999	Bentley et al.	525	6	05/20/1998
	BQ	6,057,110	05/02/2000	Au-Young et al.	435	194.1	12/17/1998
	BR	6,113,906	09/05/2000	Greenwald et al.	424		12/29/1998
	BS	6,193,963	02/27/2001	Stern et al.	424	94.6	08/21/1997
	BT	6,214,966	04/10/2001	Harris	528	322	09/25/1997
	BU	6,258,351	07/10/2001	Harris	424	78.3	11/05/1997
	BV	6,340,742	01/22/2002	Burg et al.	530	351	06/28/2000
	BW	6,413,507	07/02/2002	Bentley et al.	424	78.02	12/23/1999
	BX	6,420,339	07/16/2002	Gegg et al.	514	12	10/14/1998
	BY	6,437,025	08/20/2002	Harris et al.	523	406	11/05/2001
	BZ	6,448,369	09/10/2002	Bentley et al.	528	425	11/05/1998
	CA	6,461,802	10/08/2002	Van Thillo et al.	430	336	07/31/2000
	СВ	6,461,863	10/08/2002	Jarvis	435	320.1	11/29/1999
	CC	6,495,659	12/17/2002	Bentley et al.	528	425	12/20/2000
	CD	6,615,063	09/02/2003	Ntziachristos et al.	600	312	11/27/2000
	CE	6,737,505	05/18/2004	Bentley et al.	528	425	10/30/2002
	CF	6,828,401	12/07/2004	Nho et al.	526	333	10/29/2003
	CG	6,858,736	02/22/2005	Nho et al.	546	290	12/23/2002
	СН	7,105,330	09/12/2006	Stern et al.	435	200	07/18/2003
	CI	7,279,457	10/09/2007	Pohl et al.	514	3	03/11/2005
	CJ	7,585,940	09/08/2009	Skerra et al.	530	350	05/11/2006
	CK	7,767,429	08/03/2010	Bookbinder et al.	435	201	03/05/2004
	CL	7,781,397	08/24/2010	Stern et al.	424	94.62	10/03/2006
	CM	7,829,081	11/09/2010	Bookbinder et al.	424	94.62	03/04/2010
	CN	7,846,431	12/07/2010	Bookbinder et al.	424	94.62	03/04/2010
	CO	7,871,607	01/18/2011	Bookbinder et al.	424	094,620	02/23/2005
	CP	8,105,586	01/31/2012	Bookbinder et al.	424	94.3	06/15/2010
	CO	8,187,855	05/29/2012	Baker et al.	435	201	11/09/2010
	CR	8,202,517	06/19/2012	Bookbinder et al.	424	094.620	02/20/2009
	CS	8,257,699	09/04/2012	Bookbinder et al.	424	094.620	12/15/2011
	CT	8,318,154	11/27/2012	Frost et al.	424	094.500	04/28/2009
	CU	8,343,487	01/01/2013	Baker et al.	424	094.620	03/13/2012
	CV	8,431,124	04/30/2013	Bookbinder et al.	424	94.62	04/16/2009

Examiner Signature	Date Considered			
EXAMINER: Initial if citation considered, whether or not citation is i	n conformance with MPEP 609; Draw line through citation if not in			
conformance and not considered. Include conv. of this form with next communication to applicant				

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Publ	lications for Applicant's	Inventor(s) Wei <i>et al</i> .	
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned

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Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
Шиат	CW	8,431,380	04/30/2013	Bookbinder et al.	435	201	02/20/2009
	CX	8,450,470	05/28/2013	Bookbinder et al.	536	023.200	06/03/2009
	CY	8,568,713	10/29/2013	Frost et al.	424	023.200	05/18/2012
	CZ	8,580,252	11/12/2013	Bookbinder et al.	424	85.2	07/06/2012
	-	8,765,685	07/01/2014	Bookbinder et al.	514	020.900	05/16/2012
	DA DB	8,772,246	07/08/2014	Bookbinder et al.	435	200	10/18/2012
	DC	9,284,543	03/15/2016	Wei et al.	435	201	02/21/2012
	DD	9,447,401	09/20/2016	Wei et al.	424	094.62	12/28/2012
	DE	9,913,822	03/13/2018	Maneval et al.	435	195	03/15/2013
	DF	10,016,491	07/10/2018	Bookbinder et al.	424	94.62	11/09/2015
	DG	10,328,130	06/25/2019	Frost et al.	424	094.620	02/22/2012
	DH	10,588,983	03/17/2020	Bookbinder et al.	435	069.100	02/23/2018
	DI	11,041,149	06/22/2021	Wei et al.	435	069.100	03/19/2020
	DJ	11,066,656	07/20/2021	Wei et al.	435	069.100	06/25/2020
	DK	2001/0021763	09/13/2001	Harris	528	75	04/02/2001
	DL	2001/0044526	11/22/2001	Shen	530	409	02/21/2001
	DM	2001/0046481	11/29/2001	Bentley et al.	424	78.18	04/21/2001
	DN	2002/0052430	05/02/2002	Harris et al.	523	406	11/05/2001
	DO	2002/0072573	06/13/2002	Bentley et al.	525	409	02/08/2002
	DP	2002/0156047	10/24/2002	Zhao	514	58	01/22/2002
	DQ	2003/0017108	01/23/2003	Zamora et al.	424	001.490	04/30/2002
	DR	2003/0114647	06/19/2003	Harris et al.	530	402	04/10/2002
	DS	2003/0143596	07/31/2003	Bentley et al.	435	6	11/07/2002
	DT	2003/0158333	08/21/2003	Roberts et al.	530	402	10/09/2002
	DU	2003/0220447	11/27/2003	Harris	528	322	12/12/2002
	DV	2004/0013637	01/22/2004	Bentley et al.	424	78.17	02/10/2003
	DW	2004/0235734	11/25/2004	Bossard et al.	514	12	02/26/2004
	DX	2004/0268425	12/30/2004	Bookbinder et al.	800	18	03/05/2004
	DY	2005/0054048	03/10/2005	Grasso et al.	424	133.100	07/29/2004
	DZ	2005/0114037	05/26/2005	Desjarlais et al.	702	19	09/30/2004
	EA	2005/0171328	08/04/2005	Harris	528	322	02/04/2005
	EB	2005/0209416	09/22/2005	Harris	525	523	04/22/2005
	EC	2005/0260186	11/24/2005	Bookbinder et al.	424	094.610	02/23/2005
	ED	2006/0104968	05/18/2006	Bookbinder et al.	424	094.610	09/27/2005
	EE	2007/0067855	03/22/2007	Jarvis et al.	800	13	04/28/2006
	EF	2007/0189962	08/16/2007	Pastan et al.	424	133.100	04/11/2007
	EG	2009/0028829	01/29/2009	Gruskin et al.	424	093.7	05/17/2004

Examiner Signature	Date Considered			
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	U.S. Patent Documents						
Examiner	Desig.	Document	Publication		l		Filing Date
Initial	ID	Number 2009/0042785	Date	Patentee	Class	Subclass	If Appropriate 04/28/2008
	EH		02/12/2009	Matschiner et al.	514	012 001.490	
	EI	2009/0123367	05/14/2009	Bookbinder et al.	424		10/09/2008
	EJ	2009/0181032	07/16/2009	Bookbinder at al.	424	141.1	02/20/2009
	EK	2009/0214505	08/27/2009	Bookbinder at al.	424	94.1	04/16/2009
	EL	2009/0253175	10/08/2009	Bookbinder at al.	435	69.1	06/03/2009
	EM	2009/0304665	12/10/2009	Frost et al.	424	94.5	04/28/2009
	EN	2009/0305982	12/10/2009	Jensen et al.	435	069.100	06/11/2009
	EO	2009/0311237	12/17/2009	Frost	424	094.620	04/14/2009
	EP	2010/0003238	01/07/2010	Frost et al.	424	94.62	04/14/2009
	EQ	2010/0074885	03/25/2010	Schiff et al.	424	130.100	03/16/2009
	ER	2010/0143457	06/10/2010	Wei et al.	424	450	12/09/2009
	ES	2010/0172892	07/08/2010	Uvarkina et al.	424	94.62	12/15/2009
	ET	2011/0053247	03/03/2011	Baker et al.	435	201	11/09/2010
	EU	2011/0066111	03/17/2011	Teschner et al.	514	183	09/16/2010
	EV	2011/0152359	06/23/2011	Bookbinder et al.	435	200	12/21/2010
	EW	2012/0020951	01/26/2012	Shepard et al.	424	130.1	07/15/2011
	EX	2012/0093770	04/19/2012	Bookbinder et al.	424	094.620	12/15/2011
	EY	2012/0148555	06/14/2012	Bookbinder et al.	435	200	12/28/2011
	EZ	2012/0171153	07/05/2012	Frost et al.	424	94.62	02/22/2012
	FA	2012/0213767	08/23/2012	Wei et al.	424	450	02/21/2012
	FB	2012/0251517	10/04/2012	Frost et al.	424	094.500	05/18/2012
	FC	2012/0251620	10/04/2012	Bookbinder et al.	424	450	05/16/2012
	FD	2012/0294830	11/22/2012	Bookbinder et al.	424	85.2	07/06/2012
	FE	2013/0011378	01/10/2013	Yang et al.	424	094.300	06/15/2012
	FF	2013/0022588	01/24/2013	Yang et al.	424	094.300	06/15/2012
	FG	2013/0022592	01/24/2013	Vaughn et al.	424	094.620	06/15/2012
	FH	2013/0058893	03/07/2013	Bookbinder et al.	435	200	10/18/2012
	FI	2013/0071394	03/21/2013	Troyer et al.	435	071.100	09/14/2012
	FJ	2013/0101577	04/25/2013	Wei et al.	424	450	02/21/2012
	FK	2013/0202583	08/08/2013	Jiang et al.	424	094.620	10/24/2012
	FL	2013/0251786	09/26/2013	Li et al.	424	094.620	02/19/2013
	FM	2013/0302275	11/14/2013	Wei et al.	424	094.620	12/28/2012
	FN	2013/0302400	11/14/2013	Maneval et al.	435	195	03/15/2013
	FO	2014/0037613	02/06/2014	Bookbinder et al.	424	094.620	09/25/2013
	FP	2014/0105824	04/17/2014	Shepard et al.	424	009.200	10/16/2013
	FQ	2014/0135682	05/15/2014	Frost et al.	424	094.500	09/24/2013
	FR	2014/0199282	07/17/2014	Bookbinder et al.	435	200	02/26/2014
	1.1C	2014/01//202	07/17/2017	Dookomuci et ai.	133	200	02/20/2017

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	U.S. Patent Documents							
Examiner	Desig.	Document	Publication				Filing Date	
Initial	ID	Number	Date	Patentee	Class	Subclass	If Appropriate	
	FS	2015/0010529	01/08/2015	Wei	424	94.62	07/03/2014	
	FT	2016/0362670	12/15/2016	Wei et al.	424	094.620	08/02/2016	
	FU	2017/0290796	10/12/2017	Maneval et al.	435	195	06/16/2017	
	FV	2019/0336587	11/07/2019	Frost et al.	424	78.17	05/21/2019	
	FW	2020/0255814	08/13/2020	Wei et al.	435	069.100	03/19/2020	
	FX	2020/0318091	10/08/2020	Wei et al.	424	094.620	06/25/2020	
	FY	2020/0368330	11/26/2020	Frost et al.	424	078.170	07/16/2020	
	FZ	2021/0277376	09/09/2021	Wei et al.	424	094.620	05/21/2021	
	GA	2021/0284985	09/16/2021	Wei et al.	424	094.620	05/21/2021	

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Examiner	Desig.			Tra	nslation	
Initial	ID	Document Number	Date	Patent Office	Yes	No
	GB**	CN 102065886A	05/18/11	CN		X* (Item GR)
	GC**	EP 0400472	12/05/90	EP		
	GD**	EP 0822199	09/22/04	EP		
	GE**	EP 1064951	08/22/07	EP		
	GF**	EP 3130347	09/18/19	EP		
	GG**	EP 3636752	04/15/20	EP		
	GH**	EP 3785701	03/03/21	EP		
	GI**	JP 2007-153797	06/21/07	JР		X** (Item IM)
	GJ**	KR 10-2020-0017538	02/18/20	KR		X (Item GG)
	GK**	WO 1992/16640	10/01/92	WIPO		
	GL**	WO 1994/028024	12/08/94	WIPO		
	GM**	WO 2000/002017	01/13/00	WIPO		
	GN**	WO 2001/087925	11/22/01	WIPO		
	GO**	WO 2002/049673	06/27/02	WIPO		
	GP**	WO 2004/056312	07/08/04	WIPO		
	GQ**	WO 2005/000360	01/06/05	WIPO		
	GR**	WO 2009/128917	10/22/09	WIPO		
	GS**	WO 2009/134380	11/05/09	WIPO		
	GT**	WO 2010/077297	07/08/10	WIPO		

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	Foreign Patent Documents or Published Foreign Patent Applications						
Examiner	ner Desig. Publication		Country or	Translation			
Initial	ID	Document Number	Date	Patent Office	Yes	No	
	GU**	WO 2010/149772	12/29/10	WIPO			
	GV**	WO 2012/136768	10/11/12	WIPO			
	GW**	WO 2012/174478	12/20/12	WIPO			
	GX**	WO 2013/102144	07/04/13	WIPO			
	GY**	WO 2015/003167	01/08/15	WIPO			

<sup>\*\* =</sup> Copies not provided herewith as they have been previously provided in connection with U.S. Patent Application Serial No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which are relied upon for an earlier filing date in accordance with 35 U.S.C. §120. X\* = An English language equivalent has been previously provided in connection with U.S. Serial No. 13/694,731.

X = An English language equivalent has been previously provided in connection with U.S. Serial No. 15/226,489.

		Pocuments (include Author, Title, Date, and Place of Publication)		
Examiner	9.			
Initial	ID	Document		
	GZ	Letter/Written Disclosure of the Information Disclosure Statement for the above-referenced application, filed herewith on March 16, 2023, 2 pages.		
	HA**	Adams, G.E. and I.J. Stratford, "Bioreductive drugs for cancer therapy: the search for tumor specificity," Int. J. Radiat. Oncol. Biol. Phys., 29(2): 231-238 (1994).		
	HB**	Alexander et al., "Expression of the c-myc oncogene under control of an immunoglobulin enhancer in Eμ-myc transgenic mice," Mol. Cell. Biol. 7(4):1436-1444 (1987).		
	HC** Ansel, H. C., Introduction to Pharmaceutical Dosage Forms, Lea & Febiger, Philadelphia, PA, For Edition, p.126 (1985).			
	HD**	Anttila et al., "High levels of stromal hyaluronan predict poor disease outcome in epithelial ovarian cancer," Cancer Res. 60(1):150-155 (2000).		
	HE**	Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," Eur. J. Biochem. 247(3):810-814 (1997).		
	HF**	Atkinson, M. and E. Leiter, "The NOD mouse model of type 1 diabetes: as good as it gets?" Nature Med. 5:601-604 (1999).		
	HG**	Auvinen et al., "Hyaluronan in Peritumoral Stroma and Malignant Cells Associates with Breast Cancer Spreading and Predicts Survival," Am. J. Pathol. 156(2):529-536 (2000).		
	HH**	Baumgartner et al., "Phase I study in chemoresistant loco-regional malignant disease with hyaluronidase," Reg. Cancer Treat. 1:55-58 (1988).		
	HI**	Beckenlehner et al., "Hyaluronidase enhances the activity of adriamycin in breast cancer models in vitro and in vivo," J. Cancer Res. Oncol. 118:591-596 (1992).		
	HJ**	Benhar et al., "Pseudomonas exotoxin A mutants. Replacement of surface-exposed residues in domai III with cysteine residues that can be modified with polyethylene glycol in a site-specific manner," J. Biol. Chem. 269:13398-13404 (1994).		
	HK**	Bianchi et al., "Synthetic depsipeptide substrates for the assay of human hepatitis C virus protease," Anal. Biochem. 237: 239-244 (1996).		
	HL**	Bitter et al., "Expression and secretion vectors for yeast," Methods in Enzymol. 153:516-544 (1987).		

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 $X^*$  = An English language equivalent has been previously provided in connection with U.S. Serial No. 13/694,731.  $X^{**}$  = An English Abstract (Item IM) for Japanese Publication No. JP 2007-153797 has been previously provided in connection with With U.S. Serial No. 13/694,731.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attomey Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Publ	lications for Applicant's	Inventor(s) Wei et al.	
	losure Statement	Filing Date December 19, 2022	Group Art Unit Not yet assigned

		Documents (include Author, Title, Date, and Place of Publication)
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	HM**	Bonner, W. and E. Cantey, "Colorimetric method for determination of serum hyaluronidase activity," Clin. Chim. Acta 13:746-752 (1966).
	HN**	Bookbinder et al., "A recombinant human enzyme for enhanced interstitial transport of therapeutics," J. Control. Release, 114:230-241 (2006).
	HO**	Bordier, C., "Phase separation of integral membrane proteins in Triton X-114 solution," J. Biol. Chem. 256(4):1604-1607 (1981).
	HP**	Bouffard et al., "An in vitro assay for hepatitis C virus NS3 serine proteinase," Virology 209:52-59 (1995).
	HQ**	Brinster et al., "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs." Nature 296:39-42 (1982).
	HR**	Brown et al., "Codon utilisation in the pathogenic yeast, Candida albicans," Nucleic Acids Res. 19(15):4298 (1991).
	HS**	Brumeanu et al., "Derivatization with monomethoxypolyethylene glycol of Igs expressing viral epitopes obviates adjuvant requirements," J. Immunol. 154:3088-3095 (1995).
	HT**	Caliceti, P. and Veronese, F. M., "Pharmacokinetic and biodistribution properties of poly(ethylene glycol)-protein conjugates," Adv. Drug Deliv. Rev. 55(10):1261-1277 (2003).
	HU**	Carrillo, H. and Lipman, D., "The multiple sequence alignment problem in biology," SIAM J. Applied Math. 48(5):1073-1082 (1988).
	HV**	Cefalu, W., "Animal models of type 2 diabetes: clinical presentation and pathophysiological relevance to the human condition," ILAR Journal 47(3):186-198 (2006).
	HW**	Chapman et al., "Therapeutic antibody fragments with prolonged in vivo half-lives," Nature Biotech. 17:780-783 (1999).
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	HY**	Cherr et al., "The dual functions of GPI-anchored PH-20: hyaluronidase and intracellular signaling," Matrix Biol., 20(8):515-525 (2001).
	HZ**	Cherr et al., "The PH-20 protein in cynomolgus macaque spermatozoa: identification of two different forms exhibiting hyaluronidase activity," Dev. Biol. 175:142-153 (1996).
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	IB**	Chowpongpang et al., "Cloning and characterization of the bovine testicular PH-20 hyaluronidase core domain," Biotechnol. Lett. 26(15):1247-52 (2004).
	IC**	Colbere-Garapin et al., "A new dominant hybrid selective marker for higher eukaryotic cells," J. Mol. Biol. 150:1-14 (1981).
	ID**	Conserved domain search from US Application No. 10/795,095 of SEQ ID NO:6, Primakoff et al. US 5,721,348, performed on the NCBI website on August 5, 2008.
	IE**	Csoka et al., "Hyaluronidases in tissue invasion," Invasion Metastasis 17:297-311 (1997).
	IF**	Csoka et al., "Purification and microsequencing of hyaluronidase isozymes from human urine," FEBS Lett., 417(3):307-310 (1997).
	IG**	Csoka et al., "The six hyaluronidase-like genes in the human and mouse genomes," Matrix Biol. 20:499-508 (2001).
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l .	losure Statement	Filing Date December 19, 2022	Group Art Unit Not yet assigned

	Other [	Documents (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
	II**	De Maeyer, E. and J. De Maeyer-Guignard, "The growth rate of two transplantable murine tumors, 3LL lung carcinoma and B16F10 melanoma, is influenced by Hyal-1, a locus determining hyaluronidase levels and polymorphism," Int. J. Cancer 51:657-660 (1992).
	IJ**	De Salegui et al., "A Comparison of Serum and Testicular Hyaluronidase," Arch. Biochem. Biophys. 121:548-554 (1967).
	IK**	De Boer et al., "The <i>tac</i> promoter: a functional hybrid derived from the <i>trp</i> and <i>lac</i> promoters," Proc. Natl. Acad. Sci. USA 80:21-25 (1983).
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	IM**	Derwent English abstract for Japanese Publication No. JP 2007-153797, published Jun. 21, 2007, entitled "Therapeutic Agent And Preventive Agent Of Autoimmune Disease, Inflammation, And Nervous Disease," 3 pages.
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	IR**	Ernst et al., "Enzymatic degradation of glycosaminoglycans," Crit. Rev. Biochem. Mol. Biol. 30(5):387-444 (1995).
	IS**	Eskens et al., "Enzymatic glycocalyx treatment impairs insulin-mediated recruitment of microvascular blood volume and decreases insulin sensitivity in rats," FASEB Journal 25: 1023.13 (2011) (Abstract).
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	JA**	Frost, G. I. and Stern, R., "A microtiter-based assay for hyaluronidase activity not requiring specialized reagents," Anal. Biochem. 251:263-269 (1997).
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	List of Patents and Publications for Applicant's Information Disclosure Statement		Group Art Unit Not yet assigned

		Documents (include Author, Title, Date, and Place of Publication)
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	Љ**	Gilbert, W. and Villa-Komaroff, L., "Useful Proteins from Recombinant Bacteria," Scientific American 242(4):74-94 (1980).
	JE**	Girish et al., "Hyaluronidase inhibitors: a biological and therapeutic perspective," Curr. Med. Chem. 16(18):2261-2288 (2009).
	JF**	Gmachl et al., "The human sperm protein PH-20 has hyaluronidase activity," FEBS 336(3):545-548 (1993).
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	JT**	Have et al., "Cloning and characterization of the cDNA encoding the PH20 protein in the European red fox Vulpes," Reproduct. Fertil. Dev. 10:165-172 (1998).
	JU**	Herrera-Estrella et al., "Expression of chimaeric genes transferred into plant cells using a Ti-plasmid-derived vector," Nature 303:209-213 (1983).
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	JW**	Hibi et al., "Chondroitinase C activity of <i>Streptococcus intermedius</i> ," FEMS Microbiol. Lett. 57(2):121-124 (1989).
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	JZ**	Hooper, N. M., "Determination of glycosyl-phosphatidylinositol membrane protein anchorage" Proteomics 1:748-755 (2001)		
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	KC**	Huang, X. and W. Miller., "A time-efficient, linear-space local similarity algorithm," Adv. Appl. Math. 12:337-357 (1991).		
	KD**	Hunnicut et al., "Structural relationship of sperm soluble hyaluronidase to the sperm membrane protein PH-20," Biol. Reprod. 54(6):1343-1349 (1996).		
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	KJ**	Jay et al., "Construction of a general vector for efficient expression of mammalian proteins in bacteria: use of a synthetic ribosome binding site," Proc. Natl. Acad. Sci. USA 78(9):5543-5548 (1981).		
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	KL**	Kelsey et al., "Species- and tissue-specific expression of human $\alpha_1$ -antitrypsin in transgenic mice," Genes And Devel. 1:161-171 (1987).		
	KM**	Kim et al., "Sperm penetration through cumulus mass and zona pellucida," Int. J. Dev. Biol. 52(5-6):677-682 (2008).		
	KN**	Kodukula et al., "Biosynthesis of Phosphatidylinositol Glycan-anchored Membrane Proteins," J. Bio Chem. 266:4464-4470 (1991).		
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	KP**	Kollias et al., "Regulated expression of human $^{A}\gamma$ -, $\beta$ -, and hybrid $\gamma\beta$ -globin genes in transgenic mice manipulation of the developmental expression patterns," Cell 46:89-94 (1986).		
	KQ**	Krumlauf et al., "Developmental regulation of α-fetoprotein genes in transgenic mice," Mol. Cell. Biol. 5(7):1639-1648 (1985).		
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	KS**	Kyte et al., "A Simple Method for Displaying the Hydropathic Character of a Protein" J. Mol. Biol. 157:105-132 (1982).		
	KT**	Lalancette et al, "Characterization of an 80-kilodalton bull sperm protein identified as PH-20," Biol. Reprod. 65(2):628-636 (2001).		
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muai	KU**	Lam et al., "The effect of benzyl alcohol on recombinant human interferon-gamma," Pharm. Res. 14(6):725-729 (1997).
	KV**	Lammerts van Bueren et al., "The antibody zalutumumab inhibits epidermal growth factor receptor signaling by limiting intra- and intermolecular flexibility," Proc. Natl. Acad. Sci. U. S. A. 105(16):6109-6114 (2008).
	KW**	Lathrop et al., "cDNA cloning reveals the molecular structure of a sperm surface protein, PH-20, involved in sperm-egg adhesion and the wide distribution of its gene among mammals," J. Cell Biol. 111(6 Pt 2):2939-2949 (1990).
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	KY**	Leder et al., "Consequences of widespread deregulation of the c-myc gene in transgenic mice: multiple neoplasms and normal development," Cell 45:485-495 (1986).
	KZ**	Li et al., "Importance of Glycosylation and Disulfide Bonds in Hyaluronidase Activity of Macaque Sperm Surface PH-20," J. Androl. 23:211-219 (2002).
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	LB**	Liang et al., "Prediction of antigenic epitopes on protein surfaces by consensus scoring," BMC Bioinformatics 10:302 (2009), 10 pages.
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	LF**	Locke et al., "ENHANZE® drug delivery technology: a novel approach to subcutaneous administration using recombinant human hyaluronidase PH20," Drug Deliv. 26(1):98-106 (2019).
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	LJ**	Lu, Y. A. and Felix, A. M., "Pegylated peptides I: Solid-phase synthesis of N <sup>α</sup> -pegylated peptides using Fmoc strategy," Peptide Res. 6(3):140-146 (1993).
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	LM**	Ma et al., "Fucosylation in prokaryotes and eukaryotes" Glycobiology 16(12):158R-184R (2006)
	LN**	Maa and Hsu, "Aggregation of recombinant human growth hormone induced by phenolic compounds," Int. J. Pharm. 140(2):155-168 (1996).
	LO**	MacDonald, R. J., "Expression of the pancreatic elastase I gene in transgenic mice," Hepatology 7(1):42S-51S (1987).

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	LP**	Magram et al., "Developmental regulation of a cloned adult β-globin gene in transgenic mice," Nature 315:338-340 (1985).	
	LQ**	Marković-Housley et al., "Crystal structure of hyaluronidase, a major allergen of bee venom," Structure 8: 1025-1035 (2000).	
	LR**	Maksimenko et al., "Resistance of dextran-modified hyaluronidase to inhibition by heparin" Biochemistry (Mosc.) 66(4):456-463 (2001).	
	LS**	Mammalian Gene Collection (MGC) Program Team, "Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences," Proc. Natl. Acad. Sci. USA 99:16899-16903 (2002).	
	LT**	McIlvaine, W. B., "A buffer solution for colorimetric comparison," J. Biol. Chem. 49:183-186 (1921).	
	LU**	Mehvar, R., "Modulation of the pharmacokinetics and pharmacodynamics of proteins by polyethylene glycol conjugation," J. Pharm. Pharmaceut. Sci. 3(1):125-136 (2000).	
	LV**	Menzel, E. and C. Farr, "Hyaluronidase and its substrate hyaluronan: biochemistry, biological activities and therapeutic uses," Cancer Lett. 131:3-11 (1998).	
	LW**	Merrifield, R. B., "Solid phase peptide synthesis. I. The synthesis of a tetrapeptide," J. Am. Chem. Soc. 85:2149-2154 (1963).	
	LX**	Meyer et al., "The soluble hyaluronidase from bull testes is a fragment of the membrane-bound PH-20 enzyme," FEBS Letters 413(2):385-388 (1997).	
	LY**	Michelacci, Y. M. and Dietrich, C. P., "Chondroitinase C from <i>Flavobacterium heparinum</i> ," J. Biol. Chem. 251(4):1154-1158 (1976).	
	LZ**	Miller et al., "Use of retroviral vectors for gene transfer and expression," Meth. Enzymol. 217:581-599 (1993).	
	MA**	Mizutani et al., "Characterization of hepatitis C virus replication in cloned cells obtained from a human T-cell leukemia virus type 1-infected cell line, MT-2," J. Virol. 70:7219-7223 (1996).	
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	MD**	Monfardini et al., "A branched monomethoxypoly(ethylene glycol) for protein modification," Bioconjugate Chem. 6:62-69 (1995).	
	ME**	Nadjsombati et al., "Dose-range developmental toxicity of rHuPH20 in mice," Matrix Biology Vol. 27, December 2008, Page 23.	
	MF**	Nakayama et al., "CD15 expression in mature granulocytes is determined by $\alpha$ 1,3-fucosyltransferase IX, but in promyelocytes and monocytes by $\alpha$ 1,3-fucosyltransferase IV," J. Biol. Chem. 276(19):16100-16106 (2001).	
	MG**	NCBI Reference Sequence XP_011728213.1, Macaca nemestrina (pig-tailed macaque) PH-20 hyaluronidase. Published on Apr. 24, 2018. Retrieved from URL: <ncbi.nlm.nih.gov 2="" 20,="" 2020],="" 795324051="" [retrieved="" apr.="" on="" pages.<="" protein="" td=""></ncbi.nlm.nih.gov>	
	MH**	Needleman, S. B. and Wunsch, C. D., "A general method applicable to the search for similarities in the amino acid sequence of two proteins," J. Mol. Biol. 48:443-453 (1970).	
	MI**	Nekoroski et al., "A recombinant human hyaluronidase sustained release gel for the treatment of post-surgical edema," Int. J. Dermatol. 53(6):777-785 (2014).	
	MJ**	Omaetxebarria et al., "Computational approach for identification and characterization of GPI-anchored peptides in proteomics experiments," Proteomics 7(12):1951-1960 (2007).	

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Initial	ID	Document
		Ornitz et al., "Elastase I promoter directs expression of human growth hormone and SV40 T antigen
	MK**	genes to pancreatic acinar cells in transgenic mice," Cold Spring Harbor Symp. Quant. Biol. 50:399-409 (1985).
	ML**	Ostresh et al., "Peptide libraries: determination of relative reaction rates of protected amino acids in competitive couplings," Biopolymers 34:1681-1689 (1994).
	MM**	Padavattan, S., "Crystal structure determination of hyaluronidase: a major bee venom allergen, in complex with an IgG Fab fragment and purification and biophysical characterization of bovine testes hyaluronidase," 2006, PhD Thesis, University of Basel, Faculty of Science. DOI: 10.5451/unibas-004349798, 101 pages.
	MN**	Paul, A. and D. Sochart, "Improving the results of ganglion aspiration by the use of hyaluronidase," J. Hand Surg. 22B(2):219-221 (1997).
	MO**	Paulick, M. and C. Bertozzi, "The glycosylphosphatidylinositol anchor: A complex membrane-anchoring structure for proteins," Biochemistry 47:6991-7000 (2008).
	MP**	Pawlowski et al., "The effects of hyalurodinase upon tumor formation in BALB/c mice painted with 7,12-dimethylbenz-(α)anthracene," Int. J. Cancer 23:105-109 (1979).
	MQ**	Pedersen et al., "Sym004: a novel synergistic anti-epidermal growth factor receptor antibody mixture with superior anticancer efficacy," Cancer Res. 70(2):588-597 (2010).
	MR**	Pham et al., "Large-scale transient transfection of serum-free suspension-growing HEK293 EBNA1 cells: peptone additives improve cell growth and transfection efficiency," Biotechnology and Bioengineering 84(3):332-342 (2003).
	MS**	Phelps et al., "Restricted lateral diffusion of PH-20, a PI-anchored sperm membrane protein," Science 240:1780-1782 (1988).
	MT**	Pierleoni et al., "PredGPI: a GPI-anchor predictor," BMC Bioinformatics 9:392 (2008), 11 pages.
	MU**	Pinkert et al., "An albumin enhancer located 10 kb upstream functions along with its promoter to direct efficient, liver-specific expression in transgenic mice," Genes and Devel. 1:268-276 (1987).
	MV**	Pirinen et al., "Prognostic value of hyaluronan expression in non-small-cell lung cancer: Increased stromal expression indicates unfavorable outcome in patients with adenocarcinoma," Int. J. Cancer 95: 12-17 (2001).
	MW**	Primakoff et al., "Fully effective contraception in male and female guinea pigs immunized with the sperm protein PH-20," Nature 335:543-546 (1988).
	MX**	Prothmann et al., "Sexual size dimorphism predicts rates of sequence evolution of Sperm Adhesion Molecule 1 (SPAM1, also PH-20) in monkeys, but not in hominoids (apes including humans)," Mol. Phy. Ev. 63: 52-63 (2012).
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	MZ**	Reitinger et al., "Designed human serum hyaluronidase 1 variant, HYAL1 <sup>AL</sup> , exhibits activity up to pH 5.9," J. Biol. Chem. 284(29):19173-19177 (2009).
	NA**	Remmele et al., "Interleukin-1 receptor (IL-1R) liquid formulation development using differential scanning calorimetry," Pharm. Res. 15(2):200-208 (1998).
	NB**	Rhodes et al., "Transformation of maize by electroporation of embryos," Methods Mol Biol 55:121-131 (1995).
	NC**	Richmond, T., "Precompiled codon-usage tables," Genome Biology 1:reports 241(2000).
	ND**	Ripka et al., "Two Chinese hamster ovary glycosylation mutants affected in the conversion of GDP-mannose to GDP-fucose," Arch. Biochem. Biophys. 249(2):533-545 (1986).

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	NE**	Roberts et al., "Chemistry for peptide and protein PEGylation," Advanced Drug Delivery Reviews 54:459-476 (2002).
	NF**	Ropponen et al., "Tumor Cell-associated Hyaluronan as an Unfavorable Prognostic Factor in Colorectal Cancer," Cancer Research 58:342-347 (1998).
	NG**	Rosengren et al., "Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration," AAPS J. 17(5):1144-1156 (2015).
	NH**	Sato et al., "Cloning and expression in <i>Escherichia coli</i> of the gene encoding the <i>Proteus vulgaris</i> chondroitin ABC lyase," Appl. Microbiol. Biotechnol. 41(1):39-46 (1994).
	NI**	Sato, H., "Enzymatic procedure for site-specific pegylation of proteins," Adv. Drug Deliv. Rev. 54:487-504 (2002).
	NJ**	Sawhney et al., "Bioerodible hydrogels based on photopolymerized poly(ethylene glycol)-co-poly(α-hydroxy acid) Diacrylate Macromers," Macromolecules 26:581-587 (1993).
	NK**	Schanté et al., "Improvement of hyaluronic acid enzymatic stability by the grafting of amino-acids," Carbohydrate Polymers, 87(3):2211-2216 (2012).
	NL**	Scharf et al., "Heat stress promoters and transcription factors," in Nover, L. (eds) Plant Promnoters and Transcription Factors. Results and Problems in Cell Differentiation, vol. 20. Springer, Berlin, Heidelberg (1994).
	NM**	Scheithauer et al., "In vitro evaluation of the anticancer drug modulatory effect of hyaluronidase in human gastrointestinal cell lines," Anticancer Res. 8:391-396 (1988).
	NN**	Schuller et al., "Pharmacokinetics of intrahepatic 5-fluorouracil ± preinjected hyaluronidase (Neopermease, N)," Proc. Amer. Assoc. Cancer Res. 32:173, abstract no. 1034 (1991).
	NO**	Schwartz, R. M. and Dayhoff, M. O., eds., "Matrices for Detecting Distant Relationships," Atlas of Protein Science and Structure, National Biomedical Research Foundation, pp. 353-358 (1978).
	NP**	Schwartzman, J., "Hyaluronidase: A Review in Its Therapeutic Use in Pediatrics," J. Pediat. 39:491-502 (1951).
	NQ**	Seaton et al., "Rat sperm 2B1 glycoprotein (PH20) contains a C-terminal sequence motif for attachment of a glycosyl phosphatidylinositol anchor. Effects of endoproteolytic cleavage on hyaluronidase activity," Biol Reprod. 62(6):1667-1676 (2000).
	NR**	Shani, M., "Tissue-specific expression of rat myosin light-chain 2 gene in transgenic mice," Nature 314:283-286 (1985).
	NS**	Sharp et al., "Codon usage patterns in Escherichia coli, Bacillus subtilis, Saccharomyces cerevisiae, Schizosaccharomyces pombe, Drosophila melanogaster and Homo sapiens; a review of the considerable within-species diversity," Nucleic Acids Res. 16(17):8207-8211 (1988).
	NT**	Sharp, P.M. and E. Cowe, "Synonymous codon usage in Saccharomyces cerevisiae," Yeast. 7(7):657-678 (1991).
	NU**	Shekhar et al., "The Matrix Reloaded: Halozyme's Recombinant Enzyme Helps Injected Drugs Spread Faster," Chem. Biol. 14:603-604 (2007).
	NV**	Shimizu, Y. and H. Yoshikura, "Multicycle infection of hepatitis C virus in cell culture and inhibition by alpha and beta interferons," J. Virol. 68:8406-8408 (1994).
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	NX**	Smith, T. F. and Waterman, M. S., "Comparison of biosequences," Advances in Applied Mathematic 2:482-489 (1981).
	NY**	St. Croix et al., "Reversal of intrinsic and acquired forms of drug resistance by hyaluronidase treatment of solid tumors," Cancer Lett. 131(1):35-44 (1998).

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	NZ**	Steinkuhler et al., "Product inhibition of the hepatitis C virus NS3 protease," Biochem. 37:8899-8905 (1998).
	OA**	Stern, R., "Devising a pathway for hyaluronan catabolism: are we there yet?" Glycobiology 13:105R-115R (2003).
	OB**	Stern et al., "Hyaluronidases: their genomics, structures, and mechnisms of action," Chem. Rev. 106: 818-839 (2006).
	OC**	Sturla et al., "Core fucosylation of N-linked glycans in leukocyte adhesion deficiency/congenital disorder of glycosylation IIc fibroblasts," Glycobiology 15(10):924-934 (2005).
	OD**	Sudo et al., "Establishment of an in vitro assay system for screening hepatitis C virus protease inhibitors using high performance liquid chromatography," Antiviral Res. 32:9-18 (1996).
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	OF**	Swift et al., "Tissue-specific expression of the rat pancreatic elastase I gene in transgenic mice," Cell 38(3):639-646 (1984).
	OG**	Takahashi et al., "A fluorimetric Morgan-Elson assay method for hyaluronidase activity," Anal. Biochem. 322:257-263 (2003).
	OH**	Takeshita et al., "An enzyme-linked immunosorbent assay for detecting proteolytic activity of hepatitis C virus proteinase," (1997) Anal. Biochem. 247:242-246.
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	OK**	Tkalec et al., "Isolation and expression in <i>Escherichia coli</i> of <i>cslA</i> and <i>cslB</i> , genes coding for the chondroitin sulfate-degrading enzymes chondroitinase AC and chondroitinase B, respectively, from <i>Flavobacterium heparinum</i> ," Applied and Environmental Microbiology 66(1): 29-35 (2000).
	OL**	Tsubery et al., "Prolonging the action of protein and peptide drugs by a novel approach of reversible polyethylene glycol modification.," J. Biol. Chem. 279(37):38118-38124 (2004).
	OM**	Tsuda et al., "Substrate specificity studies of <i>Flavobacterium</i> chondroitinase C and heparitinases towards the glycosaminoglycan—protein linkage region. Use of a sensitive analytical method developed by chromophore-labeling of linkage glycoserines using dimethylaminoazobenzenesulfonyl chloride," Eur. J. Biochem. 262:127-133 (1999).
	ON**	Tung et al., "Mechanism of infertility in male guinea pigs immunized with sperm PH-20," Biol. Reprod. 56(5):1133-1141 (1997).
	00**	Udenfriend, S. and Kodukula, K., "Prediction of ω site in nascent precursor of glycosylphosphatidylinositol protein," Methods Enzymol. 250:571-582 (1995).
	OP**	UniProt Murine PH20 sequence Retrieved from: <uniprot.org 02,="" 2010],="" 5="" [retrieved="" august="" on="" p48794,="" pages.<="" td="" uniprot=""></uniprot.org>
	OQ**	United States Pharmacopeia. USP <51>. Antimicrobial effectiveness testing. United States Pharmacopeia Convention, Inc, Rockville, MD.Retreived from: <a href="http://www.pharmacopeia.cn/v2920/usp29nf24s0">http://www.pharmacopeia.cn/v2920/usp29nf24s0</a> c51.html, [retreived on Apr. 02, 2013], 5 pages.
	OR**	USP XXII-NF XVII (1990), p. 644-645 United States Pharmacopeial Convention, Inc, Rockville, MD.
	OS**	Varela et al., "Exome sequencing identifies frequent mutation of the SWI/SNF complex gene PBRM1 in renal carcinoma,"Nature 469(7331):539-542 (2011).

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	OT**	Veronese et al., "Branched and Linear Poly(Ethylene Glycol): Influence of the Polymer Structure on Enzymological, Pharmacokinetic, and Immunological Properties of Protein Conjugates," J. Bioactive Compatible Polymers 12:196-207 (1997).
	OU**	Von Sivaraman Padavattan (2006) Thesis of University of Basel, "Crystal structure determination of hyaluronidase, a major bee venom allergen, in complex with an IgG Fab fragment and purification and biophysicial charcterization of bovine testes hyaluronidase," 100 pages.
	OV**	Wagner et al., "Nucleotide sequence of the thymidine kinase gene of herpes simplex virus type 1," Proc. Natl. Acad. Sci. USA 78(3):1441-1445 (1981).
	OW**	Wang et al., "The molecular physiology of hepatic nuclear factor 3 in the regulation of gluconeogenesis," J. Biol. Chem. 275(19):14717-14721 (2000).
	OX**	Watson et al., Molecular Biology of the Gene, 4th Edition, The Benjamin/Cummings Pub. Co., Menlo Park, CA, p. 224 (1987).
	OY**	Weiss et al., "Activities of monomeric insulin analogs at position A8 are uncorrelated with their thermodynamic stabilities," J. Biol. Chem. 276(43):40018-40024 (2001).
	OZ**	Wells, J.A., "Additivity of Mutational Effects in Proteins," Biochem. 29(37):8509-8517 (1990).
	PA**	White et al., "Comparison of the glycosyl-phosphatidylinositol cleavage/attachment site between mammalian cells and parasitic protozoa," J. Cell Sci. 113(Pt.4):721-727 (2000).
	PB**	Wigler et al., "Transfer of purified herpes virus thymidine kinase gene to cultured mouse cells," Cell 11:223-232 (1977).
	PC**	Wigler et al., "Transformation of mammalian cells with an amplifiable dominant-acting gene," Proc. Natl. Acad. Sci. USA 77:3567-3570 (1980).
	PD**	Yamamoto et al., "Identification of a functional promoter in the long terminal repeat of Rous sarcoma virus," Cell 22:787-797 (1980).
	PE**	Yamane-Ohnuki et al., "Establishment of FUT8 knockout Chinese hamster ovary cells: an ideal host cell line for producing completely defucosylated antibodies with enhanced antibody-dependent cellular cytotoxicity," Biotech. Bioeng. 87:614-622 (2004).
	PF**	Yang, X. and X. Yu, "An introduction to epitope prediction methods and software," Rev. Med. Virol. 19(2):77-96 (2009).
	PG**	Yocum et al., "Assessment and Implication of the Allergic Sensitivity to a Single Dose of Recombinant Human Hyaluronidase Injection: A Double-Blind, Placebo-Controlled Clinical Trial," J. Infus. Nursing. 30:293-299 (2007).
	PH**	Yudin et al., "Characterization of the active site of monkey sperm hyaluronidase," Reproduction 121(5):735-743 (2001).
	PI**	Zalipsky, S., "Chemistry of polyethylene glycol conjugates with biologically active molecules," Adv. Drug Del. Rev. 16:157-182 (1995).
	PJ**	Zanker et al., "Induction of response in previous chemotherapy resistant patients by hyaluronidase," Proc. Amer. Assoc. Cancer Res. 27:390 Abstract 1550 (1986).
	PK**	Zhang et al., "Hyaluronidase activity of human Hyal1 requires active site acidic and tyrosine residues," J. Biol. Chem. 284(14):9433-9442 (2009).
	PL**	Zhao, X. and J. Harris, "Novel degradable poly(ethylene glycol) esters for drug delivery," in Chapter 28: Poly(ethylene glycol), ACS Symposium Series, Vol. 680, Harris, J. and Zalipsky, S., (eds), 458-472 (1997).
	PM**	Bee et al., "Recombinant human PH20 is well tolerated at higher intravenous and subcutaneous doses in cynomolgus monkeys," EUFEPS 2008, Munich, Germany. Abstract, 2 pages.

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	PN**	Bee et al., "Recombinant human PH20 is well tolerated at higher intravenous and subcutaneous doses in cynomolgus monkeys," EUFEPS 2008, Munich, Germany. Poster and individual panels, 9 pages.
	PO**	Bookbinder et al., "Biochemical characterization of recombinant human PH20 (SPAM1) hyaluronidase," Hyaluronan (ISHAS) 2007, Charleston, SC. Abstract, 1 page.
	PP**	Bookbinder et al., "Biochemical characterization of recombinant human PH20 (SPAM1) hyaluronidase," Hyaluronan (ISHAS) 2007, Charleston, SC. Poster, 1 page.
	PQ**	Bookbinder et al., "Enhancing Drug Transport Through Temporary Matrix Depolymerization," Keystone Symposia 2005. (poster -12 pages) (together poster and abstract - 13 pages)
	PR**	Bookbinder et al., "Enhancing Drug Transport Through Temporary Matrix Depolymerization," Keystone Symposium 2005. Abstract, 1 page.
	PS**	Pinkstaff et al., "Evaluation of the compatibility and pharmacokinetics of co-formulated biologics with recombinant human hyaluronidase: Dose Response," American Association of Pharmaceutical Scientists Conference, November 2006. Abstract, 2 pages.
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	PU**	Byerley et al., "'Cutting out the bull'. Recombinant human hyaluronidase: Moving to an animal-free system," Association of Clinical Embryologists, 2006, Dublin, Ireland. Abstract published in Human Fertility, June 2006; 9(2): 110.
	PV**	Frost, "Punctuated Equilibrium: The Evolution of Recombinant Human Hyaluronidase," Ophthalmic Anesthesia Society, 2006, Chicago, IL. Abstract, 1 page.
	PW**	Frost, "Punctuated Equilibrium: The Evolution of Recombinant Human Hyaluronidase," Ophthalmic Anesthesia Society, 2006, Chicago, IL. Presentation, 35 pages.
	PX**	Haller et al., "Enhanze Technology – A Revolution in Drug Dispersion," Biotechnology Industry Organization (BIO) Annual Meeting, June 19-22, 2005, Philadelphia, PA. Abstract, 3 pages.
	PY**	Haller et al., "Recombinant Human Hyaluronidase for the Interstitial Transport of Therapeutics," American Association of Pharmaceutical Scientists Conference, June 2006, San Antonio, TX. Abstract, 2 pages.
	PZ**	Haller et al., "Revolutionizing Drug Dispersion with Enhanze Technology," American Association of Pharmaceutical Scientists Annual Meeting, Nov 6-10, 2005, Nashville, TN, Poster, 1 page.
	QA**	Haller et al., "Revolutionizing Drug Dispersion with Enhanze Technology," Biotechnology Industry Organization (BIO) Annual Meeting, June 19-22, 2005, Philadelphia, PA. Poster, 1 page.
	QB**	Haller et al., "The Effects of Recombinant Human Hyaluronidase on Drug Dispersion," American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN, Abstract in AAPS Journal 7(S2) May 5, 2005; 3 pages.
	QC**	Haller, "Enhanze Technology – An Enzymatic Drug Delivery System (DDS)," Japanese Export Trade Organization, November 2005, Santa Clara, CA. Abstract, 2 pages.
	QD**	Haller, "Focus on Enhanced and Innovative Recombinant Human Enzymes," Japanese Export Trade Organization, September 2004, Chicago, IL. PRESENTATION, 16 pages.
	QE**	Haller, "Halozyme's Enhanze Technology for the Enhanced Dispersion of Co-Injected Pharmaceuticals," Japanese Export Trade Organization, September 2004, Chicago, IL. Abstract, 2 pages.
	QF**	Haller, M., "Enzyme-facilitated Parenteral Drug Transport." Strategic Research Institute's 10 <sup>th</sup> Anniversary Drug Delivery Technology and Deal-making Summit, 2005 New Brunswick, NJ. Presentation, 24 pages.

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Initial	ID	Document  Hofer et al., "Human recombinant hyaluronidase increases the convection of molecules up 0.2 μm in	
	QG**	athymic nude mice," J. Am. Assoc. Lab. Animal Sci., 45(4):120, abstract P97 (2006).	
	QH**	Hofer et al., "Human Recombinant Hyaluronidase (rHuPh20) Increases the Convection of Molecules up to 0.2 μm in Athymic Nude Mice," American Association for Laboratory Animal Science, 2006, Salt Lake City, UT. Poster P97, 1 page.	
	QI**	Jiang et al., "Effects of Recombinant Human PH20 (rHuPH20) on Interstitial Matrices: Creating a Favorable Environment for The Delivery of Cytostatic Agents," [abstract]. In: Proceedings of the 96th Annual Meeting of the American Association for Cancer Research; 2005 Apr 16-20; Anaheim, CA.:AACR; 2005. Vol. 46, page 1198, Abstract no. 5075, April 2005.	
	QJ**	Keller et al., "Pharmacokinetic, Pharmacodynamic and Toxicologic Effects of a Recombinant Human Hyaluronidase (rHuPH20) in Rodent and Non-Human Primate models," Hyaluronan (ISHAS) 2007, Charleston, SC. Abstract, 1 page.	
	QK**	Keller et al., "Pharmacokinetic, Pharmacodynamic and Toxicologic Effects of a Recombinant Human Hyaluronidase (rHuPH20) in Rodent and Non-Human Primate models," Presented at International Society for Hyaluronan Sciences (ISHAS) Annual Meeting 2007, Charleston, SC. Poster and individual panels, 14 pages.	
	QL**	Kodandapani et al., "Diverse Structural and Functional Roles of N-glycosylations on rHuPH20," Glycan Abstract, 1 page (2009).	
	QM**	Morrow et al., "Human Hyaluronidase Coinjection Accelerates Insulin Pharmacokinetics and Glucodynamics of 3 Rapid Insulin Analogs," American Diabetes Association Scientific Sessions, held on June 28, 2010 in Orlando, FL., Abstract # 353-OR, 2 pages.	
	QN**	Nadjsombati et al., "Evaluation of Developmental and Prenatal/Postnatal Reproduction Toxixity of rHuPH20 in Mice," American College of Toxicology 30th annual meeting 2009. (November 1-4) Palm Springs, CA. Abstract, 1 page.	
	QO**	Nagy et al., "Prospective, randomized study on bovine and recombinant human (Cumulase®) Hyaluronidases," American Society of Reproductive Medicine, 2006, New Orleans, LA, 06-A-886- ASRM, Abstract O-213.	
	QP**	Nagy et al., "Prospective study on rHuPH20." European Society of Human Reproduction & Embryology Annual Meeting, June 19-22, 2005, Copenhagen, Denmark. Abstract O-213, 1 page.	
	QQ**	Halozyme Therapeutics, Inc., "PEGPH20: The Science & The Strategy," presented at J. P. Morgan Healthcare Conference on Jan. 7, 2015. Presentation. 81 pages.	
	QR**	Pinkstaff et al., "Recombinant Human Hyaluronidase for Drug and Fluid Dispersion," American Association of Pharmaceutical Scientists Annual Meeting, November 2006, Boston, MA, Abstract, 2 pages.	
	QS**	Pinkstaff et al., "Recombinant Human Hyaluronidase for Drug and Fluid Dispersion," American Association of Pharmaceutical Scientists Annual Meeting, November 2006, Boston, MA, Poster and individual panels, 8 pages.	
	QT**	Stelzer, L., "Platforms for Growth: Building a Premier Oncology Biotech," Presented at the Canaccord Genuity 38th Annual Growth Conference on Aug. 09, 2018, 24 pages.	
	QU**	Torley, H., "Halozyme Therapeutics, Inc. The next chapter begins: creating value through growth," Presented at the 32nd Annual J.P. Morgan Healthcare Conference January 2014, 26 pages.	
	QV**	Wei et al., "Functions of N-linked glycans on human hyaluronidase PH20," presented at San Diego Glycobiology Symposium 2009. Poster 83 and individual panels, 5 pages.	

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	QZ**	News Release, "Halozyme Announces Presentation Of Clinical Data At The American Diabetes Association 74th Scientific Sessions," Published on 06-15-2014 [online][retrieved on 08-18-2014] Retrieved from the internet: <url: 2014="" [3="" default.aspx="" halozyme-announces-presentation-of-clinical-data-at-the-american-diabetes-association-74th-scientific-sessions="" halozyme.com="" investors="" news-release-details="" news-releases="" pages].<="" td=""></url:>	
	RA**	News Release, Halozyme Therapeutics, Inc "Halozyme Licenses New Enhanze Target For \$30 Million Upfront Payment, Future Milestones And Royalties," Published Sept. 14, 2017 [online] Retrieved from: <url: 09-14-17],="" 2017="" 3="" [retrieved="" default.aspx="" halozyme-licenses-new-enhanze-target-for-30-million-upfront-payment-future-milestones-and-royalties="" halozyme.com="" investors="" news-release-details="" news-releases="" on="" pages.<="" td=""></url:>	
	RB**	News Release, Halozyme Therapeutics, Inc., "Bristol-Myers Squibb and Halozyme Enter Global Collaboration and License Agreement for ENHANZE Technology," Published Sept. 14, 2017 [online] Retrieved from: <url: 14,="" 2017="" 2017],="" 7="" [retrieved="" bristol-myers-squibb-and-halozyme-enter-global-collaboration-and-license-agreement-for-enhanze-technology="" default.aspx="" halozyme.com="" investors="" news-release-details="" news-releases="" on="" pages.<="" sept.="" td=""></url:>	
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	RF**	News Release, Halozyme Therapeutics, Inc., "Halozyme Publication In The Journal Clinical Cancer Research Highlights New Nonclinical Data Supporting Multiple Effects Of PEGPH20 On The Tumor Microenvironment," Published Oct. 04, 2018 [online] Retrieved from: <url: 05,="" 2018="" 2018],="" 4="" [retrieved="" default.aspx="" halozyme-publication-in-the-journal-clinical-cancer-research-highlights-new-nonclinical-data-supporting-multiple-effects-of-pegph20-on-the-tumor-microenvironment="" halozyme.com="" investors="" news-release-details="" news-releases="" oct.="" on="" pages.<="" td=""></url:>	
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Publications for Applicant's Information Disclosure Statement		Inventor(s) Wei et al.	
		Filing Date December 19, 2022	Group Art Unit Not yet assigned

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	KIN	Patent Application No. PCT/US2012/072182, 6 pages.	
	RO**	International Search Report and Written Opinion, mailed Dec. 17, 2013, in connection with	
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	RP**	Response, dated March 17, 2014, to Written Opinion, mailed Dec. 17, 2013, in connection with	
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	RQ**	Second Written Opinion, mailed May 21, 2014, in connection with International Patent Application	
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	RR**	Response, dated July 21, 2014, to second Written Opinion, mailed May 21, 2014, in connection with	
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	RS**	Second Written Opinion, mailed July 30, 2014, in connection with International Patent Application	
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	RT**	Response, dated Sept. 1, 2014, to second Written Opinion, mailed July 30, 2014, in connection with	
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	RU**	International Patent Application No. PCT/US2012/072182, 11 pages.	
	DIV**	Office Action, mailed November 2, 2015, in connection with U.S. Patent Application Serial No.	
	RV**	13/694,731, 14 pages.	
	DIII	Response, filed April 20, 2016, to Office Action, mailed November 2, 2015, in connection with U.S.	
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	RY**	Office Action, issued May 15, 2019, in connection with U.S. Patent Application No. 15/226,489, 16 pages.
	RZ**	Response, filed Oct. 15, 2019, to Office Action, issued May 15, 2019, in connection with U.S. Patent Application No. 15/226,489, 30 pages.
	SA**	Office Action, issued Jan. 23, 2020, in connection with U.S. Patent Application No. 15/226,489, 19 pages.
	SB**	Response, filed Apr. 24, 2020, to Office Action, issued Jan. 23, 2020, in connection with U.S. Patent Application No. 15/226,489, 25 pages.
	SC**	Notice of Allowance, issued Jul. 16, 2020, in connection with U.S. Patent Application No. 15/226,489, 13 pages.
	SD**	Office Action, issued Oct. 27, 2020, in connection with U.S. Patent Application No. 16/824,572, 9 pages.
	SE**	Response, filed Jan. 27, 2021, to Office Action, issued Oct. 27, 2020, in connection with U.S. Patent Application Serial No. 16/824,572, 23 pages.
	SF**	Notice of Allowance, mailed Feb. 18, 2021, and Examiner-Initiated Interview Summary, summarizing the interview held on Feb. 10, 2021, issued in connection with U.S. Patent Application Serial No. 16/824,572, 10 pages.
	SG**	Non-final Office Action, issued Dec. 09, 2020, in connection with U.S. Patent Application No. 16/912,590, 12 pages.
	SH**	Response, filed Mar. 17, 2021, to Non-final Office Action, issued Dec. 09, 2020 in connection with U.S. Patent Application No. 16/912,590, 24 pages.
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	SJ**	Examination Report, issued Jan. 13, 2017, in connection with Australian Patent Application No. 2012362141, 3 pages.
	SK**	Response, filed Aug. 14, 2017, to Examination Report, issued Jan. 13, 2017, in connection with Australian Patent Application No. 2012362141, 43 pages.
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	SM**	Office Action (claims deemed allowable), dated Oct. 19, 2018, issued in connection with Australian Patent Application No. 2017245352, 7 pages.
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	SO**	Preliminary Office Action, issued April 14, 2021, in connection with Brazilian Patent Application No. BR112014016195-0 [Machine generated English translation and Office Action as issued in Portuguese], 11 pages.
	SP**	Response, filed Jul. 26, 2021, to Preliminary Office Action, published April 27, 2021, in connection with Brazilian Patent Application No. BR112014016195-0 [English instructions for Response and Response as filed in Portuguese], 111 pages.
	SQ**	Office Action, dated June 09, 2022 and published on July 26, 2022, in connection with Brazilian Patent Application No. BR 112014016195-0 [Machine generated English translation and Office Action as issued in Portuguese], 10 pages.

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Examiner	Desig.	
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		Response, filed October 24, 2022, to Official Action, dated June 09, 2022 and published on July 26,
	SR**	2022, in connection with Brazilian Patent Application No. BR 112014016195-0 [English instructions
		for Response and Response as filed in Portuguese], 57 pages.
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	SW	Patent Application No. BR 122021016549-1 [Machine generated English translation and Office
		Action as issued in Portuguese], 8 pages.
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	SX	2022, in connection with Brazilian Patent Application No. BR 122021016549-1 [English instructions
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	SY**	Examiner's Report, issued March 1, 2016, in connection with Canadian Patent Application No.
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	TD**	Response, filed Jun. 21, 2018, to Examiner's Report, dated Jan. 23, 2018, issued in connection with
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	TE**	Notice of Allowance, dated Dec. 12, 2018, issued in connection with Canadian Patent Application No. 2861919, 1 page.
		Office Action, issued May 25, 2015, in connection with Chinese Patent Application No.
	TF**	201280070954.9 [English language translation and original document in Chinese], 7 pages.
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	TP**	Communication Pursuant to Rule 71 European Patent Application No. 12	(3) (Intention to Grant), issued April 22, 2016, in connection with 816624.6, 5 pages.		
	TQ**	Extended European Search Report, Application No. 16189970.3, 11 pag	Extended European Search Report, dated Jan. 12, 2017, issued in connection with European Patent		
	TR**	Response, filed Aug. 15, 2017, to Extended European Search Report, dated Jan. 12, 2017, issued in connection with European Patent Application No. 16189970.3, 55 pages.			
	TS**	Examination Report, dated Sept. 14, 2017, issued in connection with European Patent Application No. 16189970.3, 3 pages.			
	TT**	Response, dated Oct. 13, 2017, to Examination Report, dated Sept. 14, 2017, issued in connection with European Patent Application No. 16189970.3, 19 pages.			
	TU**	Communication Pursuant to Article 94(3) EPC (claims deemed allowable), dated Feb. 26, 2018, issued in connection with European Patent Application No. 16189970.3, 3 pages.			
	TV**	Response, filed Sept. 10, 2018, to Communication Pursuant to Article 94(3) EPC (claims deemed allowable), issued Feb. 26, 2018, issued in connection with European Patent Application No. 16189970.3, 821 pages.			
	TW**	Communication Pursuant to Article 71(3) EPC (Intention to Grant), dated Apr. 08, 2019, issued in connection with European Patent Application No. 16189970.3, 7 pages.			
	TX**	16189970.3, 2 pages.	Decision to Grant, issued Aug. 22, 2019, in connection with European Patent Application No.		
	TY**	Examination Report, issued Dec. 4, 2018, in connection with Indian Patent Application No. 6272/DELNP/2014, 6 pages.			
	TZ**	Response, filed Sept. 04, 2019, to Examination Report, issued Dec. 4, 2018, in connection with Indian Patent Application No. 6272/DELNP/2014, 79 pages.			
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	UB**	connection with Indian Patent Appli	2020, responsive to Hearing Notice, issued Aug. 10, 2020, in cation No. 6272/DELNP/2014, 27 pages.		
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	losure Statement	Filing Date December 19, 2022	Group Art Unit Not yet assigned	

	Other Documents (include Author, Title, Date, and Place of Publication)			
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	UF**	Office Action, dated August 3, 2016, in connection with Israeli Patent Application No. 233192 [English language translation], 3 pages.		
	UG**	Response, filed Jan. 3, 2017, to Office Action, dated August 3, 2016, in connection with Israeli Patent Application No. 233192 [English language translation], 32 pages.		
	UH**	Office Action, dated Nov. 20, 2017, issued in connection with Israeli Patent Application No. 233192 [English language translation], 2 pages.		
	UI**	Response, filed May 21, 2018, to Office Action, dated Nov. 20, 2017, issued in connection with Israeli Patent Application No. 233192 [English language translation], 22 pages.		
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	UK**	Certificate of Grant, issued Oct. 01, 2020, in connection with Israeli Patent Application No. 233192, 3 pages.		
	UL**	Notification Prior to Acceptance, dated Dec. 14, 2020, issued in connection with Israeli Patent Application No. 274798 [English reporting letter, original document as issued in Hebrew; and English translation of allowed claims], 10 pages.		
	UM**	Official Action, issued on Aug. 11, 2021, in connection with Israeli Patent Application No. 280949 [English translation and original document as issued in Hebrew], 6 pages.		
	UN**	Response, filed Dec. 05, 2021, to Official Action, issued on Aug. 11, 2021, in connection with Israeli Patent Application No. 280949, 11 pages.		
	UO**	Notification Prior to Acceptance, issued Aug. 22, 2022, in connection with Israeli Patent Application No. 280949 [Reporting letter in English and Notification as issued in Hebrew], 6 pages.		
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	UQ**	Response, filed July 15, 2016, to Official Action, issued January 19, 2016, in connection with Japanese Patent Application No. 2014-550526 [English instructions and document as filed in Japanese], 138 pages.		
	UR**	Decision to Grant, issued November 22, 2016, in connection with Japanese Patent Application No. 2014-550526 [Letter reporting decision to grant and original document in Japanese], 5 pages.		
	US**	Office Action, issued Dec 12, 2017, in connection with Japanese Patent Application No. 2016-247708 [English translation and original document in Japanese], 6 pages.		
	UT**	Response, filed May 22, 2018, to Office Action, issued Dec. 12, 2017, in connection with Japanese Patent Application No. 2016-247708 [English instructions with amended claims, documents as filed in Japanese and English translation of claims as-filed], 90 pages.(3087BJP)		
	UU**	Decision to Grant, issued Sept. 18, 2018, in connection with Japanese Patent Application No. 2016-247708 [English reporting letter and original document in Japanese], 4 pages.		
	UV**	Office Action, dated May 25, 2018, in connection with Mexican Patent Application No. MX/a/2014/007966 [English translation and original document in Spanish], 6 pages.		
	UW**	Response, filed Oct. 10, 2018, to Office Action, dated May 25, 2018, in connection with Mexican Patent Application No. MX/a/2014/007966 [English instructions and document as-filed in Spanish], 13 pages.		
	UX**	Notice of Allowance, issued Oct. 18, 2018, in connection with Mexican Patent Application No. MX/a/2014/007966 [English reporting letter and original document in Spanish], 4 pages.		

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IIIIIIai		Office Action, dated Nov. 15, 2022, in connection with Mexican Patent Application No.	
	UY**	MX/a/2018/012394 [English translation and original document in Spanish], 14 pages.	
	UZ**	Examination Report, dated March 26, 2015, in connection with New Zealand Patent Application No. 626126, 32 pages.	
	VA**	Response, dated May 16, 2016, to Examination Report, dated March 26, 2015, in connection with New Zealand Patent Application No. 626126, 70 pages.	
	VB**	Notice of Acceptance, dated June 8, 2016, in connection with New Zealand Patent Application No. 626126, 1 page.	
	VC**	Letters Patent, issued Sept. 27, 2016, in connection with New Zealand Patent No. 626126, 1 page.	
	VD**	Examination Report, dated July 27, 2017, issued in connection with New Zealand Patent Application No. 720075, 4 pages.	
	VE**	Response, filed Feb. 26, 2018, to Examination Report, dated July 27, 2017, issued in connection with New Zealand Patent Application No. 720075, 88 pages.	
	VF**	Notice of Acceptance, dated Mar. 10, 2020, issued in connection with New Zealand Patent Application No. 720075, 1 page.	
	VG**	Search Report and Written Opinion, dated Dec. 4, 2015, in connection with Singaporean Patent Application No. 11201403714T, 7 pages.	
	VH**	Response, filed May 23, 2016, to Search Report and Written Opinion, dated Dec. 4, 2015, in connection with Singaporean Patent Application No. 11201403714T, 21 pages.	
	VI**	Written Opinion, dated Sept. 18, 2017, in connection with Singapore Patent Application No. 11201403714T, 9 pages.	
	VJ**	Response, filed Oct. 27, 2017, to Written Opinion, dated Sept. 18, 2017, in connection with Singapor Patent Application No. 11201403714T, 6 pages.	
	VK**	Notice of Eligibility for Grant and Examination Report, dated Jul. 02, 2018, in connection with Singapore Patent Application No. 11201403714T, 8 pages.	
	VL**	Certificate of Grant, dated Oct. 3, 2018, in connection with Singapore Patent Application No. 11201403714T [Grant Certificate and Granted Claims], 6 pages.	
	VM**	Search Report and Written Opinion, issued Oct. 20, 2017, in connection with Singapore Patent Application No. 10201604470T, 14 pages.	
	VN**	Response, filed Mar. 20, 2018, to Search Report and Written Opinion, issued Oct. 20, 2017, in connection with Singapore Patent Application No. 10201604470T [Response, replacement specification pages, amended claims and cited document], 105 pages.	
	VO**	Examination Report, dated Aug. 06, 2018, and Notice of Eligibility for Grant, dated Aug. 07, 2018, issued in connection with Singapore Patent Application No. 10201604470T, 6 pages.	
	VP**	English translation of Official Action, issued Mar. 20, 2020, in connection with Korean Application No. 10-2020-7002955, 6 pages.	
	VQ**	English Translation of International Search Report and Written Opinion, issued Oct. 29, 2019, in connection with International application No. PCT/KR2019/009215, 10 pages.	

\*\* = Copies not provided herewith as they have been previously provided in connection with U.S. Patent Application Serial No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which are relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

Examiner Signature	Date Considered			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in				
conformance and not considered. Include copy of this form with next communication to applicant.				

Electronic Acknowledgement Receipt		
EFS ID:	47695987	
Application Number:	18068418	
International Application Number:		
Confirmation Number:	5769	
Title of Invention:	PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF	
First Named Inventor/Applicant Name:	Ge WEI	
Customer Number:	13565	
Filer:	Stephanie L. Seidman/Anh Nguyen	
Filer Authorized By:	Stephanie L. Seidman	
Attorney Docket Number:	33320.03087.US2E/3087K	
Receipt Date:	16-MAR-2023	
Filing Date:		
Time Stamp:	19:10:40	
Application Type:	Utility under 35 USC 111(a)	

# **Payment information:**

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
			137660		
1	Transmittal Letter	3087Ktra.pdf	df7751d6d3b70c8d31bd548ed45c245475 90ad9d	no	1
Warnings:					

Information:							
2	Information Disclosure Statement (IDS) Form (SB08)	3087Kids.pdf	151083 73688f868fb5bb5a7061a59805eb3c0d0aa 7e219	no	2		
Warnings:			1				
Information:							
This is not an U	SPTO supplied IDS fillable form						
3	Information Disclosure Statement (IDS) Form (SB08)	3087Kp49.pdf	520765 	no	25		
Warnings:							
Information:							
This is not an U	SPTO supplied IDS fillable form						
			54404				
4	Non Patent Literature	GZ.pdf	2f5cee9565735510506f77f73068570132a7 7305	no	2		
Warnings:							
Information:							
5	Non Patent Literature	SS.pdf	457113	no	6		
			69de2c1a2fcdb765b75a89d010e96207749 72419				
Warnings:							
Information:			Τ				
			3010506				
6	Non Patent Literature	ST.pdf	58dfd47f4ca54edaafeefa694870cce14c93c 2cd	no	33		
Warnings:			•				
Information:							
_		a.v. ts	581605	no	•		
7	Non Patent Literature	Literature SW.pdf	3345f09f7083c7686aa574be2f11399c2bad e5c4		8		
Warnings:							
Information:							
			21207396				
8	Non Patent Literature	SX.pdf	e21fef799956ff2b276df12d893728789160 7a85	no	170		
Warnings:							

Information:	
Total Files Size (in bytes):	26120532

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### **New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket No.: 33320.03087.US2E/3087K

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) Wei et al. Art Unit Not yet assigned Serial No. : 18/068,418 Not yet assigned Examiner

5769 Filed December 19, 2022 Conf. No. Cust. No. 13565

Title PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

**THEREOF** 

## Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are an Information Disclosure Statement (2 pages), Forms PTO-1449 (25 pages), and cited non-U.S. patent documents in connection with the above-identified application. Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee is not required. However, if a fee for filing these papers is required, the Commissioner is authorized to charge the fee to Deposit Account No. 50-0911, as stated below:

 $\boxtimes$ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-0911.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP 4655 Executive Drive, Ste. 700 San Diego, California 92121 Telephone: (619) 595-8010 Facsimile: (619) 595-8135

email: stephanie.seidman@dentons.com

# CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on March 16, 2023.

> /Anh Nguyen/ Anh Nguyen

	PATEN		ON FEE DE		ION RECORI	J		tion or Docket Num 8,418	iber
	APPLIC	CATION AS FILE		olumn 2)	SMALL	ENTITY	OR	OTHER SMALL	
	FOR	NUMBER FILE		ER EXTRA	RATE(\$)	FEE(\$)	]	RATE(\$)	FEE(\$)
	SIC FEE CFR 1.16(a), (b), or (c))	N/A		N/A	N/A		1	N/A	320
SEA	ARCH FEE CFR 1.16(k), (i), or (m))	N/A		N/A	N/A		1	N/A	700
XΑ	AMINATION FEE CFR 1.16(o), (p), or (q))	N/A		N/A	N/A		1	N/A	800
ОТ	FAL CLAIMS CFR 1.16(i))	35 minus	20 = *	15			OR	× 100 =	1500
1DE	EPENDENT CLAIMS CFR 1.16(h))	1 minus	3 = *				1	x =	0
EE	PLICATION SIZE E CFR 1.16(s))	If the specification sheets of paper, tl \$310 (\$155 for sm 50 sheets or fracti 41(a)(1)(G) and 3	ne application s nall entity) for ea on thereof. See	size fee due is ach additional					1680
1UL	LTIPLE DEPENDENT	CLAIM PRESENT (3	7 CFR 1.16(j))						0
If t	the difference in colum	ın 1 is less than zero,	enter "0" in colu	ımn 2.	TOTAL		1	TOTAL	3500
		Column 1) CLAIMS	(Column 2) HIGHEST	(Column 3)	SMALL	ENTITY	OR	OTHER SMALL	ENTITY
	( Fi	(Column 1)	(Column 2)		SMALL RATE(\$)	ENTITY  ADDITIONAL FEE(\$)	OR	-	ENTITY ADDITION
	(	Column 1) CLAIMS EEMAINING AFTER	(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT		ADDITIONAL	OR OR	SMALL	ENTITY ADDITION
	(I Al Total	Column 1) CLAIMS EMAINING AFTER MENDMENT	(Column 2) HIGHEST NUMBER PREVIOUSLY	(Column 3) PRESENT	RATE(\$)	ADDITIONAL		SMALL RATE(\$)	ENTITY ADDITION
	Total (37 CFR 1.16(i))	Column 1) CLAIMS EMAINING AFTER MENDMENT  Minus  Minus	(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT	RATE(\$)	ADDITIONAL	OR	SMALL  RATE(\$)  x =	ENTITY ADDITION
	Total (37 CFR 1.16(i)) Independent (37 CFR 1.16(h)) Application Size Fee (3:	Column 1) CLAIMS EMAINING AFTER MENDMENT  Minus  Minus	(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3)  PRESENT EXTRA  =	RATE(\$)  x =  x =	ADDITIONAL	OR	SMALL  RATE(\$)  x =  x =	ENTITY ADDITION
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AIMENDIMENT	Total (37 CFR 1.16(i))  Application Size Fee (3: FIRST PRESENTATION  Total (37 CFR 1.16(ii))  Application Size Fee (3: FIRST PRESENTATION  (4)  Total (37 CFR 1.16(ii))  Independent (37 CFR 1.16(ii))  Application Size Fee (3:	Column 1) CLAIMS IEMAINING AFTER MENDMENT  Minus  7 CFR 1.16(s)) N OF MULTIPLE DEPEN  COlumn 1) CLAIMS IEMAINING AFTER MENDMENT  Minus  Minus	(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR   IDENT CLAIM (37 ·  (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3)  PRESENT EXTRA  =  CFR 1.16(j))  (Column 3)  PRESENT EXTRA  =  =	RATE(\$)  x =  x =  TOTAL ADD'L FEE  RATE(\$)  x =	ADDITIONAL FEE(\$)	OR OR OR OR	SMALL  RATE(\$)   X =   X =   TOTAL ADD'L FEE   RATE(\$)  X =	ADDITION FEE(\$)



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usmb gov.

APPLICATION	FILING or	GRP ART				
NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/068,418	12/19/2022		5000	33320.03087.US2E/3087K	35	1

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121 CONFIRMATION NO. 5769
FILING RECEIPT

Date Mailed: 03/30/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

## Inventor(s)

Ge Wei, San Diego, CA; H. Michael Shepard, Springfield, OR; Qiping Zhao, San Diego, CA; Robert James Connor, Oceanside, CA;

#### Applicant(s)

Halozyme, Inc., San Diego, CA;

#### Power of Attorney:

STEPHANIE SEIDMAN -33779 FRANK MISKIEL -53332 JOSHUA GALGANO -74802

# Domestic Priority data as claimed by applicant

This application is a DIV of 17/327,568 05/21/2021 which is a CON of 16/912,590 06/25/2020 PAT 11,066,656 which is a CON of 15/226,489 08/02/2016 PAT 10,865,400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012 and claims benefit of 61/631,313 12/30/2011 and said 17/327,568 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149 which is a CON of 15/226,489 08/02/2016 PAT 10,865,400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012

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and claims benefit of 61/631.313 12/30/2011
and said 17/327,568 05/21/2021 is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
This application is a DIV of 17/327,586 05/21/2021
    which is a CON of 16/912,590 06/25/2020 PAT 11,066,656
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
and said 17/327,586 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
and said 17/327,586 05/21/2021 is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and said 17/327,586 05/21/2021 is a CON of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796.208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
This application is a DIV of 16/912,590 06/25/2020 PAT 11,066,656
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
and said 16/912,590 06/25/2020 is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
This application is a DIV of 16/824,572 03/19/2020 PAT 11,041,149
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
and said 16/824,572 03/19/2020 is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796.208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
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**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

#### Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/29/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is **US 18/068,418** 

**Projected Publication Date:** 07/06/2023

Non-Publication Request: No Early Publication Request: No

Title

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Preliminary Class** 

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, page 3 of 5

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

# LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

## **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

#### SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit <a href="http://www.SelectUSA.gov">http://www.SelectUSA.gov</a> or call +1-202-482-6800.	
page 5 of 5	

Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Ge WEI *et al.* Art Unit : Not yet assigned Serial No. : 18/068,418 Examiner : Not yet assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

THEREOF

**Mail Stop Missing Parts** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

#### REQUEST FOR CORRECTED FILING RECEIPT

Dear Sir:

Transmitted herewith are this *Request for Corrected Filing Receipt*, a copy of the *Filing Receipt*, mailed March 30, 2023, with annotated corrections, and an updated *Application Data Sheet* (ADS), marked to show the changes.

## Please update the second Inventor's City of Residence to read as follows:

#### H. Michael Shepard, Eugene, OR;

Applicant requests the inventor's city of residence be updated from "Springfield, OR" to "Eugene, OR". The marked-up ADS provides the Office with H. Michael Shepard's new residence and mailing address information. The marked-up ADS also provides the Office with applicant Halozyme, Inc.'s change of address.

#### Please correct the Power of Attorney section to read as follows:

STEPHANIE SEIDMAN – 33779 FRANK MISKIEL – 53332 <del>JOSHUA GALGANO 74802</del>

Applicant requests correction of the error introduced by the USPTO in the Power of Attorney section, which erroneously lists Joshua Galgano – 74802. The Power of Attorney filed on December 19, 2022, does not list Joshua Galgano. Please remove Joshua Galgano–74802.

Applicant respectfully requests provision of a corrected filing receipt to reflect the updated information and correction to the power of attorney section.

Respectfully submitted, /Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP 4655 Executive Dr., Suite 700 San Diego, CA 92121 Telephone: (619) 595-8010

Facsimile: (619) 595-8135 email: stephanie.seidman@dentons.com CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on April 05, 2023.

<u>/Javier Wong/</u> Javier Wong Inventor(s): : Ge Wei *et al*.
Serial No. : 18/068,327
Filed : December 19, Attorney's Docket No.: 33320.03087.US2E/3087K : 18/068,327 : December 19, 2022 **Request for Corrected Filing Receipt** 

# **ATTACHMENT 1**

Copy of Filing Receipt, mailed March 30, 2023, with annotated corrections

# **COPY**



18/068,418

#### United States Patent and Trademark Office

GRP ART

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. BOX 1450 Alexandria, Vriginia 22313-1450 www.uspto.gov

ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS

UNIT FIL FEE REC'D ATTY.DOCKET.NO
5000 33320.03087.US2E/3087K

35 1

CONFIRMATION NO. 5769

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121

FILING or

371(c) DATE

12/19/2022

FILING RECEIPT

Date Mailed: 03/30/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Eugene

Inventor(s)

Ge Wei, San Diego, CA;

H. Michael Shepard, Springfield, OR; Qiping Zhao, San Diego, CA;

Robert James Connor, Oceanside, CA;

Applicant(s)

Halozyme, Inc., San Diego, CA;

Power of Attorney:

STEPHANIE SEIDMAN -33779 FRANK MISKIEL -53332

JOSHUA GALGANO -74802

Domestic Priority data as claimed by applicant

This application is a DIV of 17/327,568 05/21/2021 which is a CON of 16/912,590 06/25/2020 PAT 11,066,656 which is a CON of 15/226,489 08/02/2016 PAT 10,865,400

which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012

and claims benefit of 61/631,313 12/30/2011

and said 17/327,568 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149

which is a CON of 15/226,489 08/02/2016 PAT 10,865,400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401

which claims benefit of 61/796,208 11/01/2012

page 1 of 5

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and claims benefit of 61/631.313 12/30/2011
and said 17/327,568 05/21/2021 is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a DIV of 17/327,586 05/21/2021
    which is a CON of 16/912,590 06/25/2020 PAT 11,066,656
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796.208 11/01/2012
and claims benefit of 61/631.313 12/30/2011
and said 17/327,586 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and said 17/327.586 05/21/2021 is a CON of 15/226.489 08/02/2016 PAT 10.865.400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and said 17/327,586 05/21/2021 is a CON of 13/694,731 12/28/2012 PAT 9,447,401
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and claims benefit of 61/631.313 12/30/2011
This application is a DIV of 16/912,590 06/25/2020 PAT 11,066,656
    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
and said 16/912,590 06/25/2020 is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796.208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
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    which is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
and said 16/824,572 03/19/2020 is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
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**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

page 2 of 5



Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/29/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is US 18/068,418

**Projected Publication Date:** 07/06/2023

Non-Publication Request: No Early Publication Request: No

Title

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Preliminary Class** 

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, page 3 of 5



this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

#### LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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page 4 of 5

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technology, manufacture products, deliver services, and grow your business, visit  $\underline{\text{http://www.SelectUSA.gov}}$  or call +1-202-482-6800.

page 5 of 5

Application Data Sho	oot 27 CED 1 76	Attorney Docket Number	33320.03087.US2E/3087K			
Application Data Silv	eet 37 CFK 1.76	Application Number	18/068,418			
Title of Invention PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF						

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.

# **Inventor Information:**

Invent	tor 1											
Legal	Nam	е										
Prefix		Give	en Name		Middle N	ame	е		Family Nam	ne		Suffix
		Ge							Wei			
Resid	ence	Infor	mation (S	elect One) 🛚 US	Residency		] N	on US F	Residency [	Ac	tive US Military	Service
City	San	Dieg	0	State/Province	CA Count			Country	y of Residen	US		
Mailin	Mailing Address of Inventor:											
Addre	ss 1			11530 Miro Circle								
Addre	ss 2											
City			San Diego	)			Sta	ate/Prov	ince	CA		
Posta	l Cod	е		92131		Со	unt	ry	US			
Invent	tor 2											
Legal	Nam	е										
Prefix		Give	en Name		Middle N	ame	е		Family Nam	Suffix		
		Н.			Michael				Shepard			
Resid	ence	Infor	mation (S	elect One) 🛛 US	Residency Non US F			Residency [	] Ac	tive US Military	Service	
City	Spri	ngfie	d- <u>Eugene</u>	State/Province	OR			Country	y of Residen	се	US	
		dress	of Invent									
Addre	ss 1			870 Mountaingate	<del>Drive</del> 4133	Sa	brer	na Aveni	<u>ue</u>			
Addre	ss 2											
City			Springfield	<u> Eugene</u>	II.		Sta	ate/Prov	ince	OR	OR .	
Posta	I Cod	е		<del>97478</del> <u>97404</u>		Со	unt	ry	US			
Invent												
Legal					T							
Prefix			en Name		Middle N	ame	е		Family Nam	ne		Suffix
		Qipi							Zhao			
Residence Information (Select One) 🛛 US Residency 🗌 Non US Residency 🔲 Activ							tive US Military	Service				
City	San	Dieg	0	State/Province	CA Count		Country	y of Residen	се	US		
		dres	of Invent									
Addre	ss 1			11240 Windbrook	Way							

Application Data Sheet 37 CFR 1.76  Application Number 18/068,418  Title of Invention PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF  Address 2  City San Diego State/Province CA	
Address 2	
City San Diego State/Province CA	
Postal Code92131CountryUS	
Inventor 4  Legal Name	
Prefix Given Name Middle Name Family Name	Suffix
Robert James Connor	Julia
Residence Information (Select One) Substitution US Residency Non US Residency Active US Military	Service
City Oceanside State/Province CA Country of Residence US	3017100
Mailing Address of Inventor:	
Address 1 451 Lexington Circle	
Address 2	
City San Diego State/Province CA	
Postal Code 92057 Country US	
All Inventors Must Be Listed – Add Additional Inventor Information blocks for each inventor.	
Correspondence Information:	
Enter either Customer Number or complete the Correspondence Information section below. For fur information see 37 CFR 1.33(a).	ther
Customer Number 13565	
Email Address stephanie.seidman@dentons.com	
Email Address mlaipsd@dentons.com	
Application Information:	
Title of the Invention PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF	
Attorney Docket Number 33320.03087.US2E/3087K Small Entity Status Claimed	
Application Type   Nonprovisional Provisional	
Subject Matter	
Total Number of Drawing Sheets (if any) 13 Suggested Figure for Publication (if any)	
Representative Information:	
Please Select One:       □ Customer Number       □ US Patent Practitioner       □ Limited Recognition (37 Colors)	FR 11.9)
Prefix Given Name Middle Name Family Name Suffix	
Stephanie Seidman	
Registration Number: 33,779	
Registration Number:     33,779       Prefix     Given Name     Middle Name     Family Name     Suffix	
Registration Number: 33,779	

Filing Date (YYYY-MM-DD)

2021-05-21

Application Data Sheet 37 CEP 1 76		Attorney Docket Number	33320.03087.US2E/3087K				
Application Data Sil	Application Data Sheet 37 CFR 1.76		18/068,418				
Title of Invention PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF							

# **Domestic Benefit/National Stage Information:**

**Continuity Type** 

is a Divisional of

**Present Application No.** 

This application

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

17/327,568

**Prior Application Number** 

Prior Application	No. 17/3	27,568 - Statu	s:	☐ Patented ☒ Pending				☐ Abandoned ☐ Expired		
Application No.	Cont	inuity Type	Prior App	lica	ation No. Filing Date (YYYY-MM-D		)	Patent Number	Issue Date (YYYY-MM-DD)	
17/327,568	is a Co	ntinuation of	16/912,59	0	2020-06-25			11,066,656	2021-07-20	
Prior Application	No. 16/9	12,590 - Statu	s:		☑ Pate	ented 🔲 Pending	, 🗆	Abandoned	☐ Expired	
16/912,590	is a Co	ntinuation of	15/226,489			2016-08-02	1	0,865,400	2020-12-15	
Prior Application	No. 15/2	26,489 - Statu	s:		☑ Pater	nted 🔲 Pending		Abandoned [	Expired	
Application No.	Conti	ontinuity Type Prior Appli			on No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	isional of	13/694,731			2012-12-28	ę	9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Statu	s:		☑ Pate	nted 🗌 Pending		Abandoned	☐ Expired	
Application Numb	er	Continuity	Туре	Pri	ior Applic	cation No.	Fili	ing Date (YY	YY-MM-DD)	
13/694,731		claims prior	ity to	61	/796,208		201	12-11-01		
Prior Application	No. 61/7	'96,208- Statu	s:		Patented	d 🗌 Pending 🔲	Aba	andoned 🛚	Expired	
Application Numb	er	Continuity	Туре	Pri	ior Applic	cation No.	Fili	Filing Date (YYYY-MM-DD)		
13/694,731		claims prior	ity to	61/631,313			201	2011-12-30		
Prior Application	No. 61/6	31,313 - Statu	s:		Patented	d 🗌 Pending 🔲	Aba	andoned 🛚	Expired	
Application No.	Con	tinuity Type	I	Application Filing Date No. (YYYY-MM-DD)			)	Patent Number	Issue Date (YYYY-MM-DD)	
17/327,568	also is a	Continuation of	of <b>16/824,5</b>	72	2020-03-19		11,041,149		2021-06-22	
Prior Application	No. 16/8	24,572 - Statu	s:		☑ Pate	ented  Pending	g ☐ Abandoned ☐ Expired			
Application No.	Con	tinuity Type	Prior A	No.		Filing Date (YYYY-MM-DD)	1	Patent Number	Issue Date (YYYY-MM-DD)	
16/824,572	is a Co	ntinuation of	15/226,4	189		2016-08-02		10,865,400	2020-12-15	
Prior Application	No. 15/2	26,489 - Statu	s:	$\boxtimes$	Patented	I ☐ Pending	[	Abandone	d 🗌 Expired	
Application No.	Con	tinuity Type	Prior A	oppli No.		Filing Date (YYYY-MM-DD)	)	Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	isional of	13/694,7	'31		2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Statu	s:		☑ Pate	ented  Pending	, 🗀	Abandoned	Expired	
Application Numb	er	Continuity Ty	/pe	Pri	ior Applic	ation Number	ı	Filing Date (Y	YYY-MM-DD)	
13/694,731		claims priority	to	61/	796,208			2012-11-01		
Prior Application	No. 61/7	96,208 - Statu	s:	☐ Patented ☐ Pending				☐ Abandoned ☒ Expired		
Application Numb	er	Continuity Ty	/pe	Prior Application Number				Filing Date (YYYY-MM-DD)		
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Application Da	sta Sh	oot 27 CED 1.7	76	At	torney D	ocket Number	33320.03087.US2E/3087K			
Application Da	ııa 311	eet 37 CFR 1.7		Ap	plication	n Number	18/068,418			
Title of Invention		PH20 POLYPER	PTIDE V	ARIA	ARIANTS, FORMULATIONS AND USES THEREOF					
13/694,731		claims priority to		61/	631,313		2011-12-30			
	Va. C4/6					□ Dandina		ad 🔽 Euminad		
Prior Application I	VO. 61/6	551,515 - Status:		Ш	Patented	☐ Pending	Abandone	ed 🛛 Expired		
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Application No.	• • • • • • • • • • • • • • • • • • • •		Appl No.		Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)			
17/327,568	also is	a Continuation of	15/226	,489		2016-08-02	10,865,400	2020-12-15		
Prior Application I	No. 15/2	226,489 - Status:			☑ Pate	ented 🗌 Pending	☐ Abandoned	I ☐ Expired		
Application No.	Co	ntinuity Type	Prior	Appl No.	ication	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
15/226,489	is a D	ivisional of	13/694	,731		2012-12-28	9,447,401	2016-09-20		
Prior Application I	No. 13/6	94,731 - Status:			☐ Patented ☐ Pending ☐ Abandoned ☐ Expire					
Application Number	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	YYYY-MM-DD)		
13/694,731		claims priority to		61/	796,208		2012-11-01			
Prior Application I	No. 61/7	'96,208 - Status:			Patented	I ☐ Pending	Abandon	ed 🛛 Expired		
Application Numb	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	YYYY-MM-DD)		
13/694,731		claims priority to		61/	631,313		2011-12-30			
Prior Application I	No. 61/6	31,313 - Status:			Patented	I ☐ Pending	☐ Abandoned ☒ Expired			
Application No.	Co	ntinuity Type	Prior A	Appl No.	ication	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
17/327,568	also is	a Continuation of	13/694	,731		2012-12-28	9,447,401	2016-09-20		
Prior Application I	No. 13/6	94,731 - Status:			☑ Pate	ented 🗌 Pending	☐ Abandoned	I ☐ Expired		
Application Number	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (	YYYY-MM-DD)		
13/694,731		claims priority to		61/	796,208		2012-11-01			
Prior Application I	No. 61/7	'96,208 - Status:			Patented	│ □ Pending	☐ Abandoned ☒ Expired			
Application Numb	er	Continuity Type		Pri	or Applic	ation Number	Filing Date (YYYY-MM-DD)			
13/694,731		claims priority to		61/	631,313		2011-12-30			
Prior Application I	No. 61/6	31,313 - Status:			Patented	☐ Pending	☐ Abandoned ☒ Expired			

Application Da	ata Sha	of 37 CEP	1 76	A	ttorney	Docket Number	3	33320.03087.US2E/3087K		
Application De	ata Sile	et 37 Clik	1.70	A	pplication	on Number	1	18/068,418		
Title of Invention		PH20 POLY	PEPTIDE V	٩R١	ANTS, F	ORMULATIONS A	ND	USES THEF	REOF	
Present Application	n No.	Continuity Type			Prior Application Number			Filing Date	(YYYY-MM-DD)	
This application		also is a Divi	sional of		17/327,5	86		2021-05-21		
Prior Application I	No. 17/32	.7,586 - Statu	ıs:		☐ Pate	nted 🛛 Pending		Abandoned	☐ Expired	
Application No.	Contin	nuity Type	uity Type Prior Applic			Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
17/327,586	is a Con	itinuation of	16/912,590			2020-06-25		1,066,656	2021-07-20	
Prior Application I	No. 16/91	2,590 - Statu	ıs:		☑ Pate	nted  Pending		Abandoned	☐ Expired	
Application No.	Contin	nuity Type	Prior Appli	cat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
16/912,590	is a Con	tinuation of	15/226,489			2016-08-02	10	,865,400	2020-12-15	
Prior Application I	No. 15/22	.6,489 - Statu	ıs:		☑ Pate	nted  Pending		Abandoned [	Expired	
Application No.	Contin	nuity Type	Prior Appli	cat	ion No.	Filing Date (YYYY-MM-DD)	ı	Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Divi	sional of	13/694,731			2012-12-28	9	,447,401	2016-09-20	
Prior Application I	No. 13/69	4,731 - Statu	ıs:		☑ Pate	ented 🔲 Pending		Abandoned	☐ Expired	
<b>Application Numb</b>	er	Continuity	Туре	Pı	ior Appli	cation No.	Filing Date (YYYY-MM-DD)			
13/694,731		claims prior	ity to	61	61/796,208			2012-11-01		
Prior Application I	No. 61/79	96,208- Statu	ıs:		☐ Patented ☐ Pending ☐			ndoned 🛚	Expired	
<b>Application Numb</b>	er	Continuity Type			ior Appli	cation No.	Fili	ng Date (YY)	YY-MM-DD)	
13/694,731		claims prior	aims priority to				201	1-12-30		
Prior Application I	No. 61/63	31,313 - Statu	ıs:		Patente	d 🗌 Pending 🔲	Aba	ndoned 🛚	Expired	
Application No.	Con	tinuity Type			pplication Filing Date No. (YYYY-MM-DD)			Patent Number	Issue Date (YYYY-MM-DD)	
17/327,586	also is a	a Continuation	of <b>16/824</b> ,	572	2	2020-03-19	1	1,041,149	2021-06-22	
Prior Application I	No. 16/82	4,572 status	:		☑ Pate	ented  Pending		Abandoned	☐ Expired	
Application No.	Con	tinuity Type		pp No	lication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
16/824,572	is a Cor	ntinuation of	15/226,	489	)	2016-08-02	10	0,865,400	2020-12-15	
Prior Application I	No. 15/22	.6,489 - Statu	ıs:		☑ Pate	ented  Pending		Abandoned	☐ Expired	
Application No.	Con	tinuity Type		pp No	lication	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	isional of	13/694,	731		2012-12-28	9	,447,401	2016-09-20	
Prior Application I	No. 13/69	4,731 - Statu	ıs:		☑ Pate	ented 🗌 Pending		Abandoned	☐ Expired	
<b>Application Numb</b>	er	Continuity	Туре	Р	rior Appli	ication No.	Fili	ng Date (YY	YY-MM-DD)	
13/694,731		claims prio	rity to	6	1/796,208		201	2-11-01		
Prior Application I	96,208- Statu	ıs:		] Patente	ed 🗌 Pending 🔲	Aba	andoned 🛚	Expired		
Application Numb	Continuity	Туре	Р	rior Appl	ication No.	Fili	Filing Date (YYYY-MM-DD)			
13/694,731		claims prio	rity to	6	1/631,313		2011-12-30			
Prior Application I	No. 61/63	31,313 - Statu	ıs:		Patente	ed 🗌 Pending 📗	Abandoned 🛛 Expired			

Application Da	ata Sho	of 37 CED	1 76	A	ttorney l	Docket Number	33320.03087	7.US2E/3087K		
Application De	11a 311e	et 37 OFK	1.70	Α	pplicatio	on Number	18/068,418	18/068,418		
Title of Invention		PH20 POLY	PEPTIDE V	٩RI	ANTS, F	ORMULATIONS A	ND USES THE	D USES THEREOF		
Application No.	Con	ntinuity Type		Prior Application No.		Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
17/327,586	is a Co	ntinuation of	15/226,	489		2016-08-02	10,865,400	2020-12-15		
Prior Application I	No. 15/22	26,489 - Statu	s:		☑ Pate	ented 🗌 Pending	Abandoned	☐ Expired		
Application No.	Con	ntinuity Type		ppl No.	plication Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)		
15/226,489	is a Div	isional of	13/694,	731		2012-12-28	9,447,401	2016-09-20		
Prior Application I	No. 13/69	94,731 - Status	s:		☑ Pate	ented 🗌 Pending	☐ Abandoned	☐ Expired		
<b>Application Numb</b>	er	Continuity	Туре	Pr	ior Appli	ication No.	Filing Date (YY	YY-MM-DD)		
13/694,731		claims prior	ity to	61	/796,208		2012-11-01			
Prior Application I	No. 61/7	96,208- Status	s:		Patente	ed 🗌 Pending 🔲	Abandoned 🛚	Expired		
<b>Application Numb</b>	er	Continuity	Туре	Pr	ior Appli	ication No.	Filing Date (YY	YY-MM-DD)		
13/694,731		claims prior	ity to	61	/631,313		2011-12-30			
Prior Application I	No. 61/63	31,313 - Status	s:		Patente	ed 🗌 Pending 🔲	Abandoned 🛚	Expired		
Application No.	Conti	nuity Type	Prior App	ication No. Filing Date (YYYY-MM-DD)			Patent Number	Issue Date (YYYY-MM-DD)		
17/327,586	also is a of	continuation	ontinuation <b>13/694,73</b>			2012-12-28	9,447,401	2016-09-20		
Prior Application I	No. 13/69	94,731 - Status	s:		☑ Pat	ented 🗌 Pending	☐ Abandoned	☐ Expired		
<b>Application Numb</b>	er	Continuity Ty	pe	Prior Application Number			Filing Date (	YYYY-MM-DD)		
13/694,731		claims priority	to	61/	796,208		2012-11-01			
Prior Application I	No. 61/79	96,208 - Statu	s:		Patente	d Pending	☐ Abandoned ☒ Expired			
Application Numb	er (	Continuity Ty	ре	Pri	or Appli	cation Number	Filing Date (YYYY-MM-DD)			
13/694,731		claims priority	to	61/	631,313		2011-12-30			
Prior Application I	No. 61/63	31,313 - Status	s:		Patente	d Pending	☐ Abandoned ☒ Expired			
							1	1		
Present Application No.	Contir	nuity Type	Prior Appli	cati	on No.	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
This application	is a Di	ivisional of	16/912,590			2020-06-25	11,066,656	2021-07-20		
Prior Application I	No. 16/91	12,590 - Status	s:		□ Pate	nted  Pending	Abandoned	Expired		
Application No.	Contir	nuity Type	Prior Appli	cati	on No.	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
16/912,590	is a Cor	ntinuation of	15/226,489			2016-08-02	10,865,400	2020-12-15		
Prior Application I	No. 15/22	26,489 - Status	s:		□ Pate	nted  Pending	Abandoned	☐ Expired		
Application No.	Contir	nuity Type	Prior Appli	cati	on No.	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		
15/226,489	is a Divi	isional of	13/694,731			2012-12-28	9,447,401	2016-09-20		
Prior Application	No. 13/69	94,731 - Status	s:		□ Pate	ented  Pending	☐ Abandoned	☐ Expired		
Application No.	Conti	inuity Type	Prior Ap Num			Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)		

Application Data Sheet 37 CFR 1.76					torney D	Oocket Number		33320.03087.US2E/3087K		
Application Da	ata Sne	et 37 CFR	1.76	A	plicatio	n Number		18/068,418		
Title of Invention		PH20 POLYP	PEPTIDE V	ARIANTS, FORMULATIONS AND USES					REOF	
16/912,590	also is a	a Divisional of	13/694,73	1	2012-12-28		9,447,401	2016-09-20		
Prior Application	No. 13/6	94,731 - Status	:		□ Patented □ Pending			Abandoned	Expired	
Application Numb	er	Continuity 1	Гуре	Pri	or Applic	ation No.	Fi	ling Date (YY	YY-MM-DD)	
13/694,731		claims priorit	y to	61/	796,208		20	)12-11-01		
Prior Application	No. 61/7	'96,208- Status	:		Patented	d ☐ Pending ☐	Αl	pandoned 🛛	Expired	
Application Numb	er	Continuity 1	Гуре	Pri	or Applic	ation No.	Fi	ling Date (YY	YY-MM-DD)	
13/694,731		claims priorit	y to	61/	631,313		20	)11-12-30		
Prior Application	No. 61/6	31,313 - Status	:		Patented	d 🗌 Pending 🔲	Αl	pandoned 🛚	Expired	
Present	Cont	inuity Type	Prior App	olicat	ion No.	Filing Date		Patent	Issue Date	
Application No.						(YYYY-MM-DD)		Number	(YYYY-MM-DD)	
This application	is a Div	risional of	16/824,57	2		2020-03-19		11,041,149	2021-06-22	
Prior Application	No. 16/8	24,572 - Status	:		☑ Pate	ented 🗌 Pending	, [	Abandoned	☐ Expired	
Application No.	Cont	inuity Type	Prior App	olicat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
16/824,572	is a Co	ntinuation of	15/226,48	9		2016-08-02		10,865,400	2020-12-15	
Prior Application	No. 15/2	26,489 - Status	:	$\boxtimes$	Patented	I ☐ Pending		☐ Abandone	ed 🗌 Expired	
Application No.	Cont	inuity Type	Prior App	olicat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	risional of	13/694,73	1		2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Status	:		☑ Pate	ented  Pending	, [	Abandoned	Expired	
Application No.	Cont	inuity Type	Prior App	olicat	ion No.	Filing Date (YYYY-MM-DD)	Patent Number		Issue Date (YYYY-MM-DD)	
16/824,572	also is a	a Divisional of	13/694,73	1		2012-12-28		9,447,401	2016-09-20	
Prior Application	No. 13/6	94,731 - Status	:		☑ Pate	ented 🔲 Pending		☐ Abandoned ☐ Expired		
Application Numb	er	Continuity Typ	ре	Pri	or Applic	ation Number	Filing Date (YYYY-MM-DD)			
13/694,731		claims priority t	0	61/	796,208			2012-11-01		
Prior Application	No. 61/7	96,208 - Status	:		Patented	I ☐ Pending		Abandone	ed 🛛 Expired	
Application Numb	er	Continuity Typ	ре	Pri	or Applic	ation Number		Filing Date (	YYYY-MM-DD)	
13/694,731		claims priority t	.0	61/	631,313			2011-12-30		
Prior Application	No. 61/6	31,313 - Status	:		Patented	I ☐ Pending		Abandone	ed 🛛 Expired	
Present Application No.	Cont	inuity Type	Prior App	olicat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
This application	is a Co	ntinuation of	15/226,48	9		2016-08-02	1	10,865,400	2020-12-15	
Prior Application	No. 15/2	26,489 - Status	:	×	Patented	I ☐ Pending		Abandone	ed 🗌 Expired	
Application No.	Cont	inuity Type	Prior App	licat	ion No.	Filing Date (YYYY-MM-DD)		Patent Number	Issue Date (YYYY-MM-DD)	
15/226,489	is a Div	risional of	13/694,73	1		2012-12-28	$\dagger$	9,447,401	2016-09-20	
Prior Application No. 13/694.731 - Status:					☑ Pate	ented □ Pending	 ı [		L	

Application Data Sheet 37 CFR 1.76					Attorney Docket Number				33320.03087.US2E/3087K		
Application Da	eel 37 CFR 1.76			Application Number				18/068,418			
Title of Invention PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF									EOF		
Application Numb	Continuity Type			Prior Application Number				Filing Date (YYYY-MM-DD)			
13/694,731					61/796,208				2012-11-01		
Prior Application I	<u> </u>			☐ Patented ☐ Pending			ПА	☐ Abandoned ☒ Expired			
Application Number		Continuity Type			Prior Application Number				Filing Date (YYYY-MM-DD)		
13/694,731		claims priority to		61/631,313				+ -	2011-12-30		
Prior Application No. 61/63				16	☐ Patented ☐ Pending		A	☐ Abandoned ☐ Expired			
, , , , , , , , , , , , , , , , , , , ,											
Present Con Application No.		ntinuity Type	Prior		pplication No.		Filing Date (YYYY-MM- DD)	_	atent umber	Issue Date (YYYY-MM- DD)	
This application also is a		Divisional of 13/694		,73	731		2012-12-28	9,4	9,447,401 2016-09-20		
Prior Application No. 13/694,731 - Status:  ☐ Patented ☐ Pending ☐ Abandoned ☐									☐ Expired		
Application Number		Continuity Type			Prior Applicati		ion No.	Filing	Filing Date (YYYY-MM-DD)		
13/694,731		claims priority to			61/796,208			2012	2012-11-01		
Prior Application I	96,208- Status:			☐ Patented ☐ Pending ☐			] Aban	Abandoned 🛛 Expired			
Application Number		Continuity Type			Prior Application No.			Filing	Filing Date (YYYY-MM-DD)		
13/694,731		claims priority to			61/631,313			2011	2011-12-30		
Prior Application No. 61/631,313 - Status: ☐ Patented ☐ Pending ☐ Abandoned ☒ Ex								Expired			
Foreign Priority Information:											
This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55.											
Application Number		Country	Filing Date ('DD)		YYYY-MM-		Priority CI	aimed		cess Code applicable)	
			,				☐ Yes [	] No			
Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:  If checked, this application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.											
Authorization or Opt-Out of Authorization to Permit Access:											
When this Application permit a participating subsection 1 below) paragraph B in subsection 1 below) paragraph B in subsection by cheauthorization	g foreign and the ection 1 oose not cking the of the A	intellectual pro European Pate below). to provide an a e corresponding pplication Data	pperty (IP) officent Office (EP) authorization in grown box A or B on Sheet is <b>ONI</b>	ce a O) der or b <b>LY</b>	access to the in access to any natified in subsection of the reviewed and	nsta sea ection pro	ant application arch results fro on 1 below, apple 2 below.	as-filed in the ins plicant m	(see parag stant applic ust opt-out L filing of a	raph A in ation (see of the application.	
After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.											

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	33320.03087.US2E/3087K	
		Application Number	18/068,418	
Title of Invention PH20 POLYPEPTIDE VA		ARIANTS, FORMULATIONS AN	D USES THEREOF	

- A. Priority Document Exchange (PDX) Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h) (1).
- B. Search Results from U.S. Application to EPO Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2.	Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)
	A. Applicant <u>DOES NOT</u> authorize the USPTO to permit a participating foreign IP office access to the instant application

as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.
 B. Applicant <u>DOES NOT</u> authorize the USPTO to transmit to the EPO any search results from the instant patent

application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

**NOTE:** Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

#### **Applicant Information:**

	nformation in this section does not sometiment recorded by the Office.	ubstitute for	compl	liance with any	requirement of part 3 of Title 37 of	
Applicant 1						
completed. The informapplicant under 37 CFF assign the invention, or CFR 1.46. If the applic person who otherwise s	ventor (or the remaining joint inventor ation to be provided in this section is 3.1.43; or the name and address of toperson who otherwise shows sufficient is an applicant under 37 CFR 1.4 shows sufficient proprietary interest) the applicant should be identified in	s the name a the assignee ient proprieta 46 (assignee together wit	nd ad , perso ary into , pers	ddress of the leg son to whom the terest in the mat son to whom the	al representative who is the inventor is under an obligation to ter who is the applicant under 37 inventor is obligated to assign, or	
☐ Person to whom the inventor is obligated to assign ☐ Person who shows sufficient proprietary interest						
If applicant is the lega	al representative, indicate the au	thority to fil	e the	patent applica	ation, the inventor is:	
Deceased	☐ Legally in	ncapacitate	d			
Name of the Decease	ed or Legally Incapacitated Inver	ntor:				
If the Applicant is a	n Organization check here.			$\boxtimes$		
Organization Name:	HALOZYME, INC.					
Mailing Address Inf	ormation For Applicant:					
Address 1	11388 Sorrento Valley Road	12390 EI C	<u>amino</u>	o Real		
Address 2						
City San Diego State/Province CA					CA	
Country	US	Postal C	ode	<del>92121</del> <u>9213</u>	<u>0</u>	
Phone Number		Fax Num	ber			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	33320.03087.US2E/3087K	
		Application Number	18/068,418	
Title of Invention PH20 POLYPEPTIDE VA		RIANTS, FORMULATIONS AN	D USES THEREOF	

Email Address	
If needed, Additional Applicant E	Data may be added within this form.

#### Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications								
Signature /Stephanie Seidman/ Date (YYYY-MM-DD) 2023-04-05								
First Name	Stephanie	Last Name	Seidman	Registration Number	33,779			
Additional Signatures may be added within this form.								

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Electronic Acknowledgement Receipt				
EFS ID:	47795530			
Application Number:	18068418			
International Application Number:				
Confirmation Number:	5769			
Title of Invention:	PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF			
First Named Inventor/Applicant Name:	Ge Wei			
Customer Number:	13565			
Filer:	Stephanie L. Seidman/Javier Wong			
Filer Authorized By:	Stephanie L. Seidman			
Attorney Docket Number:	33320.03087.US2E/3087K			
Receipt Date:	05-APR-2023			
Filing Date:	19-DEC-2022			
Time Stamp:	15:46:02			
Application Type:	Utility under 35 USC 111(a)			

## **Payment information:**

Submitted with Payment no		no						
File Listing:								
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)		
1	Transmittal Letter		3087Ktra04-05-23.pdf	143701	no	1		
Warnings:				7ad9468bdcc75a257a3:96dc2f4e5ad12f6c a5c4				

Information	•				
			453075		
2	Request for Corrected Filing Receipt	3087Kcfr04-05-23.pdf	b5baa7415147f84bfd4fdc09151e70fe0438 d519	no	7
Warnings:			-		
Information	<b>!</b>				
			277586		
3	Application Data Sheet	3087 Kads 04-05-23. pdf	fe8756feca0bcd17e681a8e869a0855c5878 7d03	no	10
Warnings:					
Information	:				
This is not an U	JSPTO supplied ADS fillable form				
		Total Files Size (in bytes	87	74362	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Wei *et al.*Serial No.: 18/068,418

Art Unit: To be assigned
Examiner: To be assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

**THEREOF** 

**Mail Stop Missing Parts** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

#### TRANSMITTAL LETTER

#### Dear Sir:

Transmitted herewith are a *Request for Corrected Filing Receipt* (1 page); a copy of the *Filing Receipt*, mailed March 30, 2023, with annotated corrections (5 pages), and an updated *Application Data Sheet* (10 pages) for filing in connection with the above-captioned application.

A fee for filing this request should not be due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 50-0911, as stated below.



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-0911.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP 4655 Executive Drive, Ste. 700 San Diego, California 92121 Telephone: (619) 595-8010

Telephone: (619) 595-8010 Facsimile: (619) 595-8135

email: stephanie.seidman@dentons.com

#### CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on April 05, 2023.

/Javier Wong/



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FILING or GRP ART FIL FEE REC'D NUMBER UNIT ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS 371(c) DATE 18/068,418 12/19/2022 **OPAP** 5000 33320.03087.US2E/3087K

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121

**CONFIRMATION NO. 5769** REPLACEMENT FILING RECEIPT

Date Mailed: 04/28/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

#### Inventor(s)

Ge Wei, San Diego, CA; H. Michael Shepard, Eugene, OR; Qiping Zhao, San Diego, CA: Robert James Connor, Oceanside, CA;

#### Applicant(s)

Halozyme, Inc., San Diego, CA;

#### Power of Attorney:

STEPHANIE SEIDMAN -33779 FRANK MISKIEL -53332 JOSHUA GALGANO -74802

#### Domestic Priority data as claimed by applicant

This application is a DIV of 17/327,568 05/21/2021 which is a CON of 16/912,590 06/25/2020 PAT 11,066,656 which is a CON of 15/226.489 08/02/2016 PAT 10.865.400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012 and claims benefit of 61/631,313 12/30/2011 and said 17/327,568 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149 which is a CON of 15/226,489 08/02/2016 PAT 10,865,400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012 page 1 of 5

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and claims benefit of 61/631.313 12/30/2011
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**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

#### Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/29/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is **US 18/068,418** 

**Projected Publication Date:** 07/06/2023

Non-Publication Request: No Early Publication Request: No

Title

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Preliminary Class** 

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

page 3 of 5

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

## LICENSE FOR FOREIGN FILING UNDER

#### Title 35, United States Code, Section 184

#### Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

#### SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

page 4 of 5

community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <a href="http://www.SelectUSA.gov">http://www.SelectUSA.gov</a> or call +1-202-482-6800.



### UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address. COMMISSIONER FOR PATENTS PO. Box 1450 Alexandra, Virginia 22313-1450 www.uspfo.gov

 APPLICATION NUMBER
 FILING OR 371(C) DATE
 FIRST NAMED APPLICANT
 ATTY. DOCKET NO./TITLE

 18/068,418
 12/19/2022
 Ge Wei
 33320.03087.US2E/3087K

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121 CONFIRMATION NO. 5769
IMPROPER CPOA LETTER
\*OC000000056443935\*

Date Mailed: 04/28/2023

#### NOTICE REGARDING POWER OF ATTORNEY

This is in response to the power of attorney filed 04/05/2023. The power of attorney in this application is not accepted for the reason(s) listed below:

• The power of attorney you provided did not comply with the power of attorney rules that became effective on June 25, 2004. See 37 CFR 1.32 and 69 Fed. Reg. 29865.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

13565
Dentons US LLP
4655 Executive Drive
Suite 700
San Diego, CA 92121
UNITED STATES

/byemane/

page 1 of 1

Electronic Acknowledgement Receipt				
EFS ID:	48025241			
Application Number:	18068418			
International Application Number:				
Confirmation Number:	5769			
Title of Invention:	PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF			
First Named Inventor/Applicant Name:	Ge Wei			
Customer Number:	13565			
Filer:	Stephanie L. Seidman/Jimmy Schaub			
Filer Authorized By:	Stephanie L. Seidman			
Attorney Docket Number:	33320.03087.US2E/3087K			
Receipt Date:	18-MAY-2023			
Filing Date:	19-DEC-2022			
Time Stamp:	16:55:58			
Application Type:	Utility under 35 USC 111(a)			

## **Payment information:**

Submitted with Payment no		no						
File Listing:								
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)		
1	Transmittal Letter		3087Ktra_000.pdf	142455 e8a350bb206f06ffa8228af72d7bae4c5b94 6f52	no	1		
Warnings:	-	1		+				

Information	1				
			178758		
2	Request for Corrected Filing Receipt	3087Kcfr_000.pdf	d9038febf72df526942085743771747d404a e871	no	2
Warnings:					
Information	<b>!</b>				
		3087K-04-28-2023-	273182		
3	Miscellaneous Incoming Letter	Annotated_Filing_Receipt-180 68418.pdf	dca28eaf5741130e9f5927daa6aaec5de62a 9202	no	5
Warnings:	-		-		
Information	:				
		Total Files Size (in bytes)	59	94395	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Wei *et al.*Serial No. : 18/068,418

Art Unit : To be assigned Examiner : To be assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

**THEREOF** 

**Mail Stop Missing Parts** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

#### TRANSMITTAL LETTER

#### Dear Sir:

Transmitted herewith are a *Request for Corrected Filing Receipt* (1 page); a copy of the *Replacement Filing Receipt*, mailed April 28, 2023, with annotated corrections (5 pages), for filing in connection with the above-captioned application.

A fee for filing this request should not be due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 50-0911, as stated below.



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-0911.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP 4655 Executive Drive, Ste. 700 San Diego, California 92121 Telephone: (619) 595-8010 Facsimile: (619) 595-8135

email: stephanie.seidman@dentons.com

#### CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on  ${\bf May 18, 2023}$ .

/Jimmy Schaub/ Jimmy Schaub

Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Ge WEI *et al.* Art Unit : Not yet assigned Serial No. : 18/068,418 Examiner : Not yet assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

THEREOF

**Mail Stop Missing Parts** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

#### REQUEST FOR CORRECTED FILING RECEIPT

Dear Sir:

Transmitted herewith are this *Request for Corrected Filing Receipt*, a copy of the *Replacement Filing Receipt*, mailed April 28, 2023, marked to show the correction.

Please correct the Power of Attorney section to read as follows:

STEPHANIE SEIDMAN – 33779 FRANK MISKIEL – 53332

JOSHUA GALGANO 74802 JAMES M. TURNER – 74,602

Applicant requests correction of the error introduced by the USPTO in the Power of Attorney section, which erroneously lists Joshua Galgano – 74802. The Power of Attorney filed on December 19, 2022, does <u>not</u> list Joshua Galgano and does <u>not</u> list attorney registration number 74802. There is a one digit difference between the attorney registration numbers (74802 vs. 74602). Due to a USPTO clerical error in transcribing the attorney registration number, an incorrect attorney has been listed in the Power of Attorney section. Please remove Joshua Galgano–74802 and replace with the correct attorney supplied above.

Applicant respectfully requests provision of a corrected filing receipt to reflect the updated information and correction to the power of attorney section.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP

4655 Executive Drive, Suite 700

San Diego, CA 92121 Telephone: (619) 595-8010 Facsimile: (619) 595-8135

email: stephanie.seidman@dentons.com

CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and

Trademark Office on May 18, 2023.

/Jimmy Schaub/ Jimmy Schaub Inventor(s): : Ge Wei *et al*.
Serial No. : 18/068,327
Filed : December 19, Attorney's Docket No.: 33320.03087.US2E/3087K : 18/068,327 : December 19, 2022 **Request for Corrected Filing Receipt** 

## **ATTACHMENT 1**

Copy of Filing Receipt, mailed April 28, 2023, with annotated correction





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vriginia 22313-1450 www.uspio.gov

FILING or 371(c) DATE GRP ART FIL FEE REC'D UNIT ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS NUMBER 18/068,418 12/19/2022 OPAP 5000 33320.03087.US2E/3087K 35

13565 Dentons US LLP 4655 Executive Drive

Suite 700 San Diego, CA 92121

**CONFIRMATION NO. 5769** REPLACEMENT FILING RECEIPT

Date Mailed: 04/28/2023

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Halozyme, Inc., San Diego, CA;

#### Power of Attorney:

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JOSHUA GALGANO 74802 JAMES M. TURNER - 74602

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## COPY

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page 2 of 5



Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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If Required, Foreign Filing License Granted: 03/29/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is **US 18/068,418** 

**Projected Publication Date:** 07/06/2023

Non-Publication Request: No Early Publication Request: No

Title

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Preliminary Class** 

424

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Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

page 3 of 5



For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

#### LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

#### SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

page 4 of 5

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page 5 of 5



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FILING or GRP ART FIL FEE REC'D NUMBER UNIT ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS 371(c) DATE 18/068,418 12/19/2022 **OPAP** 5000 33320.03087.US2E/3087K

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121

**CONFIRMATION NO. 5769** REPLACEMENT FILING RECEIPT

Date Mailed: 05/23/2023

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

#### Inventor(s)

Ge Wei, San Diego, CA; H. Michael Shepard, Eugene, OR; Qiping Zhao, San Diego, CA: Robert James Connor, Oceanside, CA;

#### Applicant(s)

Halozyme, Inc., San Diego, CA;

#### Power of Attorney:

STEPHANIE SEIDMAN -33779 FRANK MISKIEL -53332 JAMES TURNER -74602

#### Domestic Priority data as claimed by applicant

This application is a DIV of 17/327,568 05/21/2021 which is a CON of 16/912,590 06/25/2020 PAT 11,066,656 which is a CON of 15/226.489 08/02/2016 PAT 10.865.400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012 and claims benefit of 61/631,313 12/30/2011 and said 17/327,568 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149 which is a CON of 15/226,489 08/02/2016 PAT 10,865,400 which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401 which claims benefit of 61/796,208 11/01/2012 page 1 of 5

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and claims benefit of 61/631.313 12/30/2011
and said 17/327,568 05/21/2021 is a CON of 15/226,489 08/02/2016 PAT 10,865,400
    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
and claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
This application is a DIV of 17/327,586 05/21/2021
    which is a CON of 16/912,590 06/25/2020 PAT 11,066,656
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and said 17/327,586 05/21/2021 is a CON of 16/824,572 03/19/2020 PAT 11,041,149
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    which is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
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This application is a DIV of 13/694,731 12/28/2012 PAT 9,447,401
    which claims benefit of 61/796,208 11/01/2012
and claims benefit of 61/631,313 12/30/2011
```

**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> for more information.) - None. Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

#### Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 03/29/2023

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is **US 18/068,418** 

**Projected Publication Date:** 07/06/2023

Non-Publication Request: No Early Publication Request: No

Title

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Preliminary Class** 

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

#### PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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page 3 of 5

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### Title 37, Code of Federal Regulations, 5.11 & 5.15

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

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community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <a href="http://www.SelectUSA.gov">http://www.SelectUSA.gov</a> or call +1-202-482-6800.



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

APPLICATION NUMBER FILING OR 371(C) DATE FIRST NAMED APPLICANT

12/19/2022 Ge Wei

ATTY. DOCKET NO./TITLE 33320.03087.US2E/3087K

**CONFIRMATION NO. 5769** 

13565 Dentons US LLP 4655 Executive Drive Suite 700 San Diego, CA 92121

18/068,418

\*OC00000060428970\*

**PUBLICATION NOTICE** 

Date Mailed: 08/11/2023

Title:PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

Publication No.US-2023-0250409-A1 Publication Date:08/10/2023

#### NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

page 1 of 1

Doc Code: PA..

Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number			18/068,418			
Filing Date			12/19/2022			
First Named Inventor			Ge Wei			
Title		PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF				
Art Unit			NYA			
Examiner Name			NYA			
Attorney Docket Number		lumber	063995-01-5105-US10			
SIGNATURE of A		IRE of A	oplicant or Patent Practitioner			
	Signature	/Robert Smyth/			Date (Optional)	
	Name	Robert Smyth			Registration Number	50,801
	Title (if Applicant is a juristic entity)					
	Applicant Name (if Applicant is a juristic entity)  NOTE: This form must be signed in accordance with 37			CFR 1 33. See 37 CFR 1.4(d) fo	or signature requir	ements and certifications. If
more than one applicant, use multiple forms.				omonio and ooranisations		
	*Total of 1 forms are submitted.					

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Document Description: Power of Attorney

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Approved for use through 03/31/2021, OMB 0651-0035
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#### POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in <u>either</u> the attached transmittal letter or the boxes below.						
		Application Number		Filing Date		
(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)  I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:  OR  I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)						
	recognize or the boxes		e address for the	ne application iden	tified in the attached transmittal	
	OR	associated with the above-mention associated with Customer Number	·	ber		
jananany	OR					
	Firm or Individual Na	me		***************************************		
Address						
City	***************************************		State		Zip	
Country						
Telepho	ne		Ema	311		
I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):						
HA	LOZY	ME, INC.				
	Inventor or Joint Inventor (title not required below)					
Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)						
8/	Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)					
Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)						
SIGNATURE of Applicant for Patent						
The undersigned (whose title த் பிறிர்செல்ல) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).						
Signature / Mark Swyder / Date (Optional) 05-Jan-2023						
Name Mark Srigder 1884 94						
Title	Title Senior Vice President, General Counsel, CCO & Secretary					
	NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.					
<b>✓</b> Total	of 1	forms are submitted.	***************************************			

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





## **ELECTRONIC ACKNOWLEDGEMENT RECEIPT**

APPLICATION # **18/068,418** 

RECEIPT DATE / TIME 10/27/2023 02:34:53 PM ET ATTORNEY DOCKET #

33320.03087.US2E/3087K

### **Title of Invention**

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

PATENT # -

under 35 USC 111(a)

CONFIRMATION # 5769

FILED BY Collins Mba-Jonas

PATENT CENTER # 63084735

FILING DATE 12/19/2022

**CUSTOMER # 13565** 

FIRST NAMED Ge Wei

INVENTOR

CORRESPONDENCE ADDRESS

AUTHORIZED BY Robert Smyth

#### **Documents**

## **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
20231026_POA.pdf	2	Power of Attorney	463 KB

## Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
20231026_POA.pdf	D538DEADBBD8B182E6139F05C8F2F0F103E098AA861196C4F 7B185BB550CEAF59BF50C24C34D5722ED9B446B65A6853CB9
	0415FBAA89F69F0942BFA5B55B9FC1

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. Box 1450 Alexandria, riginia 22313-1450 www.uspto.gov

 APPLICATION NUMBER
 FILING OR 371(C) DATE
 FIRST NAMED APPLICANT
 ATTY. DOCKET NO./ITTLE

 18/068,418
 12/19/2022
 Ge Wei
 063995-01-5105-US10

28977 MORGAN, LEWIS & BOCKIUS LLP (PH) 1701 MARKET STREET PHILADELPHIA, PA 19103-2921 CONFIRMATION NO. 5769
POA ACCEPTANCE LETTER

Date Mailed: 11/01/2023

### NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/27/2023.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dtdinh/	



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address. COMMISSIONER FOR PATENTS PO. Box 1450 Alexandra, Virginia 22313-1450 www.uspfo.gov

 APPLICATION NUMBER
 FILING OR 371(C) DATE
 FIRST NAMED APPLICANT
 ATTY. DOCKET NO./TITLE

 18/068,418
 12/19/2022
 Ge Wei
 33320.03087.US2E/3087K

13565

Womble Bond Dickinson/Seidman Group Attn: IP Docketing PO. Box 570489 Atlanta, GA 30357-0037 CONFIRMATION NO. 5769
POWER OF ATTORNEY NOTICE

Date Mailed: 11/01/2023

#### NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/27/2023.

• The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dtdinh/



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/068,418	12/19/2022	Ge Wei	063995-01-5105-US10	5769
	7590 02/20/202 & Bockius LLP (PH)	EXAMINER		
2222 Market St	treet		MCKNIGHT, CIARA A	
Philadelphia, P	A 19103		ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			02/20/2024	ELECTRONIC

### Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

judith.troilo@morganlewis.com phpatentcorrespondence@morganlewis.com

	18/068,418 Applicant(s) Wei et al.					
Office Action Summary	Examiner CIARA A MCKNIGHT	Art Unit 1656	AIA (FITF) Status No			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) ☑ Responsive to communication(s) filed on 12/	<u>19/2022</u> .					
☐ A declaration(s)/affidavit(s) under <b>37 CFR 1</b>	.130(b) was/were filed on	<u>_</u> ·				
2a) ☐ This action is <b>FINAL</b> . 2b) €	This action is non-final.					
3) An election was made by the applicant in res on; the restriction requirement and election						
4) Since this application is in condition for allow closed in accordance with the practice under	ance except for formal matters,	prosecution	as to the merits is			
Disposition of Claims*						
5) Claim(s) 1-35 is/are pending in the appl	lication.					
5a) Of the above claim(s) is/are withdra						
6) Claim(s) is/are allowed.						
7) Claim(s) is/are rejected.						
8) Claim(s) is/are objected to.						
9) 🗹 Claim(s) 1-35 are subject to restriction and	d/or election requirement					
* If any claims have been determined <u>allowable</u> , you may be elig	•	ecution High	way program at a			
participating intellectual property office for the corresponding ap	pplication. For more information, plea	se see				
$\underline{\text{http://www.uspto.gov/patents/init\_events/pph/index.jsp}} \text{ or send}$	an inquiry to PPHfeedback@uspto.	gov.				
Application Papers						
10)☐ The specification is objected to by the Exami	ner.					
11) ☐ The drawing(s) filed on is/are: a) ☐ a	ccepted or b) ☐ objected to by	the Examine	∍r.			
Applicant may not request that any objection to the dr	• • •	` '				
Replacement drawing sheet(s) including the correction	on is required if the drawing(s) is object	ted to. See 37	CFR 1.121(d).			
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  Certified copies:						
a) ☐ All b) ☐ Some** c) ☐ None of the	he:					
1. Certified copies of the priority docum	nents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
** See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  3) Interview Summary (PTO-413)						
	Paner No(s)/Mail D					
Paper No(s)/Mail Date  1) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  4) Other:						

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13) Application/Control Number: 18/068,418 Page 2

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#### **DETAILED ACTION**

#### Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30 and 34-35, drawn to a modified PH20 polypeptide comprising one or more amino acid substitutions or modifications and pharmaceutical composition comprising said polypeptide, classified in CPC C12N 9/2474.
- II. Claims 31-33, drawn to a method of treating hyaluronan-associated conditions or diseases, including inflammatory disease, tumor, or cancer, with a PH20 polypeptide and therapeutic agent, classified G01N 2333/914.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide of invention I can be used in a material different process apart from invention II, such as raising polyclonal antibodies in mice for diagnostic or laboratory use.

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Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

- a. the inventions have acquired a separate status in the art in view of their different classification;
- b. the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- c. the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- d. another invention;
- e. the prior art applicable to one invention would not likely be applicable to the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Each group is under a unique CPC class and will require a separate and distinct keyword search, where group I is classified under CPC C12N 9/2474 and group II is classified under G01N 2333/914.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

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The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur,

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applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CIARA A MCKNIGHT whose telephone number is (703)756-4791. The examiner can normally be reached M-F 8:00am-4:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571)272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit:

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https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-

center for more information about Patent Center and

https://www.uspto.gov/patents/docx for information about filing in DOCX format.

For additional questions, contact the Electronic Business Center (EBC) at 866-217-

9197 (toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CIARA A MCKNIGHT/ Examiner, Art Unit 1656

/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656 Page 7

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE to a collection of information unless it displays a valid OMB control number.

P	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875			NRECORD	Application or Docket Number Filing Date 18/068,418 Filing Date		To be Mailed			
	ENTITY:  LARGE SMALL MICRO									
	APPLICATION AS FILED - PART I									
_	FOR	$\longrightarrow$		Column 1 IBER FIL		(Column 2) NUMBER EXTRA		RATE (\$)	1	FEE (\$)
	BASIC FEE			N/A		N/A		N/A		
	(37 CFR 1.16(a), (b), c SEARCH FEE	or (c))		N/A		N/A		N/A		
$\Box$	(37 CFR 1.16(k), (i), or									
	(37 CFR 1.16(o), (p), o			N/A		N/A		N/A		
(37 0	CFR 1.16(i))			mir	nus 20 = *			x \$100 =		
	EPENDENT CLAIM CFR 1.16(h))	S		m	inus 3 = *			x \$480 =		
If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).										
	MULTIPLE DEPENI			•	3,,,					
* If th	ne difference in co	olumn 1 is l	ess tha	an zero,	enter "0" in colu	ımn 2.		TOTAL		
					APPLICAT	TON AS AME	NDED - PA	ART II		
$\Box$	(Column 1) CLAIMS		1 1)		(Column 2) HIGHEST	(Column 3	)			
AMENDMENT	03/05/2024	REMAININ AFTER AMENDMI			NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
Total * 35			Minus	** 35	= 0		x \$100 =		0	
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≩	Application S	`		. ,	·					
		SENTATIO	N OF N	MULTIP	LE DEPENDEN	T CLAIM (37 CF	R			
	1.10()/)							TOTAL ADD'L FE	E	0
		(Column			(Column 2)	(Column 3	)			
Þ		CLAIMS REMAINII AFTEF AMENDM	ING R		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
삘	Total (37 CFR 1.16(i))	*		Minus	**	=		x \$0 =		
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AME	Application Size Fee (37 CFR 1.16(s))									
`	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					R				
	I ···~v///							TOTAL ADD'L FE	Ε	
* If t	he entry in column	1 is less than	n the ent	try in colu	umn 2, write "0" in	column 3.		LIE		
** If	the "Highest Numbe	er Previously	Paid F	or" IN TH	HIS SPACE is less	than 20, enter "20	u.	/LISA THOMA	S/	
	*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The	The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS

ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





# **ELECTRONIC ACKNOWLEDGEMENT RECEIPT**

APPLICATION # RECEIPT DATE / TIME ATTORNEY DOCKET#

03/05/2024 12:28:29 PM Z ET 063995-01-5105-US10 18/068,418

## Title of Invention

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

# **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application PATENT# -

under 35 USC 111(a)

CONFIRMATION # 5769 FILED BY Kimberly Pollard

PATENT CENTER # 64552261 FILING DATE 12/19/2022

CUSTOMER # 28977 FIRST NAMED Ge Wei

INVENTOR

CORRESPONDENCE ADDRESS AUTHORIZED BY Kalpesh Upadhye

## **Documents**

# **TOTAL DOCUMENTS: 3**

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
063995-01-5105- US10_RESTRICTIONRESP ONSE.pdf		5	-	133 KB
063995-01-5105- US10_RESTRICTIONRES PONSE-ELCpdf	(1-1)	1	Response to Election / Restriction Filed	95 KB
063995-01-5105- US10_RESTRICTIONRES PONSE-CLM.pdf	(2-4)	3	Claims	107 KB
063995-01-5105- US10_RESTRICTIONRES PONSE-REM.pdf	(5-5)	1	Applicant Arguments/Remarks Made in an Amendment	116 KB

## **Digest**

DOOLINGENIT

DOCUMENT	MESSAGE DIGEST(SHA-512)
063995-01-5105-	86DB0D0368CCC9C2F74D7AD3B973BA11A03893C900EBA8D3
US10_RESTRICTIONRESPON	666E59782A0867F5E089539F211123BCEABAD2FB798052AE6
SE.pdf	162D62C8CA46433A8AAA3B7844B9681
063995-01-5105-	D823D08CE743ED58C454E6E4A25DA7DB4BF70D0F6FCC014
US10_RESTRICTIONRESPON	E1108B3E645C1CE7CEF73AA5E0CE01222412B73036380DE0B
SE-ELCpdf	056637B9C0760E054ECB76277357649F
063995-01-5105-	BC36FCB2E8DAC97DBD93118A31547DD908CE3E4A19692F58
US10_RESTRICTIONRESPON	35BCADF96A5CCBDC233C046782DCEA7A6B3CE8999C62616
SE-CLM.pdf	4F20CDEECE52F93959D7A7C49156C3660
063995-01-5105-	AF34FB3B116CD3EE67BD7A9344CACAD682055857EFD18508
US10_RESTRICTIONRESPON	263D5D2475D17B9BD76E984E5FD8C3E4489F55A7F227448A0
SE-REM.pdf	E50606BFA11966CB8D3CAACFA95E494

MECCACE DICECT/CHA 540)

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

## New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of <b>Ge Wei et al.</b>	)	
	)	Confirmation No. 5769
U.S. Application No. 18/068,418	)	
	)	Group Art Unit: 1656
Filing Date: 12/19/2022	)	
	)	Examiner: Ciara A. McKnight
For: PH20 Polypeptide Variants, Formulations	)	
and Uses Thereof	)	

## **RESPONSE TO RESTRICTION REQUIREMENT**

In response to the Restriction Requirement dated 2/20/2024, please enter the following provisional election for examination on the merits. This response is considered timely filed. To the extent any additional fee is due, the Director is hereby authorized to charge additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-0310.

Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

#### **LISTING OF THE CLAIMS**

This version of the claims will replace all previous versions.

1. (Original) A modified PH20 polypeptide, comprising one or more amino acid modifications in an unmodified PH20 polypeptide, wherein:

the unmodified PH20 polypeptide consists of the amino acid sequence selected from among SEQ ID NOs: 3, 7 and 32-66:

amino acid modifications are selected from among amino acid replacements(s), deletion(s), and/or insertion(s);

the modified PH20 polypeptide comprises an amino acid replacement at a position corresponding to residue 324, with reference to amino acid positions set forth in SEQ ID NO:3;

the replacement at the position corresponding to residue 324 is selected from among A, D, H, M, N, R and S;

corresponding amino acid positions are identified by alignment of the PH20 polypeptide with the polypeptide having the amino acid sequence of SEQ ID NO:3; and

the modified PH20 polypeptide has at least 91 % sequence identity to a polypeptide having the amino acid sequence selected from among SEQ ID NOs: 3, 7 and 32-66.

- 2. (Original) The modified PH20 polypeptide of claim 1, wherein the modified PH20 polypeptide has at least 95% sequence identity to the amino acid sequence selected from among SEQ ID NOs: 3, 7, and 32-66.
- 3. (Original) The modified PH20 polypeptide of claim 1 that has increased resistance to or stability in denaturing conditions compared to an unmodified PH20 polypeptide that does not contain the amino acid modification(s).
- 4. (Original) The modified PH20 polypeptide of claim 1 that exhibits increased hyaluronidase activity compared to the unmodified PH20 polypeptide not containing the amino acid replacement at position 324.
  - 5. (Original) The modified PH20 polypeptide of claim 1 that is a soluble PH20 polypeptide.
- 6. (Original) The modified PH20 polypeptide of claim 1, wherein the replacement at the position corresponding to residue 324 is D.
- 7. (Original) The modified PH20 polypeptide of claim 1, wherein the replacement at the position corresponding to residue 324 is Nor R.
- 8. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide comprises the amino acid sequence selected from among SEQ ID NOs: 3 and 32-66.
- 9. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from among SEQ ID NOs: 3 and 32-66.
- 10. (Original) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from among SEQ ID NOs: 3 and 32-66.

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- 11. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35.
- 12. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32.
- 13. (Original) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35.
- 14. (Original) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32.
- 15. (Original) The modified PH20 polypeptide of claim 1, comprising a sequence of amino acids that exhibits at least 91 % sequence identity to the sequence of amino acids set forth in any of SEQ ID NOs: 3, 32-66, 623, and 624 and that contains an amino acid replacement D at the residue corresponding to residue 324 with reference to SEQ ID NO:3.
- 16. (Original) The modified PH20 polypeptide of claim 1 that is C-terminally truncated, whereby the polypeptide is soluble.
- 17. (Original) The modified PH20 polypeptide of claim 1 that comprises one or more modifications of the polypeptide selected from among glycosylation, sialylation, albumination, famesylation, carboxylation, hydroxylation, and phosphorylation.
  - 18. (Original) The modified PH20 polypeptide of claim 1 that is glycosylated.
- 19. (Original) The modified PH20 polypeptide of claim 18, wherein the polypeptide is a glycoprotein that comprises an N-acetylglucosamine moiety linked to each of at least three asparagine (N) residues.
  - 20. (Original) The modified PH20 polypeptide of claim 1 that is conjugated to a polymer.
- 21. (Original) The modified PH20 polypeptide of claim 20, wherein the polymer is dextran or polyethylene glycol (PEG).
- 22. (Original) The modified PH20 polypeptide of claim 1, further comprising a heterologous signal sequence, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from among SEQ ID NOs: 3 and 32-66.
  - 23. (Original) A chimeric polypeptide, comprising the modified PH20 polypeptide of claim 1.
- 24. (Original) A pharmaceutical composition, comprising the modified PH20 polypeptide of claim 1.
  - 25. (Original) The modified PH20 polypeptide of claim 6, wherein: the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32; and the amino acid sequence of the modified PH20 polypeptide has at least 95% sequence
  - 26. (Original) The modified PH20 polypeptide of claim 6, wherein: the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35; and

identity to the amino acid sequence of SEQ ID NO:32.

the amino acid sequence of the modified PH20 polypeptide has at least 95% sequence identity to the amino acid sequence of SEQ ID NO:35.

- 27. (Original) The pharmaceutical composition of claim 24, further comprising a therapeutically active agent formulated in the same composition or in a separate composition.
- 28. (Original) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is a polypeptide, a protein, a nucleic acid, a drug, a small molecule, or an organic molecule.
- 29. (Original) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is selected from among a chemotherapeutic agent, an analgesic agent, an anti-inflammatory agent, an antimicrobial agent, an amoebicidal agent, a trichomonacidal agent, an anti-Parkinson agent, an anti-malarial agent, an anticonvulsant agent, an anti-depressant agent, an anti-parasite agent, an anti-fungal agent, an antihypertensive agent, an antipyretic agent, an anti-parasite agent, an antihistamine agent, an alpha-adrenergic agonist agent, an alpha blocker agent, an anesthetic agent, a bronchial dilator agent, a biocide agent, a bactericide agent, a bacteriostat agent, a beta adrenergic blocker agent, a calcium channel blocker agent, a cardiovascular drug agent, a contraceptive agent, a decongestant agent, a diuretic agent, a depressant agent, a diagnostic agent, an electrolyte agent, a hypnotic agent, a hormone agent, a hyperglycemic agent, a muscle relaxant agent, a muscle contractant agent, an ophthalmic agent, a parasympathomimetic agent, a psychic energizer agent, a sedative agent, a sympathomimetic agent, a tranquilizer agent, a urinary agent, a vaginal agent, a viricide agent, a vitamin agent, a non-steroidal anti-inflammatory agent, an angiotensin converting enzyme inhibitor agent, and a sleep inducer.
- 30. (Original) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is an antibody.
- 31. (Withdrawn) A method for treating a hyaluronan-associated disease or condition, comprising administering to a subject a modified PH20 polypeptide of claim 1.
- 32. (Withdrawn) The method of claim 31, wherein the hyaluronan-associated disease or condition is an inflammatory disease or a tumor or cancer.
- 33. (Withdrawn) The method of claim 32, wherein the hyaluronan-associated disease or condition is a solid tumor.
- 34. (Withdrawn) The modified PH20 polypeptide of claim 1 that is modified by conjugation to a moiety selected from among a multimerization domain, a toxin, a detectable label, and a drug.
- 35. (Original) The modified PH20 polypeptide of claim 34, wherein the modified PH20 polypeptide is conjugated to a multimerization domain that is an Fe domain.

DB1/ 144937442.1 4

#### **REMARKS**

In response to the Restriction Requirement, Applicant elects with traverse, Group I (claims 1-30 and 34-35) drawn to a modified PH20 polypeptide.

With regard to the traversal, the Examiner has required restriction between claims drawn to a product and claims drawn to a process of making and/or using the product. Where Applicant elects claims directed to the product, and all the product claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product claims should be considered for rejoinder. See MPEP § 821.04(b). Here, the features of the modified PH20 polypeptide as set forth in claim 1 are all included in the method for treating a hyaluronan-associated disease or condition as set forth in claims 31-33. For this reason alone, rejoinder of claims 31-33 is proper and requested by Applicant in view of the above remarks.

Applicant is thus entitled to a rejoinder of the non-elected claims should the elected claims be deemed allowable.

#### **Conclusion**

In view of the foregoing, Applicant awaits a favorable action on the merits. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned representative to expedite prosecution.

Date: March 5, 2024

**MORGAN LEWIS & BOCKIUS LLP** 

1111 Pennsylvania Ave, NW Washington, DC 20004
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Respectfully submitted,

By: /Kalpesh V. Upadhye/ Kalpesh V. Upadhye, Ph.D. Registration No. 70,236

Robert Smyth, Ph.D. Registration No. 50,801

## United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/068,418	12/19/2022	Ge Wei	063995-01-5105-US10	5769
28977 7590 05/01/2024 Morgan, Lewis & Bockius LLP (PH)			EXAM	IINER
2222 Market St	reet		MCKNIGHT, CIARA A	
Philadelphia, P.	A 19103		ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			05/01/2024	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

judith.troilo@morganlewis.com phpatentcorrespondence@morganlewis.com

	Application No.	Applicant(s)		
Office Action Summary	18/068,418	Wei et al.		
Office Action Summary	Examiner	Art Unit	AIA (FITF) Status	
	CIARA A MCKNIGHT	1656	No	
The MAILING DATE of this communication app	ears on the cover sheet with the co	orrespondenc	e address	
Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY DATE OF THIS COMMUNICATION.	_			
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.13 date of this communication.</li> </ul>			-	
<ul> <li>If NO period for reply is specified above, the maximum statutory period w</li> <li>Failure to reply within the set or extended period for reply will, by statute,</li> <li>Any reply received by the Office later than three months after the mailing adjustment. See 37 CFR 1.704(b).</li> </ul>	cause the application to become ABANDONEI	O (35 U.S.C. § 133)	).	
Status				
1) ✓ Responsive to communication(s) filed on 03/	<u>05/2024</u> .			
☐ A declaration(s)/affidavit(s) under <b>37 CFR 1</b>	.130(b) was/were filed on	<u>.</u> ,		
, —	This action is non-final.			
3) An election was made by the applicant in res				
on; the restriction requirement and elec				
4) Since this application is in condition for allow closed in accordance with the practice under				
Disposition of Claims*				
5) Claim(s) 1-35 is/are pending in the app	lication.			
5a) Of the above claim(s) 31-33 is/are withdr				
6) Claim(s) is/are allowed.				
7) 🗹 Claim(s) 1-30 and 34-35 is/are rejected.				
8) Claim(s) is/are objected to.				
9) Claim(s) are subject to restriction a	nd/or election requirement			
* If any claims have been determined <u>allowable</u> , you may be eli-	· · · · · · · · · · · · · · · · · · ·	ecution Highv	way program at a	
participating intellectual property office for the corresponding ap				
$\underline{\text{http://www.uspto.gov/patents/init\_events/pph/index.jsp}} \text{ or send} \\$	an inquiry to PPHfeedback@uspto.	gov.		
Application Papers				
10) The specification is objected to by the Examir	ner.			
11) <b>☑</b> The drawing(s) filed on <u>12/19/2022</u> is/are: a)	✓ accepted or b)  ☐ objected	to by the Ex	aminer.	
Applicant may not request that any objection to the di	<del>-</del> · · · · · · · · · · · · · · · · · · ·	. ,		
Replacement drawing sheet(s) including the correction	on is required if the drawing(s) is object	ted to. See 37	CFR 1.121(d).	
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreig	gn priority under 35 U.S.C. § 11	9(a)-(d) or (f)	).	
Certified copies: a) ☐ All b) ☐ Some** c) ☐ None of t	ha:			
1. Certified copies of the priority docun				
2. ☐ Certified copies of the priority documents of the priority documents.		nlication No		
·	·	•		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
** See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)				
1) Notice of References Cited (PTO-892)	3) Interview Summary	(PTO-413)		
2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S Paper No(s)/Mail Date	B/08b) Paper No(s)/Mail Da 4) Other:	ate		

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13)

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#### **DETAILED ACTION**

#### Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

## Status of the Application

1. Claims 1-35 are pending and subject to examination on the merits. Claims 31-33 are withdrawn from consideration as being drawn to non-elected subject matter.

#### Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-30 and 34-35, in the reply filed on 05 March 2024 is acknowledged. There seems to be an inadvertent mistake with the withdrawal of 34, where elected Group I includes claim 34 in the previous office action. The examiner will treat said claim as being under examination despite the status identifier indicating otherwise. Please update the status identifier in the next response.

The traversal is on the ground(s) that a rejoinder would be required if the product claims were found allowable, since the withdrawn claims are drawn to a process of using said product. Should the product claims become allowable, a rejoinder of the process claims will be considered. The requirement is still deemed proper and is therefore made FINAL.

## **Priority**

3. This application ultimately derives benefit to US Provisional 61/631,313 filed 12/30/2011.

#### Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 16 March 2023 have been considered by the examiner. See initialed and signed PTO/SB/08's.

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#### **Objections**

5. Claims 1 (lines 3, 5, 9, and 14), 2, 8, 9, 10, 17, 22, and 29 are objected to because of the following informalities: "selected from among" should be changed to a proper Markush term, "selected from the group consisting of," to maintain consistency with the previously allowed parent patents. Appropriate correction is required.

- 6. Claims 7 is objected to because of the following informalities: in claim 7, "Nor" should be changed to "N or." Appropriate correction is required.
- 7. Claim 15 is objected to because of the following informalities: "set forth in any of" should be changed to a proper Markush term, "selected from the group consisting of," to maintain consistency with the previously allowed parent patents. Appropriate correction is required.

## Claim Rejections - 35 USC § 112(b)

8. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 9. Claims 17 and 34-35 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.
- 10. The term "modifications" in claim 17 is a relative term which renders the claim indefinite. It is unclear if "modifications" here holds the same definition as "modification"

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in claim 1, where "modification" refers to "a modification at a position ... " Here in claim

17, however, it appears to be defined as any of the posttranslational modifications listed

afterwards. For examining purposes, the term "modification" is interpreted as referring to

the possible posttranslational modifications of the modified PH20 of claim 1. It is

recommended to change "modifications" to "posttranslational modifications" for

increased clarity.

11. The term "is modified" in claim 34 renders the claim indefinite. Claim 1 already

recites a "modified PH20;" therefore, "is modified" should be changed to "is further

modified" to increase clarity to mitigate any confusion between the usage of the similar

terms.

12. The term "Fe domain" in claim 35 renders the claim indefinite. It is unclear what a

"Fe domain" is, as it is not well-known in the art or defined in the specification. If "Fe" is a

typographical error for "Fc domain", then it should be changed to "Fc domain," which is

well-known in the art and cited in the specification as a multimerization domain on p. 37

at line 7.

Claim Rejections - 35 USC § 112(d)

13. The following is a quotation of 35 U.S.C. 112(d):

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to

incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of pre-AIA 35 U.S.C. 112, fourth paragraph:

Subject to the following paragraph [i.e., the fifth paragraph of pre-AIA 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed

to incorporate by reference all the limitations of the claim to which it refers.

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14. Claims 8 and 15 rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 1 recites that the unmodified PH20 polypeptide **consists of** the amino acid sequence of SEQ ID NOs: 3, 7, and 32-66, whereas claim 8 recites that the unmodified polypeptide **comprises** SEQ ID NOs: 3 and 32-66. Since "comprises" is broader than "consisting of," claim 8 does not further limit claim 1. Regarding claim 15, the recitation of comprises SEQ ID NOs: 3, 32-66, 623, and 624 makes these claims broader than claim 1, and therefore, not further limiting. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

16. Claims 1-30 and 34-35 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 2, 4, 6-8, 10, 12-13, 19, 23, and 27 of U.S. Patent No.

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10865400. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims in '400 would anticipate the instant claims.

The instant claims in their broadest are drawn to a modified PH20 polypeptide with one or more amino acid modifications at **position 324** (claim 1) with some sequence identity to the PH20 polypeptide encoded in SEQ ID NOs: 3, 7, and 32-66 (claim 2). Additionally, dependent claims 3 and 5 recite increased resistance or stability and solubility. Claim 4 recites increased hyaluronidase activity. Dependent claims 6-16, 22-23, and 25-26 recite variation modifications to amino acid 324 in reference to SEQ ID NOs: 3 and 32-66. Dependent claims 17-19 recite an additional modification of PH20, where the modification can be N-linked glycosylation.

Dependent claims 20-21 recite conjugation to a polymer. Dependent claims 24 and 27-30 recite the modified PH20 polypeptide comprising a pharmaceutical composition.

The claims in the '400 patent in their broadest are drawn to a modified PH20 polypeptide with an amino acid replacement at a number of positions, including 324, resulting in an increase in hyaluronidase activity compared to an unmodified PH20 polypeptide, where the reference PH20 is selected from SEQ ID NOs: 3, 7, 32-66 (claims 1, 2, 4, 6 and 13).

Dependent claims 7-8 recite additional modifications, such as N-linked glycosylation.

Dependent claim 10 and 12 recite polymer conjugation. Dependent claims 19 and 23 recite a pharmaceutical composition comprising the modified PH20 polypeptide. Dependent claim 27 recites that the modified PH20 is soluble.

It is noted that the reference sequences, SEQ ID NOs: 3, 7, and 32-66 are identical between the two claim sets. Thus, the difference between the claims in the '400 claim set specifies a modified PH20 at a variety of different amino acids. This, however, will still anticipate the instant claims because position 324 can be selected from the amino acids to be modified.

17. Claims 1-30 and 34-35 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 5-10, and 14-18 of copending Application No. 18/340,786.

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Although the claims at issue are not identical, they are not patentably distinct from each other because the claims in '786 would anticipate the instant claims.

The instant claims in their broadest are drawn to a modified PH20 polypeptide with one or more amino acid modifications at position 324 with some sequence identity to the PH20 polypeptide encoded in SEQ ID NOs: 3, 7, and 32-66 (claims 1, 2, 7-15, 22-23, and 25-26). Additionally, dependent claim 4 recite increased hyaluronidase activity. Dependent claims 5 and 16 recite that the modified PH20 is soluble. Claim 6 recites that the amino acid replacement at 324 of PH20 is specifically D. Dependent claims 17-19 recite an additional modification of PH20, where the modification can be N-linked glycosylation. Dependent claims 24 and 27-30 recite the modified PH20 polypeptide comprising a pharmaceutical composition.

The claims in the '786 application in their broadest are drawn to a modified PH20 polypeptide with an amino acid replacement of N, R, or D at position 324 in SEQ ID NO: 3, and the mutant PH20 has some sequence identity to SEQ ID NO: 35 (claims 1-4), and the PH20 polypeptide is soluble (claim 7). Dependent claims 5-6 recite increased hyaluronidase activity. Dependent claims 8-10 recite additional modifications, such as N-linked glycosylation. Dependent claims 14-18 recite a pharmaceutical composition comprising the modified PH20 polypeptide.

It is noted that the reference sequences, SEQ ID NOs: 3 and 35 are identical between the two claim sets. Thus, the difference between the claims in the '786 claim set specifies a modified PH20 with reference polypeptide SEQ ID NO: 35, specifically. However, since the instant claim set recites the reference sequences, SEQ ID NOs: 3, 7, and 32-66, SEQ ID NO: 35 is included in the reference sequence choices.

#### Conclusion

All claims are rejected. Additionally, claims 1, 7, and 15 are objected to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CIARA A MCKNIGHT whose telephone number is (703)756-4791. The examiner can normally be reached M-F 8:00am-4:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CIARA A MCKNIGHT/ Examiner, Art Unit 1656

/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

CPC - Searched*			
Symbol	Date	Examiner	
C12N9/2474, A61P35/00, A61K9/0019, A61K38/28, A61K38/47, A61K4506, A61K47/10, C07K14/47, C12Q1/34, C12Y302/01035, Y02A50/30, A61K38/00, C07K2319/30, G01N2333/926, G01N2333/928			

CPC Combination Sets - Searched*			
Symbol	Date	Examiner	

US Classification - Searched*			
Class	Subclass	Date	Examiner
_			

<sup>\*</sup> See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes			
Search Notes	Date	Examiner	
PALM inventor name search, all inventors searched	04/18/2024	/CAM/	
SEARCH inventor name and assignee search, all inventors searched	04/18/2024	/CAM/	
SEARCH keyword search, see attached printouts for search strategy and databases searched	04/18/2024	/CAM/	
PUBMED keyword search, see attached printout for strategy	04/18/2024	/CAM/	
STIC sequence search	04/18/2024	/CAM/	

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

Interference Search					
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner		

U.S. Patent and Trademark Office
Page 2 of 2
Part of Paper No.: 20240419

Attorney Docket No.: 33320.03087.US2E/3087K

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Wei et al. Art Unit : Not yet assigned Serial No. : 18/068,418 Examiner : Not yet assigned

Filed : December 19, 2022 Conf. No. : 5769 Cust. No. : 13565

Title : PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES

THEREOF

#### Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Dear Sir:

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee is not required. If a fee for filing these papers is required, the Commissioner is authorized to charge the fee to Deposit Account No. 50-0911.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98. Forms PTO-1449 (25 pages) and copies of the cited non-U.S. patent documents listed thereon are provided herewith in connection with the above-captioned application. The documents cited comprise the references cited in the application and incorporated by reference, and any additional information of which those associated with the prosecution are aware.

In accordance with 37 C.F.R. § 1.98(d), copies of the references listed on the Forms PTO-1449 that are marked with a double asterisk (\*\*) are not provided herewith as they have been previously provided in connection with U.S. Patent Application Serial No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which is relied upon for an earlier filing date in accordance with 35 U.S.C. § 120.

The documents cited on the Forms PTO-1449 are in the English Language with the exception of the items noted below. Item GB (CN 102065886A) is in the Chinese Language and an English Language equivalent is listed (Item GR). Item GI (JP 2007-153797) is in the Japanese Language and an English Language Abstract is listed (Item IM). Item GJ (KR 10-2020-0017538) is in the Korean Language and an English Language equivalent is listed (Item GG). Hence, in

#### CERTIFICATE OF TRANSMISSION VIA EFS-WEB

I hereby certify that this paper is being transmitted via the Electronic Filing System (EFS-WEB) to the United States Patent and Trademark Office on March 16, 2023.

/Anh Nguyen /
Anh Nguyen

Inventor(s) : Wei *et al.*Serial No. : 18/068,418

Attorney Docket No.: 33320.03087.US2E/3087K
Information Disclosure Statement

Filed : December 19, 2022

accordance with the requirements of 37 C.F.R. § 1.98, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S. Applications that have one or more common inventors and/or an owner in common.

Examiner's	U.S.S.N.	Filing Date	Publ. No.	Publ. Date	Docket
Initials					No.
	16/930,766	07/16/2020	2020/0368330	11/26/2020	3066D
	17/062,425	10/02/2020	2021/0023184	01/28/2021	3051M
	17/327,568	05/21/2021	2021/0284985	09/16/2021	3087E
	17/327,586	05/21/2021	2021/0277376	09/09/2021	3087F
	17/850,903	06/27/2022	2022/0372151	11/24/2022	3122B
	18/064,886	12/12/2022	n.a.	n.a.	3087G
	18/066,960	12/15/2022	n.a.	n.a.	3087H
	18/068,218	12/19/2022	n.a.	n.a.	3087I
	18/068,327	12/19/2022	n.a.	n.a.	3087J
	18/068,443	12/19/2022	n.a.	n.a.	3087L
	18/069,651	12/21/2022	n.a.	n.a.	3087M

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §§ 1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

/Stephanie Seidman/ Stephanie Seidman Reg. No. 33,779

Attorney Docket No.: 33320.03087.US2E/3087K

Address all correspondence to: 13565

Stephanie Seidman Dentons US LLP 4655 Executive Drive, Ste. 700 San Diego, California 92121 Telephone: (619) 595-8010 Facsimile: (619) 595-8135

email: stephanie.seidman@dentons.com

# PE2E SEARCH - Search History (Prior Art)

Ref#	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1484	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/02/02 02:56 PM
L2	66	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/02/02 02:57 PM
L3	53	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/02/02 02:57 PM
L4	55	((("HALOZYME") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2024/02/02 02:59 PM

# PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

# **Bibliographic Data**

FILING or 371(c) DATE	CLASS	GROUP ART	LINIT	ATTORNEY DOCKET NO.
Title:	PH20 POL THEREOF		NTS, FORM	ULATIONS AND USES
	Examiner's	Signature	Initials	
Verified and Acknowledged:	/CIARA A MCKNIGHT/			
35 USC 119 (a-d) conditions met:	Yes	□No		t After Allowance
Foreign Priority claimed:	<b>O</b> Yes	<b>⊙</b> No		
Application No: 18/068,4	18			

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/19/2022	424	1656	
RULE			

#### **APPLICANTS**

Halozyme, Inc., San Diego, CA, UNITED STATES

## **INVENTORS**

Ge Wei, San Diego, CA, UNITED STATES

H. Michael Shepard,

Qiping Zhao,

Robert James Connor,

#### **CONTINUING DATA**

This application is a DIV of 17327568 05/21/2021

This application is a DIV of 17327586 05/21/2021

17327568 is a CON of 16912590 06/25/2020 PAT 11066656

17327586 is a CON of 16912590 06/25/2020 PAT 11066656

This application is a DIV of 16912590 06/25/2020 PAT 11066656

17327568 is a CON of 16824572 03/19/2020 PAT 11041149

17327586 is a CON of 16824572 03/19/2020 PAT 11041149

This application is a DIV of 16824572 03/19/2020 PAT 11041149

17327568 is a CON of 15226489 08/02/2016 PAT 10865400

16824572 is a CON of 15226489 08/02/2016 PAT 10865400

17327586 is a CON of 15226489 08/02/2016 PAT 10865400

16912590 is a CON of 15226489 08/02/2016 PAT 10865400

This application is a CON of 15226489 08/02/2016 PAT 10865400

This application is a DIV of 13694731 12/28/2012 PAT 9447401

15226489 is a DIV of 13694731 12/28/2012 PAT 9447401

16824572 is a DIV of 13694731 12/28/2012 PAT 9447401 16912590 is a DIV of 13694731 12/28/2012 PAT 9447401 17327586 is a CON of 13694731 12/28/2012 PAT 9447401 13694731 has PRO of 61796208 11/01/2012 13694731 has PRO of 61631313 12/30/2011

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Search	Actions	Details	Query	Results	Time
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#3	***		Search: hyaluronidase PH20 therapy	63	09:17:10
#1	***		Search: hyaluronidase PH20		09:16:28

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#1	***		Search: Michael Shepard PH20	8	08:58:14

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attomey Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418	
List of Patents and Publications for Applicant's Information Disclosure Statement		Inventor(s) Wei et al.		
		Filing Date December 19, 2022	Group Art Unit Not yet assigned	
(37 CFR §1.98(b))		<i>'</i>		

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Examiner	Desig.	Document	Publication	Datantas	Class	Cubalass	Filing Date
Initial	ID AA	Number 3,536,809	Date 10/27/1970	Patentee Applezweig	Class 424	Subclass 28	If Appropriate 02/17/1969
			08/10/1971	Zaffaroni		268	04/01/1969
	AB	3,598,123			128		
	AC	3,630,200	12/28/1971	Higuchi	128	260	06/09/1969
	AD	3,710,795	01/16/1973	Higuchi et al.	128	260	09/29/1970
	AE	3,845,770	11/05/1974	Theeuwes et al.	128	260	06/05/1972
	AF	3,916,899	11/04/1975	Theeuwes et al.	128	260	02/07/1974
	AG	4,002,531	01/11/1977	Royer	195	68	01/22/1976
	AH	4,008,719	02/22/1977	Theeuwes et al.	128	260	02/02/1976
	AI	4,044,126	08/23/1977	Cook et al.	514	180	07/09/1976
	AJ	4,179,337	12/18/1979	Davis et al.	435	181	07/28/1977
	AK	4,364,923	12/21/1982	Cook et al.	424	46	04/30/1981
	AL	4,414,209	11/08/1983	Cook et al.	514	180	06/13/1977
	AM	4,769,027	09/06/1988	Baker et al.	424	493	02/24/1987
	AN	4,952,496	08/28/1990	Studier et al.	435	91	12/29/1986
	AO	4,980,286	12/25/1990	Morgan et al.	435	371	01/03/1989
	AP	5,033,252	07/23/1991	Carter	53	425	07/30/1990
	AQ	5,052,558	10/01/1991	Carter	206	439	07/27/1990
	AR	5,059,595	10/22/1991	Le Grazie	424	468	03/20/1990
	AS	5,073,543	12/17/1991	Marshall et al.	514	21	07/21/1988
	AT	5,120,548	06/09/1992	McClelland et al.	424	473	11/07/1989
	AU	5,122,614	06/16/1992	Zalipsky	548	520	04/19/1990
	AV	5,323,907	06/28/1994	Kalvelage	206	531	03/15/1993
	AW	5,324,844	06/28/1994	Zalipsky	548	520	01/08/1992
	AX	5,446,090	08/29/1995	Harris	525	54.1	11/12/1993
	AY	5,591,767	01/07/1997	Mohr et al.	514	413	06/06/1995
	AZ	5,612,460	03/18/1997	Zalipsky	530	391.9	02/17/1994
	BA	5,639,476	06/17/1997	Oshlack et al.	424	468	06/02/1995
	BB	5,643,575	07/01/1997	Martinez et al.	424	194.1	10/27/1993
	BC	5,672,662	09/30/1997	Harris et al.	525	408	10/02/1995
	BD	5,674,533	10/07/1997	Santus et al.	424	493	05/26/1995
	BE	5,721,348	02/24/1998	Primakoff et al.	536	22.1	10/21/1991
	BF	5,733,566	03/31/1998	Lewis	424	426	10/30/1995
	BG	5,766,581	06/16/1998	Bartley et al.	424	85.1	03/30/1995
	BH	5,795,569	08/18/1998	Bartley et al.	424	85.1	10/12/1994
		5,808,096	09/15/1998	Zalipsky	548	520	01/21/1997
	BI	5,854,046	12/29/1998	Au-Young et al.	435	201	01/21/1997
	BJ		05/04/1999	<u>-</u>			
	BK	5,900,461	05/04/1999	Harris	525	54.11	02/23/1998

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418	
List of Patents and Publ	lications for Applicant's	Inventor(s) Wei et al.		
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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	BM	5,932,462	08/03/1999	Harris et al.	435	188	05/17/1995
	BN	5,958,750	09/28/1999	Au-Young et al.	435	201	07/03/1996
	ВО	5,985,263	11/16/1999	Lee et al.	424	85.2	12/19/1997
	BP	5,990,237	11/23/1999	Bentley et al.	525	54.2	05/20/1998
	BQ	6,057,110	05/02/2000	Au-Young et al.	435	6	12/17/1998
	BR	6,113,906	09/05/2000	Greenwald et al.	424	194.1	12/29/1998
	BS	6,193,963	02/27/2001	Stern et al.	424	94.6	08/21/1997
	BT	6,214,966	04/10/2001	Harris	528	322	09/25/1997
	BU	6,258,351	07/10/2001	Harris	424	78.3	11/05/1997
	BV	6,340,742	01/22/2002	Burg et al.	530	351	06/28/2000
	BW	6,413,507	07/02/2002	Bentley et al.	424	78.02	12/23/1999
	BX	6,420,339	07/16/2002	Gegg et al.	514	12	10/14/1998
	BY	6,437,025	08/20/2002	Harris et al.	523	406	11/05/2001
	BZ	6,448,369	09/10/2002	Bentley et al.	528	425	11/05/1998
	CA	6,461,802	10/08/2002	Van Thillo et al.	430	336	07/31/2000
	СВ	6,461,863	10/08/2002	Jarvis	435	320.1	11/29/1999
	CC	6,495,659	12/17/2002	Bentley et al.	528	425	12/20/2000
	CD	6,615,063	09/02/2003	Ntziachristos et al.	600	312	11/27/2000
	CE	6,737,505	05/18/2004	Bentley et al.	528	425	10/30/2002
	CF	6,828,401	12/07/2004	Nho et al.	526	333	10/29/2003
	CG	6,858,736	02/22/2005	Nho et al.	546	290	12/23/2002
	CH	7,105,330	09/12/2006	Stern et al.	435	200	07/18/2003
	CI	7,279,457	10/09/2007	Pohl et al.	514	3	03/11/2005
	CJ	7,585,940	09/08/2009	Skerra et al.	530	350	05/11/2006
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	CL	7,781,397	08/24/2010	Stern et al.	424	94.62	10/03/2006
	CM	7,829,081	11/09/2010	Bookbinder et al.	424	94.62	03/04/2010
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	CO	7,871,607	01/18/2011	Bookbinder et al.	424	094.620	02/23/2005
	CP	8,105,586	01/31/2012	Bookbinder et al.	424	94.3	06/15/2010
	CQ	8,187,855	05/29/2012	Baker et al.	435	201	11/09/2010
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	CV	8,431,124	04/30/2013	Bookbinder et al.	424	94.62	04/16/2009

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Pul	olications for Applicant's	Inventor(s) Wei et al.	
List of Patents and Publications for Applicant's Information Disclosure Statement		Filing Date December 19, 2022	Group Art Unit Not yet assigned

			U.S. Pate	ent Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	CW	8,431,380	04/30/2013	Bookbinder et al.	435	201	02/20/2009
	CX	8,450,470	05/28/2013	Bookbinder et al.	536	023.200	06/03/2009
	CY	8,568,713	10/29/2013	Frost et al.	424	094.500	05/18/2012
	CZ	8,580,252	11/12/2013	Bookbinder et al.	424	85.2	07/06/2012
	DA	8,765,685	07/01/2014	Bookbinder et al.	514	020.900	05/16/2012
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	DC	9,284,543	03/15/2016	Wei et al.	435	201	02/21/2012
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	DE	9,913,822	03/13/2018	Maneval et al.	435	195	03/15/2013
	DF	10,016,491	07/10/2018	Bookbinder et al.	424	94.62	11/09/2015
	DG	10,328,130	06/25/2019	Frost et al.	424	094.620	02/22/2012
	DH	10,588,983	03/17/2020	Bookbinder et al.	435	069.100	02/23/2018
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	DK	2001/0021763	09/13/2001	Harris	528	75	04/02/2001
	DL	2001/0044526	11/22/2001	Shen	530	409	02/21/2001
	DM	2001/0046481	11/29/2001	Bentley et al.	424	78.18	04/21/2001
	DN	2002/0052430	05/02/2002	Harris et al.	523	406	11/05/2001
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	DP	2002/0156047	10/24/2002	Zhao	514	58	01/22/2002
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	DR	2003/0114647	06/19/2003	Harris et al.	530	402	04/10/2002
	DS	2003/0143596	07/31/2003	Bentley et al.	435	6	11/07/2002
	DT	2003/0158333	08/21/2003	Roberts et al.	530	402	10/09/2002
	DU	2003/0220447	11/27/2003	Harris	528	322	12/12/2002
	DV	2004/0013637	01/22/2004	Bentley et al.	424	78.17	02/10/2003
	DW	2004/0235734	11/25/2004	Bossard et al.	514	12	02/26/2004
	DX	2004/0268425	12/30/2004	Bookbinder et al.	800	18	03/05/2004
	DY	2005/0054048	03/10/2005	Grasso et al.	424	133.100	07/29/2004
	DZ	2005/0114037	05/26/2005	Desjarlais et al.	702	19	09/30/2004
	EA	2005/0171328	08/04/2005	Harris	528	322	02/04/2005
	EB	2005/0209416	09/22/2005	Harris	525	523	04/22/2005
	EC	2005/0260186	11/24/2005	Bookbinder et al.	424	094.610	02/23/2005
	ED	2006/0104968	05/18/2006	Bookbinder et al.	424	094.610	09/27/2005
	EE	2007/0067855	03/22/2007	Jarvis et al.	800	13	04/28/2006
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List of Patents and Publications for Applicant's Information Disclosure Statement		Filing Date December 19, 2022	Group Art Unit Not yet assigned
(37 CFR §1.98(b))		<i>'</i>	

			U.S. Pat	ent Documents			
Examiner	Desig.	Document	Publication				Filing Date
Initial	ID	Number	Date	Patentee	Class	Subclass	If Appropriate
	EH	2009/0042785	02/12/2009	Matschiner et al.	514	012	04/28/2008
	EI	2009/0123367	05/14/2009	Bookbinder et al.	424	001.490	10/09/2008
	EJ	2009/0181032	07/16/2009	Bookbinder at al.	424	141.1	02/20/2009
	EK	2009/0214505	08/27/2009	Bookbinder at al.	424	94.1	04/16/2009
	EL	2009/0253175	10/08/2009	Bookbinder at al.	435	69.1	06/03/2009
	EM	2009/0304665	12/10/2009	Frost et al.	424	94.5	04/28/2009
	EN	2009/0305982	12/10/2009	Jensen et al.	435	069.100	06/11/2009
	EO	2009/0311237	12/17/2009	Frost	424	094.620	04/14/2009
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	ER	2010/0143457	06/10/2010	Wei et al.	424	450	12/09/2009
	ES	2010/0172892	07/08/2010	Uvarkina et al.	424	94.62	12/15/2009
	ET	2011/0053247	03/03/2011	Baker et al.	435	201	11/09/2010
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	EV	2011/0152359	06/23/2011	Bookbinder et al.	435	200	12/21/2010
	EW	2012/0020951	01/26/2012	Shepard et al.	424	130.1	07/15/2011
	EX	2012/0093770	04/19/2012	Bookbinder et al.	424	094,620	12/15/2011
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	FG	2013/0022592	01/24/2013	Vaughn et al.	424	094.620	06/15/2012
	FH	2013/0058893	03/07/2013	Bookbinder et al.	435	200	10/18/2012
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	FJ	2013/0101577	04/25/2013	Wei et al.	424	450	02/21/2012
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	FP	2014/0105824	04/17/2014	Shepard et al.	424	009.200	10/16/2013
	FQ	2014/0135682	05/15/2014	Frost et al.	424	094.500	09/24/2013
	FR	2014/0199282	07/17/2014	Bookbinder et al.	435	200	02/26/2014
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418	
List of Patents and Pub	lications for Applicant's	Inventor(s) Wei <i>et al</i> .		
Information Disc	losure Statement	Filing Date December 19, 2022	Group Art Unit Not yet assigned	
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	U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate	
	FS	2015/0010529	01/08/2015	Wei	424	94.62	07/03/2014	
	FT	2016/0362670	12/15/2016	Wei et al.	424	094.620	08/02/2016	
	FU	2017/0290796	10/12/2017	Maneval et al.	435	195	06/16/2017	
	FV	2019/0336587	11/07/2019	Frost et al.	424	78.17	05/21/2019	
	FW	2020/0255814	08/13/2020	Wei et al.	435	069.100	03/19/2020	
	FX	2020/0318091	10/08/2020	Wei et al.	424	094.620	06/25/2020	
	FY	2020/0368330	11/26/2020	Frost et al.	424	078.170	07/16/2020	
	FZ	2021/0277376	09/09/2021	Wei et al.	424	094.620	05/21/2021	
	GA	2021/0284985	09/16/2021	Wei et al.	424	094.620	05/21/2021	

	Foreig	gn Patent Docume	nts or Publis	hed Foreign P	atent Applica	ations
Examiner	Desig.		Publication	Country or	Translation	
Initial	ID	Document Number	Date	Patent Office	Yes	No
	GB**	CN 102065886A	05/18/11	CN		X* (Item GR)
	GC**	EP 0400472	12/05/90	EP		
	GD**	EP 0822199	09/22/04	EP		
	GE**	EP 1064951	08/22/07	EP		
	GF**	EP 3130347	09/18/19	EP		
	GG**	EP 3636752	04/15/20	EP		
	GH**	EP 3785701	03/03/21	EP		
	GI**	JP 2007-153797	06/21/07	JP		X** (Item IM)
	GJ**	KR 10-2020-0017538	02/18/20	KR		X (Item GG)
	GK**	WO 1992/16640	10/01/92	WIPO		
	GL**	WO 1994/028024	12/08/94	WIPO		
	GM**	WO 2000/002017	01/13/00	WIPO		
	GN**	WO 2001/087925	11/22/01	WIPO		
	GO**	WO 2002/049673	06/27/02	WIPO		
	GP**	WO 2004/056312	07/08/04	WIPO		
	GQ**	WO 2005/000360	01/06/05	WIPO		
	GR**	WO 2009/128917	10/22/09	WIPO		
	GS**	WO 2009/134380	11/05/09	WIPO		
	GT**	WO 2010/077297	07/08/10	WIPO		

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conformance and not considered. Include copy of this form with nex	xt communication to applicant.		

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I .	losure Statement	Filing Date December 19, 2022	Group Art Unit Not yet assigned

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.		Publication	Country or	Tran	slation		
Initial	ID	Document Number	Date	Patent Office	Yes	No		
	GU**	WO 2010/149772	12/29/10	WIPO				
	GV**	WO 2012/136768	10/11/12	WIPO				
	GW**	WO 2012/174478	12/20/12	WIPO				
	GX**	WO 2013/102144	07/04/13	WIPO				
	GY**	WO 2015/003167	01/08/15	WIPO				

<sup>\*\* =</sup> Copies not provided herewith as they have been previously provided in connection with U.S. Patent Application Serial No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which are relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

X = An English language equivalent has been previously provided in connection with U.S. Serial No. 15/226,489.

	Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document		
	GZ	Letter/Written Disclosure of the Information Disclosure Statement for the above-referenced application, filed herewith on March 16, 2023, 2 pages.		
	HA**	Adams, G.E. and I.J. Stratford, "Bioreductive drugs for cancer therapy: the search for tumor specificity," Int. J. Radiat. Oncol. Biol. Phys., 29(2): 231-238 (1994).		
	HB**	Alexander et al., "Expression of the c-myc oncogene under control of an immunoglobulin enhancer in Eμ-myc transgenic mice," Mol. Cell. Biol. 7(4):1436-1444 (1987).		
	HC**	Ansel, H. C., Introduction to Pharmaceutical Dosage Forms, Lea & Febiger, Philadelphia, PA, Fourth Edition, p.126 (1985).		
	HD**	Anttila et al., "High levels of stromal hyaluronan predict poor disease outcome in epithelial ovarian cancer," Cancer Res. 60(1):150-155 (2000).		
HF** Arming et al., "In vitro mutagenesis of PH-20 hyalur		Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," Eur. J. Biochem. 247(3):810-814 (1997).		
	HF**	Atkinson, M. and E. Leiter, "The NOD mouse model of type 1 diabetes: as good as it gets?" Nature Med. 5:601-604 (1999).		
	HG**	Auvinen et al., "Hyaluronan in Peritumoral Stroma and Malignant Cells Associates with Breast Cancer Spreading and Predicts Survival," Am. J. Pathol. 156(2):529-536 (2000).		
	HH**	Baumgartner et al., "Phase I study in chemoresistant loco-regional malignant disease with hyaluronidase," Reg. Cancer Treat. 1:55-58 (1988).		
Beckenlehner et al., "Hyalur		Beckenlehner et al., "Hyaluronidase enhances the activity of adriamycin in breast cancer models in vitro and in vivo," J. Cancer Res. Oncol. 118:591-596 (1992).		
	HJ**	Benhar et al., "Pseudomonas exotoxin A mutants. Replacement of surface-exposed residues in domain III with cysteine residues that can be modified with polyethylene glycol in a site-specific manner," J. Biol. Chem. 269:13398-13404 (1994).		
	HK**	Bianchi et al., "Synthetic depsipeptide substrates for the assay of human hepatitis C virus protease," Anal. Biochem. 237: 239-244 (1996).		
	HL**	Bitter et al., "Expression and secretion vectors for yeast," Methods in Enzymol. 153:516-544 (1987).		

Examiner Signature			Date Considered	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in				

X\* = An English language equivalent has been previously provided in connection with U.S. Serial No. 13/694,731. X\*\* = An English Abstract (Item IM) for Japanese Publication No. JP 2007-153797 has been previously provided in connection with U.S. Serial No. 13/694,731.

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		Documents (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
	HM**	Bonner, W. and E. Cantey, "Colorimetric method for determination of serum hyaluronidase activity," Clin. Chim. Acta 13:746-752 (1966).
	HN**	Bookbinder et al., "A recombinant human enzyme for enhanced interstitial transport of therapeutics," J. Control. Release, 114:230-241 (2006).
	НО**	Bordier, C., "Phase separation of integral membrane proteins in Triton X-114 solution," J. Biol. Chem. 256(4):1604-1607 (1981).
	HP**	Bouffard et al., "An in vitro assay for hepatitis C virus NS3 serine proteinase," Virology 209:52-59 (1995).
	HQ**	Brinster et al., "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs," Nature 296:39-42 (1982).
	HR**	Brown et al., "Codon utilisation in the pathogenic yeast, Candida albicans," Nucleic Acids Res. 19(15):4298 (1991).
	HS**	Brumeanu et al., "Derivatization with monomethoxypolyethylene glycol of Igs expressing viral epitopes obviates adjuvant requirements," J. Immunol. 154:3088-3095 (1995).
	HT**	Caliceti, P. and Veronese, F. M., "Pharmacokinetic and biodistribution properties of poly(ethylene glycol)-protein conjugates," Adv. Drug Deliv. Rev. 55(10):1261-1277 (2003).
	HU**	Carrillo, H. and Lipman, D., "The multiple sequence alignment problem in biology," SIAM J. Applied Math. 48(5):1073-1082 (1988).
	HV**	Cefalu, W., "Animal models of type 2 diabetes: clinical presentation and pathophysiological relevance to the human condition," ILAR Journal 47(3):186-198 (2006).
	HW**	Chapman et al., "Therapeutic antibody fragments with prolonged in vivo half-lives," Nature Biotech. 17:780-783 (1999).
	HX**	Cheng et al., "PEGylated adenoviruses for gene delivery to the intestinal epithelium by the oral route," Pharm. Res. 20(9):1444-1451 (2003).
	HY**	Cherr et al., "The dual functions of GPI-anchored PH-20: hyaluronidase and intracellular signaling," Matrix Biol., 20(8):515-525 (2001).
	HZ**	Cherr et al., "The PH-20 protein in cynomolgus macaque spermatozoa: identification of two different forms exhibiting hyaluronidase activity," Dev. Biol. 175:142-153 (1996).
	IA**	Cho et al., "Construction of hepatitis C-SIN virus recombinants with replicative dependency on hepatitis C virus serine protease activity," J. Virol. Meth. 65:201-207 (1997).
	IB**	Chowpongpang et al., "Cloning and characterization of the bovine testicular PH-20 hyaluronidase core domain," Biotechnol. Lett. 26(15):1247-52 (2004).
	IC**	Colbere-Garapin et al., "A new dominant hybrid selective marker for higher eukaryotic cells," J. Mol. Biol. 150:1-14 (1981).
	ID**	Conserved domain search from US Application No. 10/795,095 of SEQ ID NO:6, Primakoff et al. US 5,721,348, performed on the NCBI website on August 5, 2008.
	IE**	Csoka et al., "Hyaluronidases in tissue invasion," Invasion Metastasis 17:297-311 (1997).
	IF**	Csoka et al., "Purification and microsequencing of hyaluronidase isozymes from human urine," FEBS Lett., 417(3):307-310 (1997).
	IG**	Csoka et al., "The six hyaluronidase-like genes in the human and mouse genomes," Matrix Biol. 20:499-508 (2001).
	IH**	Czejka et al., "Influence of hyaluronidase on the blood plasma levels of 5-fluorouracil in patients," Pharmazie 45(9):693-694 (1990).

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List of Patents and Publ	lications for Applicant's	Inventor(s) Wei et al.	
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned

Examiner	Desig.	Documents (include Author, Title, Date, and Place of Publication)
Initial	Desig.	Document
muai	II**	De Maeyer, E. and J. De Maeyer-Guignard, "The growth rate of two transplantable murine tumors, 3LL lung carcinoma and B16F10 melanoma, is influenced by Hyal-1, a locus determining hyaluronidase levels and polymorphism," Int. J. Cancer 51:657-660 (1992).
	IJ**	De Salegui et al., "A Comparison of Serum and Testicular Hyaluronidase," Arch. Biochem. Biophys 121:548-554 (1967).
	IK**	De Boer et al., "The <i>tac</i> promoter: a functional hybrid derived from the <i>trp</i> and <i>lac</i> promoters," Proc. Natl. Acad. Sci. USA 80:21-25 (1983).
	IL**	Delpech et al., "Enzyme-linked hyaluronectin: a unique reagent for hyaluronan assay and tissue location and for hyaluronidase activity detection," Anal. Biochem. 229:35-41 (1995).
	IM**	Derwent English abstract for Japanese Publication No. JP 2007-153797, published Jun. 21, 2007, entitled "Therapeutic Agent And Preventive Agent Of Autoimmune Disease, Inflammation, And Nervous Disease," 3 pages.
	IN**	Dorfman, A. and M. Ott, "A turbidimetric method for the assay of hyaluronidase," J. Biol. Chem. 172:367-375 (1948).
	IO**	D'Souza et al., "In vitro cleavage of hepatitis C virus polyprotein substrates by purified recombinant NS3 protease," J. Gen. Virol. 76:1729-1736 (1995).
	IP**	Duttaroy et al., "Development of a long-acting insulin analog using albumin fusion technology," Diabetes 54(1):251-258 (2005).
	IQ**	Elder et. al, "Intra-arterial hyaluronidase in severe peripheral arterial disease," Lancet 1(8169):648-649 (1980).
	IR**	Ernst et al., "Enzymatic degradation of glycosaminoglycans," Crit. Rev. Biochem. Mol. Biol. 30(5):387-444 (1995).
	IS**	Eskens et al., "Enzymatic glycocalyx treatment impairs insulin-mediated recruitment of microvascul blood volume and decreases insulin sensitivity in rats," FASEB Journal 25: 1023.13 (2011) (Abstract).
	IT**	European Pharmacopoeia, Chapter 5.1.3, "Efficacy of antimicrobial preservation," pp. 447-449 (2005).
	IU**	Fankhauser, N. and Mäser, P., "Identification of GPI anchor attachment signals by a Kohonen self- organizing map," Bioinformatics 21(9):1846-1852 (2005).
	IV**	Felix et al., "Pegylated peptides IV. Enhanced biological activity of site-directed pegylated GRF analogs," Int. J. Peptide Protein Res. 46:253-264 (1995).
	IW**	Few, B., "Hyaluronidase for treating intravenous extravasations," MCN Amer. J. Matern. Child Nur. 12(1):23 (1987).
	IX**	Filocamo et al., "Chimeric Sindbis viruses dependent on the NS3 protease of hepatitis C virus," J. Virology 71:1417-1427 (1997).
	IY**	Forsburg, S.L., "Codon usage table for Schizosaccharomyces pombe," Yeast 10(8):1045-1047 (199
	IZ**	Fransson et al., "Solvent effects on the solubility and physical stability of human insulin-like growtl factor I," Pharm. Res. 14(5):606-12 (1997).
	JA**	Frost, G. I. and Stern, R., "A microtiter-based assay for hyaluronidase activity not requiring specialized reagents," Anal. Biochem. 251:263-269 (1997).
	ЈВ**	Gardner et al., "The complete nucleotide sequence of an infectious clone of cauliflower mosaic viru by M13mp7 shotgun sequencing," Nucleic Acids Res. 9(12):2871-2888 (1981).
	JC**	GenBank Accession No. AAC60607, PH-20 [Homo sapiens], published on 06-05-2000 [online] [retrieved on Dec. 12, 2012][retrieved from the Internet: URL: <ncbi.nlm.nih.gov 1="" aac6060="" page.<="" protein="" td=""></ncbi.nlm.nih.gov>

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List of Patents and Duk	alications for Applicant's	Inventor(s) Wei et al.	
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		Documents (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
miliai	љ**	Gilbert, W. and Villa-Komaroff, L., "Useful Proteins from Recombinant Bacteria," Scientific American 242(4):74-94 (1980).
	ЈЕ**	Girish et al., "Hyaluronidase inhibitors: a biological and therapeutic perspective," Curr. Med. Chem. 16(18):2261-2288 (2009).
	JF**	Gmachl et al., "The human sperm protein PH-20 has hyaluronidase activity," FEBS 336(3):545-548 (1993).
	JG**	Good et al., "Hydrogen ion buffers for biological research," Biochemistry 5(2):467-477 (1966).
	JH**	Gribskov, M. and Burgess, R. R., "Sigma factors from <i>E. coli</i> , <i>B. subtilis</i> , phage SP01, and phage T4 are homologous proteins," Nucl. Acids Res. 14(16):6745-6763 (1986).
	Л**	Grosschedl et al., "Introduction of a μ immunoglobulin gene into the mouse germ line: specific expression in lymphoid cells and synthesis of functional antibody," Cell 38:647-658 (1984).
	JJ**	Guiotto et al., "An improved procedure for the synthesis of branched polyethylene glycols (PEGs) with the reporter dipeptide Met-βAla for protein conjugation," Bioorg. Med. Chem. Lett. 12:177-180 (2002).
	ЈК**	Guntenhoner et al., "A substrate-gel assay for hyaluronidase activity," Matrix 12:388-396 (1992).
	JL**	Guo et al., "Protein tolerance to random amino acid change," Proc. Nat'l. Acad. Sci. USA, 101:9205 9210, 2004.
	JM**	Hahm et al., "Generation of a novel poliovirus with a requirement of hepatitis C virus protease NS3 activity," Virology 226:318-326 (1996).
	JN**	Haller et al., "Escaping the Interstitial Matrix With Enzyme-Mediated Drug Delivery," Drug Delivery Technology, 5(5):1-6 (2005).
	JO**	Hamatake et al., "Establishment of an in vitro assay to characterize hepatitis C virus NS3-4A proteat trans-processing activity," Intervirology 39:249-258 (1996).
	JP**	Hammer et al., "Diversity of alpha-fetoprotein gene expression in mice is generated by a combination of separate enhancer elements," Science 235:53-58 (1987).
	JQ**	Hanahan, D., "Heritable formation of pancreatic β-cell tumours in transgenic mice expressing recombinant insulin/simian virus 40 oncogenes," Nature 315(6015):115-122 (1985).
	JR**	Harris, J. and R. Chess, "Effect of pegylation on pharmaceuticals," Nat. Rev. Drug Discov. 2(3):214 221 (2003).
	JS**	Hartman S. and R. Mulligan, "Two dominant-acting selectable markers for gene transfer studies in mammalian cells," Proc. Natl. Acad. Sci. 85:8047-8051 (1988).
	JT**	Have et al., "Cloning and characterization of the cDNA encoding the PH20 protein in the European red fox Vulpes vulpes," Reproduct. Fertil. Dev. 10:165-172 (1998).
	JU**	Herrera-Estrella et al., "Expression of chimaeric genes transferred into plant cells using a Ti-plasmic derived vector," Nature 303:209-213 (1983).
	JV**	Herrera-Estrella et al., "Light-inducible and chloroplast-associated expression of a chimaeric gene introduced into <i>Nicotiana tabacum</i> using a Ti plasmid vector," Nature 310(5973):115-120 (1984).
	JW**	Hibi et al., "Chondroitinase C activity of <i>Streptococcus intermedius</i> ," FEMS Microbiol. Lett. 57(2):121-124 (1989).
	JX**	Hofinger et al., "Isoenzyme-specific differences in the degradation of hyaluronic acid by mammaliatype hyaluronidases," Glycoconj. J. 25:101-109 (2008).
	JY**	Holash et al., "VEGF-Trap: a VEGF blocker with potent antitumor effects," Proc. Natl. Acad. Sci. U. S. A. 99(17):11393-11398 (2002).

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Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner Desig.				
Initial ID		Document		
	JZ**	Hooper, N. M., "Determination of glycosyl-phosphatidylinositol membrane protein anchorage" Proteomics 1:748-755 (2001)		
	KA**	Horn et al., "Intravesical chemotherapy of superficial bladder tumors in a controlled trial with cisplatinum versus cis-platinum plus hyaluronidase," J. Surg. Oncol. 28:304-307 (1985).		
	KB**	Huang et al., "Recombinant Human Hyaluronidase PH20 Does Not Stimulate an Acute Inflammatory Response and Inhibits Lipopolysaccharide-Induced Neutrophil Recruitment in the Air Pouch Model of Inflammation," (2014) J. Immunol. 192(11):5285-5295.		
	KC**	Huang, X. and W. Miller, "A time-efficient, linear-space local similarity algorithm," Adv. Appl. Math. 12:337-357 (1991).		
	KD**	Hunnicut et al., "Structural relationship of sperm soluble hyaluronidase to the sperm membrane protein PH-20," Biol. Reprod. 54(6):1343-1349 (1996).		
	KE**	Infante et al., "Phase 1 trials of PEGylated recombinant human hyaluronidase PH20 in patients with advanced solid tumours," Br. J. Cancer 118(2):153-161 (2018).		
	KF**	Ito et al., "Cultivation of hepatitis C virus in primary hepatocyte culture from patients with chronic hepatitis C results in release of high titre infectious virus," J. Gen. Virol. 77:1043-1054 (1996).		
	KG**	IUPAC-IUB Commission on Biochemical Nomenclature, "A One-Letter Notation for Amino Acid Sequences: Tentative Rules," J. Biol. Chem. 243(13):3557-3559 (1968).		
	KH**	IUPAC-IUB Commission on Biochemical Nomenclature, "Abbreviated nomenclature of synthetic poypeptides-polymerized amino acids-revised recommendations," The Journal of Biological Chemistry 247(2):323-325 (1972).		
	KI**	Jadin et al., "A comprehensive model of hyaluronan turnover in the mouse," Matrix Biol. 31(2):81-8(2012).		
	KJ**	Jay et al., "Construction of a general vector for efficient expression of mammalian proteins in bacteria: use of a synthetic ribosome binding site," Proc. Natl. Acad. Sci. USA 78(9):5543-5548 (1981).		
	KK**	Karvinen et al., "Hyaluronan, CD44 and versican in epidermal keratinocyte tumours," British Journal of Dermatology 148: 86-94 (2003).		
	KL**	Kelsey et al., "Species- and tissue-specific expression of human $\alpha_1$ -antitrypsin in transgenic mice," Genes And Devel. 1:161-171 (1987).		
	KM**	Kim et al., "Sperm penetration through cumulus mass and zona pellucida," Int. J. Dev. Biol. 52(5-6):677-682 (2008).		
	KN**	Kodukula et al., "Biosynthesis of Phosphatidylinositol Glycan-anchored Membrane Proteins," J. Biol. Chem. 266:4464-4470 (1991).		
	КО**	Kohno et al., "Effects of hyaluronidase on doxorubicin penetration into squamous carcinoma multicellular tumor spheroids and its cell lethality," J. Cancer Res. Clin. Oncol. 120(5):293-297 (1994).		
	KP**	Kollias et al., "Regulated expression of human <sup>A</sup> γ-, β-, and hybrid γβ-globin genes in transgenic mice: manipulation of the developmental expression patterns," Cell 46:89-94 (1986).		
	KQ**	Krumlauf et al., "Developmental regulation of α-fetoprotein genes in transgenic mice," Mol. Cell. Biol. 5(7):1639-1648 (1985).		
	KR**	Krupers et al., "Complexation of poly(ethylene oxide) with poly(acrylic acid-co-hydroxyethyl methacrylate)s," Eur. Polym J. 32(6):785-790 (1996).		
	KS**	Kyte et al., "A Simple Method for Displaying the Hydropathic Character of a Protein" J. Mol. Biol. 157:105-132 (1982).		
	KT**	Lalancette et al, "Characterization of an 80-kilodalton bull sperm protein identified as PH-20," Biol. Reprod. 65(2):628-636 (2001).		
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Other Documents (include Author, Title, Date, and Place of Publication)		
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	KU**	Lam et al., "The effect of benzyl alcohol on recombinant human interferon-gamma," Pharm. Res. 14(6):725-729 (1997).
	KV**	Lammerts van Bueren et al., "The antibody zalutumumab inhibits epidermal growth factor receptor signaling by limiting intra- and intermolecular flexibility," Proc. Natl. Acad. Sci. U. S. A. 105(16):6109-6114 (2008).
	KW**	Lathrop et al., "cDNA cloning reveals the molecular structure of a sperm surface protein, PH-20, involved in sperm-egg adhesion and the wide distribution of its gene among mammals," J. Cell Biol. 111(6 Pt 2):2939-2949 (1990).
	KX**	Laurent, T. and J. Fraser, "Hyaluronan," FASEB J 6:2397-2404 (1992).
	KY**	Leder et al., "Consequences of widespread deregulation of the c-myc gene in transgenic mice: multiple neoplasms and normal development," Cell 45:485-495 (1986).
	KZ**	Li et al., "Importance of Glycosylation and Disulfide Bonds in Hyaluronidase Activity of Macaque Sperm Surface PH-20," J. Androl. 23:211-219 (2002).
	LA**	Li et al., "Structural basis for EGF receptor inhibition by the therapeutic antibody IMC-11F8," Structure 16(2):216-227 (2008).
	LB**	Liang et al., "Prediction of antigenic epitopes on protein surfaces by consensus scoring," BMC Bioinformatics 10:302 (2009), 10 pages.
	LC**	Lin et al., "A hyaluronidase activity of the sperm plasma membrane protein PH-20 enables sperm to penetrate the cumulus cell layer surrounding the egg," J. Cell Bio. 125(5):1157-1163 (1994).
	LD**	Lin et al., "Molecular cloning of the human and monkey sperm surface protein PH-20," Proc. Natl. Acad. Sci. USA 90:10071-10075 (1993).
	LE**	Lipponen et al., "High stromal hyaluronan level is associated with poor differentiation and metastasis in prostate cancer," Euro. J. Can. 37(3):849-856 (2001).
	LF**	Locke et al., "ENHANZE® drug delivery technology: a novel approach to subcutaneous administration using recombinant human hyaluronidase PH20," Drug Deliv. 26(1):98-106 (2019).
	LG**	Louveau, I. and F. Gondret, "GH and insulin affect fatty acid synthase activity in isolated porcine adipocytes in culture without any modifications of sterol regulatory element binding protein-1 expression," J. Endocrin. 181:271-280 (2004).
	LH**	Lowe et al., "Flexible eating and flexible insulin dosing in patients with diabetes: Results of an intensive self-management course," Diabetes Res. Clin. Pract. 80(3):439-443 (2008).
	LI**	Lu, H. and E. Wimmer., "Poliovirus chimeras replicating under the translational control of genetic elements of hepatitis C virus reveal unusual properties of the internal ribosomal entry site of hepatitis C virus," Proc. Natl. Acad. Sci. USA 93:1412-1417 (1996).
	LJ**	Lu, Y. A. and Felix, A. M., "Pegylated peptides I: Solid-phase synthesis of N <sup>e</sup> -pegylated peptides using Fmoc strategy," Peptide Res. 6(3):140-146 (1993).
	LK**	Lu, Y. A. and Felix, A. M., "Pegylated peptides II. Solid-phase synthesis of amino-, carboxy- and side-chain pegylated peptides," Int. J. Peptide Protein Res. 43:127-138 (1994).
	LL**	M3WD76 Felca (2015, updated) Hyaluronidase/PH20 from Felis catus, 3 pages.
	LM**	Ma et al., "Fucosylation in prokaryotes and eukaryotes" Glycobiology 16(12):158R-184R (2006)
	LN**	Maa and Hsu, "Aggregation of recombinant human growth hormone induced by phenolic compounds," Int. J. Pharm. 140(2):155-168 (1996).
	LO**	MacDonald, R. J., "Expression of the pancreatic elastase I gene in transgenic mice," Hepatology 7(1):42S-51S (1987).

Sheet <u>12</u> of <u>25</u>

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Publications for Applicant's Information Disclosure Statement		Inventor(s) Wei et al.	
		Filing Date December 19, 2022	Group Art Unit Not yet assigned

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	LP**	Magram et al., "Developmental regulation of a cloned adult $\beta$ -globin gene in transgenic mice," Nature 315:338-340 (1985).
	LQ**	Marković-Housley et al., "Crystal structure of hyaluronidase, a major allergen of bee venom," Structure 8: 1025-1035 (2000).
	LR**	Maksimenko et al., "Resistance of dextran-modified hyaluronidase to inhibition by heparin" Biochemistry (Mosc.) 66(4):456-463 (2001).
	LS**	Mammalian Gene Collection (MGC) Program Team, "Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences," Proc. Natl. Acad. Sci. USA 99:16899-16903 (2002).
	LT**	McIlvaine, W. B., "A buffer solution for colorimetric comparison," J. Biol. Chem. 49:183-186 (1921).
	LU**	Mehvar, R., "Modulation of the pharmacokinetics and pharmacodynamics of proteins by polyethylene glycol conjugation," J. Pharm. Pharmaceut. Sci. 3(1):125-136 (2000).
	LV**	Menzel, E. and C. Farr, "Hyaluronidase and its substrate hyaluronan: biochemistry, biological activities and therapeutic uses," Cancer Lett. 131:3-11 (1998).
	LW**	Merrifield, R. B., "Solid phase peptide synthesis. I. The synthesis of a tetrapeptide," J. Am. Chem. Soc. 85:2149-2154 (1963).
	LX**	Meyer et al., "The soluble hyaluronidase from bull testes is a fragment of the membrane-bound PH-20 enzyme," FEBS Letters 413(2):385-388 (1997).
	LY**	Michelacci, Y. M. and Dietrich, C. P., "Chondroitinase C from <i>Flavobacterium heparinum</i> ," J. Biol. Chem. 251(4):1154-1158 (1976).
	LZ**	Miller et al., "Use of retroviral vectors for gene transfer and expression," Meth. Enzymol. 217:581-599 (1993).
	MA**	Mizutani et al., "Characterization of hepatitis C virus replication in cloned cells obtained from a human T-cell leukemia virus type 1-infected cell line, MT-2," J. Virol. 70:7219-7223 (1996).
	MB**	Mizutani et al., "Inhibition of hepatitis C virus replication by antisense oligonucleotide in culture cells," Biochem. Biophys. Res. Commun. 212:906-911 (1995).
	MC**	Molineux, G., "Pegylation: engineering improved biopharmaceuticals for oncology," Pharmacotherapy 23 (8 Pt 2):3S-8S (2003).
	MD**	Monfardini et al., "A branched monomethoxypoly(ethylene glycol) for protein modification," Bioconjugate Chem. 6:62-69 (1995).
	ME**	Nadjsombati et al., "Dose-range developmental toxicity of rHuPH20 in mice," Matrix Biology Vol. 27, December 2008, Page 23.
	MF**	Nakayama et al., "CD15 expression in mature granulocytes is determined by α1,3-fucosyltransferase IX, but in promyelocytes and monocytes by α1,3-fucosyltransferase IV," J. Biol. Chem. 276(19):16100-16106 (2001).
	MG**	NCBI Reference Sequence XP_011728213.1, Macaca nemestrina (pig-tailed macaque) PH-20 hyaluronidase. Published on Apr. 24, 2018. Retrieved from URL: <ncbi.nlm.nih.gov 2="" 20,="" 2020],="" 795324051="" [retrieved="" apr.="" on="" pages.<="" protein="" td=""></ncbi.nlm.nih.gov>
_	MH**	Needleman, S. B. and Wunsch, C. D., "A general method applicable to the search for similarities in the amino acid sequence of two proteins," J. Mol. Biol. 48:443-453 (1970).
	MI**	Nekoroski et al., "A recombinant human hyaluronidase sustained release gel for the treatment of post-surgical edema," Int. J. Dermatol. 53(6):777-785 (2014).
	MJ**	Omaetxebarria et al., "Computational approach for identification and characterization of GPI-anchored peptides in proteomics experiments," Proteomics 7(12):1951-1960 (2007).

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		Filing Date December 19, 2022	Group Art Unit Not yet assigned

Other Documents (include Author, Title, Date, and Place of Publication)		
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miliar	MK**	Ornitz et al., "Elastase I promoter directs expression of human growth hormone and SV40 T antigen genes to pancreatic acinar cells in transgenic mice," Cold Spring Harbor Symp. Quant. Biol. 50:399-409 (1985).
	ML**	Ostresh et al., "Peptide libraries: determination of relative reaction rates of protected amino acids in competitive couplings," Biopolymers 34:1681-1689 (1994).
	MM**	Padavattan, S., "Crystal structure determination of hyaluronidase: a major bee venom allergen, in complex with an IgG Fab fragment and purification and biophysical characterization of bovine testes hyaluronidase," 2006, PhD Thesis, University of Basel, Faculty of Science. DOI: 10.5451/unibas-004349798, 101 pages.
	MN**	Paul, A. and D. Sochart, "Improving the results of ganglion aspiration by the use of hyaluronidase," J. Hand Surg. 22B(2):219-221 (1997).
	MO**	Paulick, M. and C. Bertozzi, "The glycosylphosphatidylinositol anchor: A complex membrane-anchoring structure for proteins," Biochemistry 47:6991-7000 (2008).
	MP**	Pawlowski et al., "The effects of hyalurodinase upon tumor formation in BALB/c mice painted with 7,12-dimethylbenz-(α)anthracene," Int. J. Cancer 23:105-109 (1979).
	MQ**	Pedersen et al., "Sym004: a novel synergistic anti-epidermal growth factor receptor antibody mixture with superior anticancer efficacy," Cancer Res. 70(2):588-597 (2010).
	MR**	Pham et al., "Large-scale transient transfection of serum-free suspension-growing HEK293 EBNA1 cells: peptone additives improve cell growth and transfection efficiency," Biotechnology and Bioengineering 84(3):332-342 (2003).
	MS**	Phelps et al., "Restricted lateral diffusion of PH-20, a PI-anchored sperm membrane protein," Science 240:1780-1782 (1988).
	MT**	Pierleoni et al., "PredGPI: a GPI-anchor predictor," BMC Bioinformatics 9:392 (2008), 11 pages.
	MU**	Pinkert et al., "An albumin enhancer located 10 kb upstream functions along with its promoter to direct efficient, liver-specific expression in transgenic mice," Genes and Devel. 1:268-276 (1987).
	MV**	Pirinen et al., "Prognostic value of hyaluronan expression in non-small-cell lung cancer: Increased stromal expression indicates unfavorable outcome in patients with adenocarcinoma," Int. J. Cancer 95: 12-17 (2001).
	MW**	Primakoff et al., "Fully effective contraception in male and female guinea pigs immunized with the sperm protein PH-20," Nature 335:543-546 (1988).
	MX**	Prothmann et al., "Sexual size dimorphism predicts rates of sequence evolution of Sperm Adhesion Molecule 1 (SPAM1, also PH-20) in monkeys, but not in hominoids (apes including humans)," Mol. Phy. Ev. 63: 52-63 (2012).
	MY**	Readhead et al., "Expression of a myelin basic protein gene in transgenic shiverer mice: correction of the dysmyelinating phenotype," Cell 48:703-712 (1987).
	MZ**	Reitinger et al., "Designed human serum hyaluronidase 1 variant, HYAL1 <sup>ΔL</sup> , exhibits activity up to pH 5.9," J. Biol. Chem. 284(29):19173-19177 (2009).
	NA**	Remmele et al., "Interleukin-1 receptor (IL-1R) liquid formulation development using differential scanning calorimetry," Pharm. Res. 15(2):200-208 (1998).
	NB**	Rhodes et al., "Transformation of maize by electroporation of embryos," Methods Mol Biol 55:121-131 (1995).
	NC**	Richmond, T., "Precompiled codon-usage tables," Genome Biology 1:reports 241(2000).
	ND**	Ripka et al., "Two Chinese hamster ovary glycosylation mutants affected in the conversion of GDP-mannose to GDP-fucose," Arch. Biochem. Biophys. 249(2):533-545 (1986).

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	NE**	Roberts et al., "Chemistry for peptide and protein PEGylation," Advanced Drug Delivery Reviews 54:459-476 (2002).
	NF**	Ropponen et al., "Tumor Cell-associated Hyaluronan as an Unfavorable Prognostic Factor in Colorectal Cancer," Cancer Research 58:342-347 (1998).
	NG**	Rosengren et al., "Clinical Immunogenicity of rHuPH20, a Hyaluronidase Enabling Subcutaneous Drug Administration," AAPS J. 17(5):1144-1156 (2015).
	NH**	Sato et al., "Cloning and expression in <i>Escherichia coli</i> of the gene encoding the <i>Proteus vulgaris</i> chondroitin ABC lyase," Appl. Microbiol. Biotechnol. 41(1):39-46 (1994).
	NI**	Sato, H., "Enzymatic procedure for site-specific pegylation of proteins," Adv. Drug Deliv. Rev. 54:487-504 (2002).
	NJ**	Sawhney et al., "Bioerodible hydrogels based on photopolymerized poly(ethylene glycol)-co-poly(α-hydroxy acid) Diacrylate Macromers," Macromolecules 26:581-587 (1993).
	NK**	Schanté et al., "Improvement of hyaluronic acid enzymatic stability by the grafting of amino-acids," Carbohydrate Polymers, 87(3):2211-2216 (2012).
	NL**	Scharf et al., "Heat stress promoters and transcription factors," in Nover, L. (eds) Plant Promnoters and Transcription Factors. Results and Problems in Cell Differentiation, vol. 20. Springer, Berlin, Heidelberg (1994).
	NM**	Scheithauer et al., "In vitro evaluation of the anticancer drug modulatory effect of hyaluronidase in human gastrointestinal cell lines," Anticancer Res. 8:391-396 (1988).
	NN**	Schuller et al., "Pharmacokinetics of intrahepatic 5-fluorouracil ± preinjected hyaluronidase (Neopermease, N)," Proc. Amer. Assoc. Cancer Res. 32:173, abstract no. 1034 (1991).
	NO**	Schwartz, R. M. and Dayhoff, M. O., eds., "Matrices for Detecting Distant Relationships," Atlas of Protein Science and Structure, National Biomedical Research Foundation, pp. 353-358 (1978).
	NP**	Schwartzman, J., "Hyaluronidase: A Review in Its Therapeutic Use in Pediatrics," J. Pediat. 39:491-502 (1951).
	NQ**	Seaton et al., "Rat sperm 2B1 glycoprotein (PH20) contains a C-terminal sequence motif for attachment of a glycosyl phosphatidylinositol anchor. Effects of endoproteolytic cleavage on hyaluronidase activity," Biol Reprod. 62(6):1667-1676 (2000).
	NR**	Shani, M., "Tissue-specific expression of rat myosin light-chain 2 gene in transgenic mice," Nature 314:283-286 (1985).
	NS**	Sharp et al., "Codon usage patterns in Escherichia coli, Bacillus subtilis, Saccharomyces cerevisiae, Schizosaccharomyces pombe, Drosophila melanogaster and Homo sapiens; a review of the considerable within-species diversity," Nucleic Acids Res. 16(17):8207-8211 (1988).
	NT**	Sharp, P.M. and E. Cowe, "Synonymous codon usage in Saccharomyces cerevisiae," Yeast. 7(7):657-678 (1991).
	NU**	Shekhar et al., "The Matrix Reloaded: Halozyme's Recombinant Enzyme Helps Injected Drugs Spread Faster," Chem. Biol. 14:603-604 (2007).
	NV**	Shimizu, Y. and H. Yoshikura, "Multicycle infection of hepatitis C virus in cell culture and inhibition by alpha and beta interferons," J. Virol. 68:8406-8408 (1994).
	NW**	Singh et al., "Mechanisms of m-cresol-induced protein aggregation studied using a model protein cytochrome c," J. Pharm. Sci. 100(5):1679-1689 (2011).
	NX**	Smith, T. F. and Waterman, M. S., "Comparison of biosequences," Advances in Applied Mathematics 2:482-489 (1981).
	NY**	St. Croix et al., "Reversal of intrinsic and acquired forms of drug resistance by hyaluronidase treatment of solid tumors," Cancer Lett. 131(1):35-44 (1998).

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Examiner	Desig.	
Initial	ID	Document
	NZ**	Steinkuhler et al., "Product inhibition of the hepatitis C virus NS3 protease," Biochem. 37:8899-8905 (1998).
	OA**	Stern, R., "Devising a pathway for hyaluronan catabolism: are we there yet?" Glycobiology 13:105R-115R (2003).
	OB**	Stern et al., "Hyaluronidases: their genomics, structures, and mechnisms of action," Chem. Rev. 106: 818-839 (2006).
	OC**	Sturla et al., "Core fucosylation of N-linked glycans in leukocyte adhesion deficiency/congenital disorder of glycosylation IIc fibroblasts," Glycobiology 15(10):924-934 (2005).
	OD**	Sudo et al., "Establishment of an in vitro assay system for screening hepatitis C virus protease inhibitors using high performance liquid chromatography," Antiviral Res. 32:9-18 (1996).
	OE**	Sutton, S. and D. Porter, "Development of the antimicrobial effectiveness test as USP chapter <51>," PDA J. Pharm. Sci Technol., 56(6):300-311 (2002).
	OF**	Swift et al., "Tissue-specific expression of the rat pancreatic elastase I gene in transgenic mice," Cell 38(3):639-646 (1984).
	OG**	Takahashi et al., "A fluorimetric Morgan-Elson assay method for hyaluronidase activity," Anal. Biochem. 322:257-263 (2003).
	OH**	Takeshita et al., "An enzyme-linked immunosorbent assay for detecting proteolytic activity of hepatitis C virus proteinase," (1997) Anal. Biochem. 247:242-246.
	OI**	Taliani et al., "A continuous assay of hepatitis C virus protease based on resonance energy transfer depsipeptide substrates," Anal. Biochem. 240:60-67 (1996).
	OJ**	ten Have et al., "Cloning and characterization of the cDNA encoding the PH20 protein in the European red fox Vulpes vulpes," Reprod. Fertil. Dev. 10(2):165-172 (1998).
	OK**	Tkalec et al., "Isolation and expression in <i>Escherichia coli</i> of <i>cslA</i> and <i>cslB</i> , genes coding for the chondroitin sulfate-degrading enzymes chondroitinase AC and chondroitinase B, respectively, from <i>Flavobacterium heparinum</i> ," Applied and Environmental Microbiology 66(1): 29-35 (2000).
	OL**	Tsubery et al., "Prolonging the action of protein and peptide drugs by a novel approach of reversible polyethylene glycol modification.," J. Biol. Chem. 279(37):38118-38124 (2004).
	OM**	Tsuda et al., "Substrate specificity studies of <i>Flavobacterium</i> chondroitinase C and heparitinases towards the glycosaminoglycan—protein linkage region. Use of a sensitive analytical method developed by chromophore-labeling of linkage glycoserines using dimethylaminoazobenzenesulfony chloride," Eur. J. Biochem. 262:127-133 (1999).
	ON**	Tung et al., "Mechanism of infertility in male guinea pigs immunized with sperm PH-20," Biol. Reprod. 56(5):1133-1141 (1997).
	OO**	Udenfriend, S. and Kodukula, K., "Prediction of ω site in nascent precursor of glycosylphosphatidylinositol protein," Methods Enzymol. 250:571-582 (1995).
	OP**	UniProt Murine PH20 sequence Retrieved from: <uniprot.org 02,="" 2010],="" 5="" [retrieved="" august="" on="" p48794,="" pages.<="" td="" uniprot=""></uniprot.org>
	OQ**	United States Pharmacopeia. USP <51>. Antimicrobial effectiveness testing. United States Pharmacopeia Convention, Inc, Rockville, MD.Retreived from: <a href="http://www.pharmacopeia.cn/v2920/usp29nf24s0_c51.html">http://www.pharmacopeia.cn/v2920/usp29nf24s0_c51.html</a> , [retreived on Apr. 02, 2013], 5 pages.
	OR**	USP XXII-NF XVII (1990), p. 644-645 United States Pharmacopeial Convention, Inc, Rockville, MD.
	OS**	Varela et al., "Exome sequencing identifies frequent mutation of the SWI/SNF complex gene PBRM in renal carcinoma," Nature 469(7331):539-542 (2011).

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Initial	ID	Document
	OT**	Veronese et al., "Branched and Linear Poly(Ethylene Glycol): Influence of the Polymer Structure on Enzymological, Pharmacokinetic, and Immunological Properties of Protein Conjugates," J. Bioactive Compatible Polymers 12:196-207 (1997).
	OU**	Von Sivaraman Padavattan (2006) Thesis of University of Basel, "Crystal structure determination of hyaluronidase, a major bee venom allergen, in complex with an IgG Fab fragment and purification and biophysicial charcterization of bovine testes hyaluronidase," 100 pages.
	OV**	Wagner et al., "Nucleotide sequence of the thymidine kinase gene of herpes simplex virus type 1," Proc. Natl. Acad. Sci. USA 78(3):1441-1445 (1981).
	OW**	Wang et al., "The molecular physiology of hepatic nuclear factor 3 in the regulation of gluconeogenesis," J. Biol. Chem. 275(19):14717-14721 (2000).
	OX**	Watson et al., Molecular Biology of the Gene, 4th Edition, The Benjamin/Cummings Pub. Co., Menlo Park, CA, p. 224 (1987).
	OY**	Weiss et al., "Activities of monomeric insulin analogs at position A8 are uncorrelated with their thermodynamic stabilities," J. Biol. Chem. 276(43):40018-40024 (2001).
	OZ**	Wells, J.A., "Additivity of Mutational Effects in Proteins," Biochem. 29(37):8509-8517 (1990).
	PA**	White et al., "Comparison of the glycosyl-phosphatidylinositol cleavage/attachment site between mammalian cells and parasitic protozoa," J. Cell Sci. 113(Pt.4):721-727 (2000).
	PB**	Wigler et al., "Transfer of purified herpes virus thymidine kinase gene to cultured mouse cells," Cell 11:223-232 (1977).
	PC**	Wigler et al., "Transformation of mammalian cells with an amplifiable dominant-acting gene," Proc. Natl. Acad. Sci. USA 77:3567-3570 (1980).
	PD**	Yamamoto et al., "Identification of a functional promoter in the long terminal repeat of Rous sarcoma virus," Cell 22:787-797 (1980).
	PE**	Yamane-Ohnuki et al., "Establishment of FUT8 knockout Chinese hamster ovary cells: an ideal host cell line for producing completely defucosylated antibodies with enhanced antibody-dependent cellular cytotoxicity," Biotech. Bioeng. 87:614-622 (2004).
	PF**	Yang, X. and X. Yu, "An introduction to epitope prediction methods and software," Rev. Med. Virol. 19(2):77-96 (2009).
	PG**	Yocum et al., "Assessment and Implication of the Allergic Sensitivity to a Single Dose of Recombinant Human Hyaluronidase Injection: A Double-Blind, Placebo-Controlled Clinical Trial," J. Infus. Nursing. 30:293-299 (2007).
	PH**	Yudin et al., "Characterization of the active site of monkey sperm hyaluronidase," Reproduction 121(5):735-743 (2001).
	PI**	Zalipsky, S., "Chemistry of polyethylene glycol conjugates with biologically active molecules," Adv. Drug Del. Rev. 16:157-182 (1995).
	PJ**	Zanker et al., "Induction of response in previous chemotherapy resistant patients by hyaluronidase," Proc. Amer. Assoc. Cancer Res. 27:390 Abstract 1550 (1986).
	PK**	Zhang et al., "Hyaluronidase activity of human Hyal1 requires active site acidic and tyrosine residues," J. Biol. Chem. 284(14):9433-9442 (2009).
	PL**	Zhao, X. and J. Harris, "Novel degradable poly(ethylene glycol) esters for drug delivery," in Chapter 28: Poly(ethylene glycol), ACS Symposium Series, Vol. 680, Harris, J. and Zalipsky, S., (eds), 458-472 (1997).
	PM**	Bee et al., "Recombinant human PH20 is well tolerated at higher intravenous and subcutaneous doses in cynomolgus monkeys," EUFEPS 2008, Munich, Germany. Abstract, 2 pages.

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		Bee et al., "Recombinant human PH20 is well tolerated at higher intravenous and subcutaneous doses
	PN**	in cynomolgus monkeys," EUFEPS 2008, Munich, Germany. Poster and individual panels, 9 pages.
	DO##	Bookbinder et al., "Biochemical characterization of recombinant human PH20 (SPAM1)
	PO**	hyaluronidase," Hyaluronan (ISHAS) 2007, Charleston, SC. Abstract, 1 page.
		Bookbinder et al., "Biochemical characterization of recombinant human PH20 (SPAM1)
	PP**	hyaluronidase," Hyaluronan (ISHAS) 2007, Charleston, SC. Poster, 1 page.
		Bookbinder et al., "Enhancing Drug Transport Through Temporary Matrix Depolymerization,"
	PQ**	Keystone Symposia 2005. (poster -12 pages) (together poster and abstract - 13 pages)
		Bookbinder et al., "Enhancing Drug Transport Through Temporary Matrix Depolymerization,"
	PR**	Keystone Symposium 2005. Abstract, 1 page.
		Pinkstaff et al., "Evaluation of the compatibility and pharmacokinetics of co-formulated biologics
	PS**	with recombinant human hyaluronidase: Dose Response," American Association of Pharmaceutical
	15	Scientists Conference, November 2006. Abstract, 2 pages.
		Pinkstaff et al., "Evaluation of the compatibility and pharmacokinetics of co-formulated biologics
	PT**	with recombinant human hyaluronidase: Dose Response," American Association of Pharmaceutical
	F1	Scientists Conference, November 2006. Poster, 1 page.
	DT Librit	Byerley et al., "'Cutting out the bull'. Recombinant human hyaluronidase: Moving to an animal-free
	PU**	system," Association of Clinical Embryologists, 2006, Dublin, Ireland. Abstract published in Human
		Fertility, June 2006; 9(2): 110.
	PV**	Frost, "Punctuated Equilibrium: The Evolution of Recombinant Human Hyaluronidase," Ophthalmic
		Anesthesia Society, 2006, Chicago, IL. Abstract, 1 page.
	PW**	Frost, "Punctuated Equilibrium: The Evolution of Recombinant Human Hyaluronidase," Ophthalmic
		Anesthesia Society, 2006, Chicago, IL. Presentation, 35 pages.
	PX**	Haller et al., "Enhanze Technology – A Revolution in Drug Dispersion," Biotechnology Industry
	171	Organization (BIO) Annual Meeting, June 19-22, 2005, Philadelphia, PA. Abstract, 3 pages.
		Haller et al., "Recombinant Human Hyaluronidase for the Interstitial Transport of Therapeutics,"
	PY**	American Association of Pharmaceutical Scientists Conference, June 2006, San Antonio, TX.
		Abstract, 2 pages.
	PZ**	Haller et al., "Revolutionizing Drug Dispersion with Enhanze Technology," American Association of
	rz	Pharmaceutical Scientists Annual Meeting, Nov 6-10, 2005, Nashville, TN, Poster, 1 page.
	QA**	Haller et al., "Revolutionizing Drug Dispersion with Enhanze Technology," Biotechnology Industry
	QA	Organization (BIO) Annual Meeting, June 19-22, 2005, Philadelphia, PA. Poster, 1 page.
		Haller et al., "The Effects of Recombinant Human Hyaluronidase on Drug Dispersion," American
	QB**	Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN, Abstract in AAPS Journal
		7(S2) May 5, 2005; 3 pages.
	00***	Haller, "Enhanze Technology – An Enzymatic Drug Delivery System (DDS)," Japanese Export Trade
	QC**	Organization, November 2005, Santa Clara, CA. Abstract, 2 pages.
	05.44	Haller, "Focus on Enhanced and Innovative Recombinant Human Enzymes," Japanese Export Trade
	QD**	Organization, September 2004, Chicago, IL. PRESENTATION, 16 pages.
		Haller, "Halozyme's Enhanze Technology for the Enhanced Dispersion of Co-Injected
	OE**	Pharmaceuticals," Japanese Export Trade Organization, September 2004, Chicago, IL. Abstract, 2
	~-	pages.
		Haller, M., "Enzyme-facilitated Parenteral Drug Transport." Strategic Research Institute's 10 <sup>th</sup>
	OF**	Anniversary Drug Delivery Technology and Deal-making Summit, 2005 New Brunswick, NJ.
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Publications for Applicant's Information Disclosure Statement		Inventor(s) Wei et al.	
		Filing Date December 19, 2022	Group Art Unit Not yet assigned

	Other I	Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	
Initial	ID	Document
	QG**	Hofer et al., "Human recombinant hyaluronidase increases the convection of molecules up 0.2 μm in athymic nude mice," J. Am. Assoc. Lab. Animal Sci., 45(4):120, abstract P97 (2006).
	QH**	Hofer et al., "Human Recombinant Hyaluronidase (rHuPh20) Increases the Convection of Molecules up to 0.2 µm in Athymic Nude Mice," American Association for Laboratory Animal Science, 2006, Salt Lake City, UT. Poster P97, 1 page.
	QI**	Jiang et al., "Effects of Recombinant Human PH20 (rHuPH20) on Interstitial Matrices: Creating a Favorable Environment for The Delivery of Cytostatic Agents," [abstract]. In: Proceedings of the 96th Annual Meeting of the American Association for Cancer Research; 2005 Apr 16-20; Anaheim, CA.:AACR; 2005. Vol. 46, page 1198, Abstract no. 5075, April 2005.
	QJ**	Keller et al., "Pharmacokinetic, Pharmacodynamic and Toxicologic Effects of a Recombinant Human Hyaluronidase (rHuPH20) in Rodent and Non-Human Primate models," Hyaluronan (ISHAS) 2007, Charleston, SC. Abstract, 1 page.
	QK**	Keller et al., "Pharmacokinetic, Pharmacodynamic and Toxicologic Effects of a Recombinant Human Hyaluronidase (rHuPH20) in Rodent and Non-Human Primate models," Presented at International Society for Hyaluronan Sciences (ISHAS) Annual Meeting 2007, Charleston, SC. Poster and individual panels, 14 pages.
	QL**	Kodandapani et al., "Diverse Structural and Functional Roles of N-glycosylations on rHuPH20," Glycan Abstract, 1 page (2009).
	QM**	Morrow et al., "Human Hyaluronidase Coinjection Accelerates Insulin Pharmacokinetics and Glucodynamics of 3 Rapid Insulin Analogs," American Diabetes Association Scientific Sessions, held on June 28, 2010 in Orlando, FL., Abstract # 353-OR, 2 pages.
	QN**	Nadjsombati et al., "Evaluation of Developmental and Prenatal/Postnatal Reproduction Toxixity of rHuPH20 in Mice," American College of Toxicology 30th annual meeting 2009. (November 1-4) Palm Springs, CA. Abstract, 1 page.
	QO**	Nagy et al., "Prospective, randomized study on bovine and recombinant human (Cumulase®) Hyaluronidases," American Society of Reproductive Medicine, 2006, New Orleans, LA, 06-A-886-ASRM, Abstract O-213.
	QP**	Nagy et al., "Prospective study on rHuPH20." European Society of Human Reproduction & Embryology Annual Meeting, June 19-22, 2005, Copenhagen, Denmark. Abstract O-213, 1 page.
	QQ**	Halozyme Therapeutics, Inc., "PEGPH20: The Science & The Strategy," presented at J. P. Morgan Healthcare Conference on Jan. 7, 2015. Presentation. 81 pages.
	QR**	Pinkstaff et al., "Recombinant Human Hyaluronidase for Drug and Fluid Dispersion," American Association of Pharmaceutical Scientists Annual Meeting, November 2006, Boston, MA, Abstract, 2 pages.
	QS**	Pinkstaff et al., "Recombinant Human Hyaluronidase for Drug and Fluid Dispersion," American Association of Pharmaceutical Scientists Annual Meeting, November 2006, Boston, MA, Poster and individual panels, 8 pages.
	QT**	Stelzer, L., "Platforms for Growth: Building a Premier Oncology Biotech," Presented at the Canaccord Genuity 38th Annual Growth Conference on Aug. 09, 2018, 24 pages.
	QU**	Torley, H., "Halozyme Therapeutics, Inc. The next chapter begins: creating value through growth," Presented at the 32nd Annual J.P. Morgan Healthcare Conference January 2014, 26 pages.
	QV**	Wei et al., "Functions of N-linked glycans on human hyaluronidase PH20," presented at San Diego Glycobiology Symposium 2009. Poster 83 and individual panels, 5 pages.

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	Other [	Documents (include Author, Title, Date, and Place of Publication)
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	QW**	Wei et al., "Structure function analysis of the human hyaluronidase enzymes," Matrix Biology 27 (Supplement 1):S41, December 2008, American Society for Matrix Biology (ASMB) Biennial Meeting, San Diego, CA, (available on-line November 17, 2008), ABSTRACT 132 (corresponding to poster B4), 2 pages.
	QX**	Wei et al., "Structure function analysis of the human hyaluronidase enzymes," Presented at American Society for Matrix Biology (ASMB) Biennial Meeting, San Diego, CA, December 9, 2008. Poster B4 and individual panels, 5 pages.
	QY**	Wilson, M.S., "Enhanze Technology – An Enzymatic Drug Delivery System (DDS)," Japanese Export Trade Organization, November 2005, Santa Clara, CA. Oral presentation, 22 pages.
	QZ**	News Release, "Halozyme Announces Presentation Of Clinical Data At The American Diabetes Association 74th Scientific Sessions," Published on 06-15-2014 [online][retrieved on 08-18-2014] Retrieved from the internet: <url: 2014="" [3="" default.aspx="" halozyme-announces-presentation-of-clinical-data-at-the-american-diabetes-association-74th-scientific-sessions="" halozyme.com="" investors="" news-release-details="" news-releases="" pages].<="" td=""></url:>
	RA**	News Release, Halozyme Therapeutics, Inc "Halozyme Licenses New Enhanze Target For \$30 Million Upfront Payment, Future Milestones And Royalties," Published Sept. 14, 2017 [online] Retrieved from: <url: 09-14-17],="" 2017="" 3="" [retrieved="" default.aspx="" halozyme-licenses-new-enhanze-target-for-30-million-upfront-payment-future-milestones-and-royalties="" halozyme.com="" investors="" news-release-details="" news-releases="" on="" pages.<="" td=""></url:>
	RB**	News Release, Halozyme Therapeutics, Inc., "Bristol-Myers Squibb and Halozyme Enter Global Collaboration and License Agreement for ENHANZE Technology," Published Sept. 14, 2017 [online] Retrieved from: <url: 14,="" 2017="" 2017],="" 7="" [retrieved="" bristol-myers-squibb-and-halozyme-enter-global-collaboration-and-license-agreement-for-enhanze-technology="" default.aspx="" halozyme.com="" investors="" news-release-details="" news-releases="" on="" pages.<="" sept.="" td=""></url:>
	RC**	News Release, "Bristol, Roche tap Halozyme for tech platform," Published September 14, 2017 [online] Retrieved from: <url: 09-18-17],="" 3="" 504958="" [retrieved="" biopharmadive.com="" bristol-roche-tap-halozyme-for-tech-platform="" news="" on="" pages.<="" td=""></url:>
	RD**	News Article, "Alteogen Inc. to Develop Herceptin Biosimilar for Subcutaneous Injection," Published on Aug. 23, 2018 [online] Retrieved from: <url:thebell.co.kr 4="" [original="" and="" articleview.asp?="" content="" documents="" english="" free="" from="" internet="" key="201808220100037100002360" pages.<="" retrieved="" td="" the="" translation],=""></url:thebell.co.kr>
	RE**	News Article, "[Promising biocompany] Alteogen Inc. tries to differentiate itself with specialized bio technology and strategy," Published on Sept. 17, 2018 [online] Retrieved from: <url:edaily.co.kr 4="" [original="" and="" documents="" english="" from="" internet="" news="" pages.<="" read?newsid="01105366619341104&amp;mediaCodeNo=257&amp;OutLnkChk=Y" retrieved="" td="" the="" translation],=""></url:edaily.co.kr>
	RF**	News Release, Halozyme Therapeutics, Inc., "Halozyme Publication In The Journal Clinical Cancer Research Highlights New Nonclinical Data Supporting Multiple Effects Of PEGPH20 On The Tumor Microenvironment," Published Oct. 04, 2018 [online] Retrieved from: <url: 05,="" 2018="" 2018],="" 4="" [retrieved="" default.aspx="" halozyme-publication-in-the-journal-clinical-cancer-research-highlights-new-nonclinical-data-supporting-multiple-effects-of-pegph20-on-the-tumor-microenvironment="" halozyme.com="" investors="" news-release-details="" news-releases="" oct.="" on="" pages.<="" td=""></url:>
	RG**	News Article, "Alteogen, Inc. challenges to the ethical drug market by utilizing 'Human Hyaluronidase'," Published on Oct. 29, 2018 [online] Retrieved from: <url:fnnews.com 201810290941498520="" 6="" [original="" and="" documents="" english="" from="" internet="" news="" pages.<="" retrieved="" td="" the="" translation],=""></url:fnnews.com>

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		Filing Date December 19, 2022	Group Art Unit Not yet assigned

Examiner	Desig.	Documents (include Author, Title, Date, and Place of Publication)
Initial	ID ID	Document
	RH**	News Article, "Alteogen names bio drug business development expert Arun Swaminathan as new CBO," Published on Dec. 19, 2018 [online] Retrieved from: <url:biospectator.com 7="" [original="" and="" documents="" english="" from="" internet="" news_view.php?varatcid="6825" pages.<="" retrieved="" td="" the="" translation],="" view=""></url:biospectator.com>
	RI**	News Article, "Maximizing patient convenience by changing intravenous injection to subcutaneous injection Alteogen expects increased exports of the technology this year," Published on Jan. 20, 2019 [online] Retrieved from: <url:http: 2019012023181="" 5="" [original="" and="" article="" documents="" english="" from="" internet="" news.hankyung.com="" pages.<="" retrieved="" td="" the="" translation],=""></url:http:>
	RJ**	News Release, Halozyme Therapeutics, Inc., "Halozyme Announces Actions To Focus Strategy On ENHANZE® Drug Delivery Technology," Published Nov. 04, 2019 [online], Retrieved from: <url: 11,="" 2019="" 2019],="" 4="" [retrieved="" default.aspx="" halozyme-announces-actions-to-focus-strategy-on-enhanze-drug-delivery-technology="" halozyme.com="" investors="" news-release-details="" news-releases="" nov.="" on="" pages.<="" td=""></url:>
	RK**	News Release, Halozyme Therapeutics, Inc., "Halozyme Announces HALO-301 Phase 3 Study Fails To Meet Primary Endpoint," Published Nov. 04, 2019 [online], Retrieved from: <url: 11,="" 2019="" 2019],="" 3="" [retrieved="" default.aspx="" halozyme-announces-halo-301-phase-3-study-fails-to-meet-primary-endpoint="" halozyme.com="" investors="" news-release-details="" news-releases="" nov.="" on="" pages.<="" td=""></url:>
	RL**	News Article, "Alteogen files a PCT application for subcutaneous pharmaceutical composition," Published on Mar. 24, 2020 [online], retrieved from <url: 2="" 2&vkind="" 2020]="" 26,="" [original="" [retrieved="" and="" documents="" english="" from="" internet="" mar.="" medipana.com="" news="" news_viewer.asp?newsnum="254556&amp;MainKind=A&amp;NewsKind=5&amp;vCount=1" on="" pages.<="" retrieved="" td="" the="" translation],=""></url:>
	RM**	News Article, "MK biotech publishes an article demonstrating the safety of Alteogen's human hyaluronidase (ALT-B4) in germ cells," Published on Apr. 29, 2021 [online], retrieved on Aprl. 29, 2021 from <url:news.heraldcorp.com 3="" [original="" and="" article="" english="" in="" korean="" pages.<="" td="" translation],="" view.php?ud="20210429000267"></url:news.heraldcorp.com>
	RN**	Invitation to Pay Additional Fees, sent by facsimile Sept. 9, 2013, in connection with International Patent Application No. PCT/US2012/072182, 6 pages.
	RO**	International Search Report and Written Opinion, mailed Dec. 17, 2013, in connection with International Patent Application No. PCT/US2012/072182, 18 pages.
	RP**	Response, dated March 17, 2014, to Written Opinion, mailed Dec. 17, 2013, in connection with International Patent Application No. PCT/US2012/072182, 94 pages.
	RQ**	Second Written Opinion, mailed May 21, 2014, in connection with International Patent Application No. PCT/US2012/072182, 8 pages.
	RR**	Response, dated July 21, 2014, to second Written Opinion, mailed May 21, 2014, in connection with International Patent Application No. PCT/US2012/072182, 72 pages.
	RS**	Second Written Opinion, mailed July 30, 2014, in connection with International Patent Application No. PCT/US2012/072182, 9 pages.
	RT**	Response, dated Sept. 1, 2014, to second Written Opinion, mailed July 30, 2014, in connection with International Patent Application No. PCT/US2012/072182, 73 pages
	RU**	International Preliminary Report on Patentability, mailed Sept. 12, 2014, in connection with International Patent Application No. PCT/US2012/072182, 11 pages.
	RV**	Office Action, mailed November 2, 2015, in connection with U.S. Patent Application Serial No. 13/694,731, 14 pages.
	RW**	Response, filed April 20, 2016, to Office Action, mailed November 2, 2015, in connection with U.S. Patent Application Serial No. 13/694,731, 43 pages.
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	RX**	Notice of Allowance, mailed May 20, 2016, in connection with U.S. Patent Application Serial No. 13/694,731, 16 pages.
	RY**	Office Action, issued May 15, 2019, in connection with U.S. Patent Application No. 15/226,489, 16 pages.
	RZ**	Response, filed Oct. 15, 2019, to Office Action, issued May 15, 2019, in connection with U.S. Patent Application No. 15/226,489, 30 pages.
	SA**	Office Action, issued Jan. 23, 2020, in connection with U.S. Patent Application No. 15/226,489, 19 pages.
	SB**	Response, filed Apr. 24, 2020, to Office Action, issued Jan. 23, 2020, in connection with U.S. Patent Application No. 15/226,489, 25 pages.
	SC**	Notice of Allowance, issued Jul. 16, 2020, in connection with U.S. Patent Application No. 15/226,489, 13 pages.
	SD**	Office Action, issued Oct. 27, 2020, in connection with U.S. Patent Application No. 16/824,572, 9 pages.
	SE**	Response, filed Jan. 27, 2021, to Office Action, issued Oct. 27, 2020, in connection with U.S. Patent Application Serial No. 16/824,572, 23 pages.
	SF**	Notice of Allowance, mailed Feb. 18, 2021, and Examiner-Initiated Interview Summary, summarizing the interview held on Feb. 10, 2021, issued in connection with U.S. Patent Application Serial No. 16/824,572, 10 pages.
	SG**	Non-final Office Action, issued Dec. 09, 2020, in connection with U.S. Patent Application No. 16/912,590, 12 pages.
	SH**	Response, filed Mar. 17, 2021, to Non-final Office Action, issued Dec. 09, 2020 in connection with U.S. Patent Application No. 16/912,590, 24 pages.
	SI**	Notice of Allowance, issued Apr. 14, 2021, and Examiner-Initiated Interview Summary, of interview conducted Apr. 08, 2021, in connection with U.S. Patent Application No. 16/912,590, 10 pages.
	SJ**	Examination Report, issued Jan. 13, 2017, in connection with Australian Patent Application No. 2012362141, 3 pages.
	SK**	Response, filed Aug. 14, 2017, to Examination Report, issued Jan. 13, 2017, in connection with Australian Patent Application No. 2012362141, 43 pages.
	SL**	Notice of Acceptance, dated Sept. 11, 2017, issued in connection with Australian Patent Application No. 2012362141, 3 pages.
	SM**	Office Action (claims deemed allowable), dated Oct. 19, 2018, issued in connection with Australian Patent Application No. 2017245352, 7 pages.
	SN**	Notice of Acceptance, issued Jul. 17, 2019, in connection with Australian Patent Application No. 2017245352, 3 pages.
	SO**	Preliminary Office Action, issued April 14, 2021, in connection with Brazilian Patent Application No. BR112014016195-0 [Machine generated English translation and Office Action as issued in Portuguese], 11 pages.
	SP**	Response, filed Jul. 26, 2021, to Preliminary Office Action, published April 27, 2021, in connection with Brazilian Patent Application No. BR112014016195-0 [English instructions for Response and Response as filed in Portuguese], 111 pages.
	SQ**	Office Action, dated June 09, 2022 and published on July 26, 2022, in connection with Brazilian Patent Application No. BR 112014016195-0 [Machine generated English translation and Office Action as issued in Portuguese], 10 pages.

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Initial	ID	Document
		Response, filed October 24, 2022, to Official Action, dated June 09, 2022 and published on July 26,
	SR**	2022, in connection with Brazilian Patent Application No. BR 112014016195-0 [English instructions
		for Response and Response as filed in Portuguese], 57 pages.
		Office Action, dated November 10, 2022 and published on Dec. 06, 2022, in connection with
	SS	Brazilian Patent Application No. BR 112014016195-0 [Machine generated English translation and
		Office Action as issued in Portuguese], 6 pages.
		Response, filed February 06, 2023, to Office Action, dated November 10, 2022 and published on Dec.
	ST	06, 2022, in connection with Brazilian Patent Application No. BR 112014016195-0 [English
		instructions for Response and Response as-filed in Portuguese], 33 pages.
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	SU**	Patent Application No. BR 122021016549-1 [Machine generated English translation and Office
		Action as issued in Portuguese], 8 pages.
		Response, filed October 24, 2022, to Official Action, dated June 09, 2022 and published on July 26,
	SV**	2022, in connection with Brazilian Patent Application No. BR 122021016549-1 [English instructions
		for Response and Response as filed in Portuguese], 101 pages.
		Office Action, dated Nov. 11, 2022 and published on Dec. 06, 2022, in connection with Brazilian
	SW	Patent Application No. BR 122021016549-1 [Machine generated English translation and Office
		Action as issued in Portuguese], 8 pages.
		Response, filed March 06, 2023, to Office Action, dated Nov. 11, 2022 and published on Dec. 06,
	SX	2022, in connection with Brazilian Patent Application No. BR 122021016549-1 [English instructions
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	SY**	Examiner's Report, issued March 1, 2016, in connection with Canadian Patent Application No.
		2861919, 7 pages.
	SZ**	Response, filed July 14, 2016, to Examiner's Report, issued March 1, 2016, in connection with
		Canadian Patent Application No. 2861919, 37 pages.
	TA**	Examiner's Report, issued Jan. 24, 2017, in connection with Canadian Patent Application No.
		2861919, 4 pages.
	TB**	Response, filed July 24, 2017, to Examiner's Report, issued Jan. 24, 2017, in connection with
		Canadian Patent Application No. 2861919, 26 pages.
	TC**	Examiner's Report, issued Jan. 23, 2018, in connection with Canadian Patent Application No.
		2861919, 4 pages.
	TD**	Response, filed Jun. 21, 2018, to Examiner's Report, dated Jan. 23, 2018, issued in connection with
		Canadian Patent Application No. 2861919, 39 pages.
	TE**	Notice of Allowance, dated Dec. 12, 2018, issued in connection with Canadian Patent Application No.
		2861919, 1 page.
	TF**	Office Action, issued May 25, 2015, in connection with Chinese Patent Application No.
		201280070954.9 [English language translation and original document in Chinese], 7 pages.
		Response, filed Oct. 9, 2015, to Office Action, issued May 25, 2015, in connection with Chinese
	TG**	Patent Application No. 201280070954.9 [English instructions and document as filed in Chinese], 37
		pages.
	TH**	Office Action, issued Feb. 3, 2016, in connection with Chinese Patent Application No.
		201280070954.9 [English language translation and original document in Chinese], 6 pages.
	CELL at a str	Response, filed June 20, 2016, to Office Action, issued Feb. 3, 2016, in connection with Chinese
	TI**	Patent Application No. 201280070954.9 [English language instructions, document as filed in Chinese
		and claims, as filed, in English], 58 pages.

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as filed in Chinese]. 10 pages.  Notice of Granting Patent Right for Invention, issued April 28, 2017, in connection with Chinese Patent Application No. 201280070954.9 [English translation and original document in Chinese], 4 pages.  TO** Notice of Allowance, dated Dec. 7, 2017, issued in connection with Eurasian Patent Application No. 201400772 [English letter and original document in Russian]. 2 pages.  Communication Pursuant to Rule 71(3) (Intention to Grant), issued April 22, 2016, in connection with European Patent Application No. 12816624.6, 5 pages.  Extended European Search Report, dated Jan. 12, 2017, issued in connection with European Patent Application No. 16189970.3, 11 pages.  Response, filed Aug. 15, 2017, to Extended European Search Report, dated Jan. 12, 2017, issued in connection with European Patent Application No. 16189970.3, 55 pages.  TS** Examination Report, dated Sept. 14, 2017, issued in connection with European Patent Application No. 16189970.3, 19 pages.  TU** Response, dated Oct. 13, 2017, to Examination Report, dated Sept. 14, 2017, issued in connection with European Patent Application No. 16189970.3, 19 pages.  TU** Communication Pursuant to Article 94(3) EPC (claims deemed allowable), dated Feb. 26, 2018, issued in connection with European Patent Application No. 16189970.3, 3 pages.  Response, filed Sept. 10, 2018, to Communication Pursuant to Article 94(3) EPC (claims deemed allowable), issued Feb. 26, 2018, issued in connection with European Patent Application No. 16189970.3, 7 pages.  TW** Communication Pursuant to Article 71(3) EPC (Intention to Grant), dated Apr. 08, 2019, issued in connection with European Patent Application No. 16189970.3, 7 pages.  Decision to Grant, issued Aug. 22, 2019, in connection with European Patent Application No. 16189970.3, 2 pages.  Examination Report, issued Dec. 4, 2018, in connection with Indian Patent Application No. 6272/DELNP/2014, 6 pages.		Other [	Documents (include Author, Title, Date, and Place of Publication)			
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Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418		
List of Patents and Pub	dications for Applicant's	Inventor(s) Wei et al.			
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned		

	Other [	Documents (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	
Initial	ID	Document
	UE**	Examination Report, issued Aug. 29, 2022, in connection with Indian Patent Application No. 201918041329, 7 pages.
		Office Action, dated August 3, 2016, in connection with Israeli Patent Application No. 233192
	UF**	[English language translation], 3 pages.
		Response, filed Jan. 3, 2017, to Office Action, dated August 3, 2016, in connection with Israeli Patent
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	OIL	pages.
		Notification Prior to Acceptance, dated Dec. 14, 2020, issued in connection with Israeli Patent
	UL**	Application No. 274798 [English reporting letter; original document as issued in Hebrew; and English
		translation of allowed claims], 10 pages.
	UM**	Official Action, issued on Aug. 11, 2021, in connection with Israeli Patent Application No. 280949
		[English translation and original document as issued in Hebrew], 6 pages.
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		Office Action, issued Dec 12, 2017, in connection with Japanese Patent Application No. 2016-247708
	US**	[English translation and original document in Japanese], 6 pages.
		Response, filed May 22, 2018, to Office Action, issued Dec. 12, 2017, in connection with Japanese
	UT**	Patent Application No. 2016-247708 [English instructions with amended claims, documents as filed
	_	in Japanese and English translation of claims as-filed], 90 pages.(3087BJP)
	UU**	Decision to Grant, issued Sept. 18, 2018, in connection with Japanese Patent Application No. 2016-
	00**	247708 [English reporting letter and original document in Japanese], 4 pages.
	UV**	Office Action, dated May 25, 2018, in connection with Mexican Patent Application No.
	U V ***	MX/a/2014/007966 [English translation and original document in Spanish], 6 pages.
		Response, filed Oct. 10, 2018, to Office Action, dated May 25, 2018, in connection with Mexican
	UW**	Patent Application No. MX/a/2014/007966 [English instructions and document as-filed in Spanish],
		13 pages.
	UX**	Notice of Allowance, issued Oct. 18, 2018, in connection with Mexican Patent Application No.
	UA	MX/a/2014/007966 [English reporting letter and original document in Spanish], 4 pages.

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is i conformance and not considered. Include copy of this form with next	

Sheet <u>25</u> of <u>25</u>

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 33320.03087.US2E/3087K	Application No. 18/068,418
List of Patents and Pul	plications for Applicant's	Inventor(s) Wei <i>et al</i> .	
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Filing Date December 19, 2022	Group Art Unit Not yet assigned

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Examiner Initial	Desig.	Document
miliai		Office Action, dated Nov. 15, 2022, in connection with Mexican Patent Application No.
	UY**	MX/a/2018/012394 [English translation and original document in Spanish], 14 pages.
	*****	Examination Report, dated March 26, 2015, in connection with New Zealand Patent Application No.
	UZ**	626126, 32 pages.
	VA**	Response, dated May 16, 2016, to Examination Report, dated March 26, 2015, in connection with
	VA	New Zealand Patent Application No. 626126, 70 pages.
	VB**	Notice of Acceptance, dated June 8, 2016, in connection with New Zealand Patent Application No.
	,,,	626126, 1 page.
	VC**	Letters Patent, issued Sept. 27, 2016, in connection with New Zealand Patent No. 626126, 1 page.
	VD**	Examination Report, dated July 27, 2017, issued in connection with New Zealand Patent Application
	VD***	No. 720075, 4 pages.
	VE**	Response, filed Feb. 26, 2018, to Examination Report, dated July 27, 2017, issued in connection wit
	VL.	New Zealand Patent Application No. 720075, 88 pages.
	VF**	Notice of Acceptance, dated Mar. 10, 2020, issued in connection with New Zealand Patent
		Application No. 720075, 1 page.
	VG**	Search Report and Written Opinion, dated Dec. 4, 2015, in connection with Singaporean Patent
		Application No. 11201403714T, 7 pages.  Response, filed May 23, 2016, to Search Report and Written Opinion, dated Dec. 4, 2015, in
	VH**	connection with Singaporean Patent Application No. 11201403714T, 21 pages.
		Written Opinion, dated Sept. 18, 2017, in connection with Singapore Patent Application No.
	VI**	11201403714T, 9 pages.
		Response, filed Oct. 27, 2017, to Written Opinion, dated Sept. 18, 2017, in connection with Singapo
	VJ**	Patent Application No. 11201403714T, 6 pages.
	VK**	Notice of Eligibility for Grant and Examination Report, dated Jul. 02, 2018, in connection with
	VK**	Singapore Patent Application No. 11201403714T, 8 pages.
	VL**	Certificate of Grant, dated Oct. 3, 2018, in connection with Singapore Patent Application No.
	VL	11201403714T [Grant Certificate and Granted Claims], 6 pages.
	VM**	Search Report and Written Opinion, issued Oct. 20, 2017, in connection with Singapore Patent
	, , , , ,	Application No. 10201604470T, 14 pages.
		Response, filed Mar. 20, 2018, to Search Report and Written Opinion, issued Oct. 20, 2017, in
	VN**	connection with Singapore Patent Application No. 10201604470T [Response, replacement
		specification pages, amended claims and cited document], 105 pages.
	VO**	Examination Report, dated Aug. 06, 2018, and Notice of Eligibility for Grant, dated Aug. 07, 2018,
		issued in connection with Singapore Patent Application No. 10201604470T, 6 pages.
	VP**	English translation of Official Action, issued Mar. 20, 2020, in connection with Korean Application
		No. 10-2020-7002955, 6 pages.  English Translation of International Search Report and Written Opinion, issued Oct. 29, 2019, in
	VQ**	connection with International application No. PCT/KR2019/009215, 10 pages.

No. 13/694,731, 15/226,489, 16/824,572, 17/327,568 and/or 17/327,586, which are relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.A.M./

Examiner Signature	Date Considered
/CIARA A MCKNIGHT/	04/19/2024
EXAMINER: Initial if citation considered, whether or not citation is	in conformance with MPEP 609; Draw line through citation if not in
conformance and not considered. Include copy of this form with ne	xt communication to applicant.

# PE2E SEARCH - Search History (Prior Art)

Ref#	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	177	C12N9/2474.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:41 PM
L2	201200	A61P35/00.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:42 PM
L3	37518	A61K9/0019.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:42 PM
L4	5108	A61K38/28.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:42 PM
L5	3445	A61K38/47.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:42 PM
L6	104356	A61K45/06.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:43 PM
L7	20876	A61K47/10.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:43 PM
L8	19375	C07K14/47.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:43 PM
L9	2749	C12Q1/34.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:44 PM
L10	395	C12Y302/01035.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:44 PM
L11	51269	Y02A50/30.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:44 PM
L12	81483	A61K38/00.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:45 PM
L13	14088	C07K2319/30.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:45 PM
L14	65	G01N2333/926.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:45 PM
L15	78	G01N2333/928.CPC.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/02 02:45 PM
L16	1594	L1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:49 PM
L17	1768127	L2	(US-PGPUB; USPAT;	OR	ON	ON	2024/02/02

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			USOCR; FIT (AU, AP,				02:49 PM
			AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L18	280370	L3	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:49 PM
L19	36146	L4	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:49 PM
L20	24207	L5	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2024/02/02 02:49 PM

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			NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L21	722177	L6	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:49 PM
L22	169938	L7	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:49 PM
L23	126070	L8	_ ′	OR	ON	ON	2024/02/02 02:49 PM
L24	20002	L9	(US-PGPUB; USPAT; USOCR; FIT (AU, AP,	OR	ON	ON	2024/02/02 02:49 PM

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			AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L25	2691	L10	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM
L26	508581	L11	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM
L27	634584	L12	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2024/02/02 02:50 PM

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			RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L28	87091	L13	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM
L29	356	L14	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM
L30	424	L15	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM
L31	906	L1 AND L2	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2024/02/02 02:50 PM

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	220		CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	0.5			2024/02/02
L32	336	L1 AND L3	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/02 02:50 PM

## PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

# PE2E SEARCH - Search History (Prior Art)

Ref#	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	3740	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR "sperm adhesion molecule 1")	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/03 03:41 PM
L2	14861	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR "sperm adhesion molecule 1")	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:41 PM
L3	18888646	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm adhesion molecule 1))	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:41 PM
L4	14691	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1))	_ ′	OR	ON	ON	2024/02/03 03:42 PM

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		<b>,</b>	T				,
			TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L5	9369	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL5 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:42 PM
L6	2585	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND "309"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:46 PM
L7	91	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND "position 309"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:46 PM
L8	7278	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2024/02/03 03:50 PM

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		OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND insertion	CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L9	8855	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:51 PM
L10	7638	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:55 PM
L11	7638	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance	Í	OR	ON	ON	2024/02/03 03:57 PM

Page 3 of 9 CM

		AND denaturing) AND (arginine OR N)	VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L12	1	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL5 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND "increased hyaluronidase acitivity"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:58 PM
L13	0	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increaesd	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:58 PM
L14	7424	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increased	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 03:58 PM
L15	6739	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2024/02/03 04:00 PM

Page 4 of 9 CM

		OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increased AND glycoprotein	CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L16	5960	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 04:00 PM
L17	4146	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increased AND glycoprotein AND glycosylation AND "pharmaceutical composition"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 04:01 PM
L18	585	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	OR	ON	ON	2024/02/03 04:01 PM

Page 5 of 9 CM

		ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increased AND glycoprotein AND glycosylation AND "pharmaceutical composition" AND "heterologous signal sequence"	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L19	41	(Artificial Intelligence) Similar to: 17/327,586 with 0 CPC Selections and 0 Text Selections Text: (US-9447401-B2 OR AU-2012362141-A1 OR AU-2012362141-B2 OR MX-2014007966-A OR NZ-626126-A OR EP- 2797622-B1 OR CA- 2861919-C OR US- 20130302275-A1 OR US-20140178330-A9 OR EP-2797622-T3 OR NZ-626126-B2 OR ES- 2609582-T3 OR JP- 2017112999-A OR WO- 2013102144-A2 OR EP-3130347-B1 OR US-20160362670-A1 OR EP-3130347-B1 OR US-20160362670-A1 OR EP-3130347-A1 OR AU-2017245352-A1 OR US-10865400-B2 OR IL-298330-A OR CA- 2861919-A1 OR ES- 2749620-T3 OR JP- 6067746-B2 OR JP- 6067746-B2 OR NZ- 720075-A OR NZ- 720075-B2 OR US- 11041149-B2 OR AU- 2017245352-B2 OR US-11066656-B2 OR CN-104244968-B OR JP-6422933-B2 OR US- 20200255814-A1 OR US-20210284985-A1		OR	ON	ON	2024/02/03 04:09 PM

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		OR HR-P20192249-T1 OR WO-2015003167- A1 OR US- 20150010529-A1).did.					
L20	578	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH20 OR SPAG15 OR (sperm ADJ adhesion	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/02/03 04:24 PM
L21	138	L18 AND proline	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/08 04:06 PM
L22	41	(Artificial Intelligence) Similar to: 18/068,418 with 0 CPC Selections and 0 Text Selections Text: (DK-2797622-T3 OR EP-2797622-B1 OR AU-2012362141-A1 OR EP-2797622-A2 OR AU-2012362141-B2 OR US-9447401-B2 OR MX-2014007966-A OR	MC, MD, MY, NL, NO,	OR	ON	ON	2024/04/18 04:39 PM

Page 7 of 9 CM

		NZ-626126-A OR WO-	√N))				
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		12861919-C OR JP-					
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		280949-B2 OR NZ-					
		626126-B2 OR CA-					
		2861919-A1 OR US-					
		20140178330-A9 OR					
		US-20130302275-A1					
		OR ES-2609582-T3 OR					
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		OR AU-2017245352-A1					
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L23	230	· -	ILIS DODILO: LISDAT:	OR	ON	ON	2024/04/40
23	230	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1				ON	2024/04/19 09:03 AM
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		OR PH-20 OR PH20	AU, BE, BG, BR, BY,				
			CA, CH, CN, CS, CU,				
		OR SPAG15 OR (sperm ADJ adhesion	CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,				
		1					
		AND hyaluronidase	HR, HU, ID, IE, IL, IS,				
		AND flyalurofildase AND (insertion OR	IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL,				
		VIAD (III POLITOLI OK	INC, MO, MD, MI, NL,				

04/19/2024 09:15:43 AM Workspace: 18068418 keyword

		deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND (arginine OR N) AND increased AND glycoprotein AND glycosylation AND "pharmaceutical composition" AND "heterologous signal sequence" AND antibody AND "324"	NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L24	230	(SPAM1 OR HEL-S-96n OR HYA1 OR HYAL1 OR HYAL3 OR HYAL5 OR PH-20 OR PH-20 OR SPAG15 OR (sperm ADJ adhesion ADJ molecule ADJ 1)) AND hyaluronidase AND (insertion OR deletion OR modification OR replacement) AND (stability OR ressitance AND denaturing) AND increased AND glycoprotein AND glycosylation AND "pharmaceutical composition" AND "heterologous signal sequence" AND antibody AND "324"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/04/19 09:05 AM

# PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.



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Office of the Commissioner for Patents

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 ${\mathcal U}$ Vaishali Udupa

Commissioner for Patents

**United States Patent and Trademark Office** 

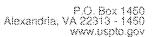
PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				n or Docket Number 18/068,418	Filing Date 12/19/2022	To be Mailed			
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	SEARCH FEE (37 CFR 1.16(k), (i), or	r (m))	N/A		N/A		N/A		
	EXAMINATION FEE (37 CFR 1.16(o), (p), c		N/A		N/A		N/A		
	FAL CLAIMS DFR 1.16(i))		m	inus 20 = *			x \$100 =		
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MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If th	* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL		
				APPLICA	TION AS AME	NDED - PA	ART II		
		(Column	1)	(Column 2)	(Column 3	3)			
AMENDMENT	05/21/2024	CLAIMS REMAININ AFTER AMENDME		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	(TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
Į≅į	Total (37 CFR 1.16(i))	* 35	Minus	** 35	= 0		x \$100 =		0
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₩	Application S	Size Fee (3	7 CFR 1.16(	5))	•				
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ENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=		x \$0 =		
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This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS

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## ELECTRONIC PAYMENT RECEIPT

APPLICATION # 18/068,418 RECEIPT DATE / TIME

05/21/2024 04:51:30 PM Z ET

ATTORNEY DOCKET #

063995-01-5105-US10

### Title of Invention

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

## **Application Information**

Utility - Nonprovisional Application APPLICATION TYPE

PATENT #

under 35 USC 111(a)

CONFIRMATION # 5769

FILED BY Collins Mba-Jonas

PATENT CENTER # 65615907

AUTHORIZED BY Kalpesh Upadhye

CUSTOMER# 28977

FILING DATE 12/19/2022

CORRESPONDENCE **ADDRESS** 

FIRST NAMED Ge Wei **INVENTOR** 

# Payment Information

PAYMENT METHOD CARD / 5344

**PAYMENT TRANSACTION ID** E20245KG51498405

**PAYMENT AUTHORIZED BY** Kalpesh Upadhye

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL AMOUNT:	\$170.00

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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

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#### New International Application Filed with the USPTO as a Receiving Office

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APPLICATION # 18068418

FILING DATE 12/19/2022

FIRST NAMED INVENTOR Ge Wei ATTORNEY DOCKET # 063995-01-5105-US10

### Title of Invention

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF



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Owner	Percent interest	
HALOZYME, INC.	100%	
Total	100%	

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Application #	Filing Date
18340786	06/23/2023

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Patent #	
10865400	

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- \* is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- \* is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.



Terminal disclaimer fee under 37 CFR 1.20(d) included with Electronic Terminal Disclaimer request.

### Applicant claims the following entity status:

Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statemnts made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Loertify, in accordance with 37 CFR 1.4(d)(4) that Lam: An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Signature	Name	Registration #
/Kalpesh V. Upadhye/	Kalpesh Upadhye	70236

<sup>\*</sup> Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP 324.



# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # RECEIPT DATE / TIME ATTORNEY DOCKET # 05/21/2024 04:51:30 PM Z ET 063995-01-5105-US10

**Title of Invention** 

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

**Application Information** 

CONFIRMATION # 5769

PATENT CENTER #

APPLICATION TYPE Utility - Nonprovisional Application

65615907

under 35 USC 111(a)

under 00 000 FFF(a)

CUSTOMER # 28977 FIRST NAMED Ge Wei

INVENTOR

PATENT# -

FILED BY Collins Mba-Jonas

FILING DATE 12/19/2022

CORRESPONDENCE - AUTHORIZED BY Kalpesh Upadhye

ADDRESS

### **Documents**

# **TOTAL DOCUMENTS: 2**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	48 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic- Approved	19 KB

# Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	C4D412E79F47C26C42E58C26F22382A280F781DA4E29A9F509
	1CA7E7885D1FCA6621BDB0DBD152C41A295A33341F316A970

	BC6031CACF7AE5BFA2E3C8219ACFB
grantLetter.pdf	F236555CD8516AD3A9CB1446022F7B0241B7BDAA6E4FD63B2
	D9957F67A3DA1A10F3D78D6F8015E93F5AC4ADC5FF3E26E5 CBD6B0E924449E4BD29E7989E61F08D

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#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313 - 1450 www.uspto.gov

# **APPROVAL LETTER**

APPLICATION # 18/068,418

FILING DATE 12/19/2022 APPLICANT/PATENT UNDER REEXAMINATION Ge Wei

### **Title of Invention**

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

Electronic terminal disclaimer filed on 05/21/2024

Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of <b>Ge Wei et al.</b>	)	
	)	Confirmation No. 5769
U.S. Application No. 18/068,418	)	
	)	Group Art Unit: 1656
Filing Date: <b>12/19/2022</b>	)	
	)	Examiner: Ciara McKnight
For: PH20 Polypeptide Variants, Formulations and Uses Thereof	)	

#### AMENDMENT UNDER 37 C.F.R. § 1.111

In response to the Non-Final Office Action dated 05/01/2024, having a three-month shortened statutory period for response set to expire 08/01/2024, Applicant requests entry of the following amendments and remarks in the above patent application. To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-0310 and please credit any excess fees to such deposit account.

Listing of the Claims begins on page 2.

Remarks begin on page 6.

Conclusion is on page 7.

#### LISTING OF THE CLAIMS

This version of the claims will replace all previous versions.

1. (Currently amended) A modified PH20 polypeptide, comprising one or more amino acid modifications in an unmodified PH20 polypeptide, wherein:

the unmodified PH20 polypeptide consists of the amino acid sequence selected from among the group consisting of SEQ ID NO: 3, 7 and 32-66;

amino acid modifications are selected from among the group consisting of amino acid replacements(s), deletion(s), and/or insertion(s);

the modified PH20 polypeptide comprises an amino acid replacement at a position corresponding to residue 324, with reference to amino acid positions set forth in SEQ ID NO: 3;

the replacement at the position corresponding to residue 324 is selected from among the group consisting of A, D, H, M, N, R and S;

corresponding amino acid positions are identified by alignment of the PH20 polypeptide with the polypeptide having the amino acid sequence of SEQ ID NO: 3; and

the modified PH20 polypeptide has at least 91 % sequence identity to a polypeptide having the amino acid sequence selected from among the group consisting of SEQ ID NO: 3, 7 and 32-66.

- 2. (Currently amended) The modified PH20 polypeptide of claim 1, wherein the modified PH20 polypeptide has at least 95% sequence identity to the amino acid sequence selected from among the group consisting of SEQ ID NO: 3, 7, and 32-66.
- 3. (Original) The modified PH20 polypeptide of claim 1 that has increased resistance to or stability in denaturing conditions compared to an unmodified PH20 polypeptide that does not contain the amino acid modification(s).
- 4. (Original) The modified PH20 polypeptide of claim 1 that exhibits increased hyaluronidase activity compared to the unmodified PH20 polypeptide not containing the amino acid replacement at position 324.
- 5. (Original) The modified PH20 polypeptide of claim 1 that is a soluble PH20 polypeptide.
- 6. (Original) The modified PH20 polypeptide of claim 1, wherein the replacement at the position corresponding to residue 324 is D.
- 7. (Currently amended) The modified PH20 polypeptide of claim 1, wherein the replacement at the position corresponding to residue 324 is [[Nor]] Nor R.
- 8. (Currently amended) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide comprises consists of the amino acid sequence selected from among the group consisting of SEQ ID NO: 3 and 32-66.
- 9. (Currently amended) The modified PH20 polypeptide of claim [[1]] <u>7</u>, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from <del>among</del> the group consisting of SEQ ID NO: 3 and 32-66.

- 10. (Currently amended) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from among the group consisting of SEQ ID NO: 3 and 32-66.
- 11. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35.
- 12. (Original) The modified PH20 polypeptide of claim 1, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32.
- 13. (Original) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35.
- 14. (Original) The modified PH20 polypeptide of claim 6, wherein the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32.
- 15. (Currently amended) The modified PH20 polypeptide of claim 1, comprising a sequence of amino acids that exhibits at least 91 % sequence identity to the sequence of amino acids set forth in any selected from the group consisting of SEQ ID NO: 3, and 32-66[[, 623, and 624]] and that contains an amino acid replacement D at the residue corresponding to residue 324 with reference to SEQ ID NO: 3.
- 16. (Original) The modified PH20 polypeptide of claim 1 that is C-terminally truncated, whereby the polypeptide is soluble.
- 17. (Currently amended) The modified PH20 polypeptide of claim 1 that comprises one or more post-translational modifications of the polypeptide selected from among the group consisting of glycosylation, sialylation, albumination, famesylation farnesylation, carboxylation, hydroxylation, and phosphorylation.
- 18. (Currently amended) The modified PH20 polypeptide of claim 1 that is glycosylated 17, wherein the post-translational modification is glycosylation.
- 19. (Original) The modified PH20 polypeptide of claim 18, wherein the polypeptide is a glycoprotein that comprises an N-acetylglucosamine moiety linked to each of at least three asparagine (N) residues.
- 20. (Original) The modified PH20 polypeptide of claim 1 that is conjugated to a polymer.
- 21. (Original) The modified PH20 polypeptide of claim 20, wherein the polymer is dextran or polyethylene glycol (PEG).
- 22. (Currently amended) The modified PH20 polypeptide of claim 1, further comprising a heterologous signal sequence, wherein the unmodified PH20 polypeptide consists of the amino acid sequence selected from among the group consisting of SEQ ID NO: 3 and 32-66.
- 23. (Original) A chimeric polypeptide, comprising the modified PH20 polypeptide of claim 1.
- 24. (Original) A pharmaceutical composition, comprising the modified PH20 polypeptide of claim 1.
- 25. (Original) The modified PH20 polypeptide of claim 6, wherein:

the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:32; and the amino acid sequence of the modified PH20 polypeptide has at least 95% sequence identity to the amino acid sequence of SEQ ID NO:32.

26. (Original) The modified PH20 polypeptide of claim 6, wherein:

the unmodified PH20 polypeptide consists of the amino acid sequence of SEQ ID NO:35; and the amino acid sequence of the modified PH20 polypeptide has at least 95% sequence identity to the amino acid sequence of SEQ ID NO:35.

- 27. (Original) The pharmaceutical composition of claim 24, further comprising a therapeutically active agent formulated in the same composition or in a separate composition.
- 28. (Original) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is a polypeptide, a protein, a nucleic acid, a drug, a small molecule, or an organic molecule.
- 29. (Currently amended) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is selected from among the group consisting of a chemotherapeutic agent, an analgesic agent, an anti-inflammatory agent, an antimicrobial agent, an amoebicidal agent, a trichomonacidal agent, an anti-Parkinson agent, an anti-malarial agent, an anticonvulsant agent, an anti-depressant agent, an antiarthritics agent, an anti-fungal agent, an antihypertensive agent, an antipyretic agent, an anti-parasite agent, an antihistamine agent, an alpha-adrenergic agonist agent, an alpha blocker agent, an anesthetic agent, a bronchial dilator agent, a biocide agent, a bactericide agent, a bacteriostat agent, a beta adrenergic blocker agent, a calcium channel blocker agent, a cardiovascular drug agent, a contraceptive agent, a decongestant agent, a diuretic agent, a depressant agent, a diagnostic agent, an electrolyte agent, a hypnotic agent, a hormone agent, a hyperglycemic agent, a muscle relaxant agent, a muscle contractant agent, an ophthalmic agent, a parasympathomimetic agent, a psychic energizer agent, a sedative agent, a sympathomimetic agent, a tranquilizer agent, a urinary agent, a vaginal agent, a viricide agent, a vitamin agent, a nonsteroidal anti-inflammatory agent, an angiotensin converting enzyme inhibitor agent, and a sleep inducer.
- 30. (Original) The pharmaceutical composition of claim 27, wherein the therapeutically active agent is an antibody.
- 31. (Withdrawn) A method for treating a hyaluronan-associated disease or condition, comprising administering to a subject a modified PH20 polypeptide of claim 1.
- 32. (Withdrawn) The method of claim 31, wherein the hyaluronan-associated disease or condition is an inflammatory disease or a tumor or cancer.
- 33. (Withdrawn) The method of claim 32, wherein the hyaluronan-associated disease or condition is a solid tumor.

- 34. (Currently amended) The modified PH20 polypeptide of claim 1 that is <u>further</u> modified by conjugation to a moiety selected from <del>among</del> the group consisting of a multimerization domain, a toxin, a detectable label, and a drug.
- 35. (Currently amended) The modified PH20 polypeptide of claim 34, wherein the modified PH20 polypeptide is conjugated to a multimerization domain that is an [[Fe]] Fc domain.

#### **REMARKS**

Claims 1-30, 34 and 35 are examination in this application. Claims 1, 2, 7-10, 15, 17, 18, 22, 29, 34 and 35 are amended herein to correct informalities. Claims 31-33 are withdrawn as being drawn to non-elected subject matter. Written support for the claim amendments is found throughout the specification and original claims. No prohibited new matter is added herein. Entry of the amendments and reconsideration of the application are requested.

The arguments and contentions presented in the Office Action should not be construed as any acquiescence or agreement by Applicant with the stated reasoning therein regardless of whether or not the following remarks specifically address any particular argument or contention from the Office Action. Furthermore, although certain distinctions between the claims of the present application and the cited references are addressed below, these distinctions are not necessarily exhaustive.

#### **Claim Objections**

Claims 1, 2, 7-10, 15, 17, 22 and 29 are objected to because of informalities. *See* Office Action at Section No. 5-7. These claims have been amended in accordance with the Examiner's suggestions. Withdrawal of the objections is requested in view of the amendments.

#### Rejections Under 35 U.S.C. § 112

Claims 17, 34 and 35 stand rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite. *See* Office Action at Section No. 8-12. Claims 17, 34 and 35 have been amended in accordance with the Examiner's suggestions. Claim 18 is amended for consistency with claim 17. Withdrawal of the rejection is requested in view of the amendments.

Claims 8 and 15 stand rejected under 35 U.S.C. § 112 (fourth paragraph) as being indefinite. *See* Office Action at Section No. 13-14. Claim 8 has been amended in accordance with the Examiner's suggestion and Claim 9 has been amended to depend on claim 7. Withdrawal of the rejection is requested in view of the amendment.

Claim 15 stands rejected because "the recitation of comprises SEQ ID NO: 3, 32-66, 623 and 624 makes this claim broader than claim 1, and therefore, not further limiting" (see Office Action at Section No. 14). Without acquiescing to the propriety of the rejection and solely in an effort to expedite prosecution, Applicant has amended claim 15 to remove the recitation of SEQ ID NO: 623 and 624. Withdrawal of the rejection is requested in view of the amendment.

#### **Double Patenting Rejections**

Claims 1-30 and 34-35 are rejected on the ground of non-statutory double patenting as being unpatentable over claims 1, 2, 4, 6-8, 10, 12, 13, 19, 23 and 27 of U.S. Patent No. 10,865,400. *See* Office Action at Section No. 16.

Claims 1-30 and 34-35 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-3, 5-10 and 14-18 of co-pending Application No. 18/340,786. *See* Office Action at Section No. 17.

Applicant concurrently files terminal disclaimers obviating the rejections in view of the cited patent and patent application. Withdrawal of the double patenting rejections is requested in view of the terminal disclaimers.

#### Conclusion

In view of the foregoing, Applicant awaits a favorable action on the merits. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned representative to expedite prosecution.

Date: May 21, 2024

MORGAN LEWIS & BOCKIUS LLP 1111 Pennsylvania Ave, NW Washington, DC 20004 Customer Number: 28977 Telephone: 202.739.5139

robert.smyth@morganlewis.com

Respectfully submitted,

By: /Kalpesh V. Upadhye/ Kalpesh V. Upadhye, Ph.D. Registration No. 70,236

Robert Smyth, Ph.D. Registration No. 50,801



# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # RECEIPT DATE / TIME ATTORNEY DOCKET # 05/21/2024 04:53:21 PM Z ET 063995-01-5105-US10

### **Title of Invention**

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

CONFIRMATION # 5769

PATENT CENTER # 65616083

CUSTOMER # 28977

CORRESPONDENCE - ADDRESS

FILED BY Collins Mba-Jonas

FILING DATE 12/19/2022

FIRST NAMED Ge Wei

INVENTOR

PATENT# -

AUTHORIZED BY Kalpesh Upadhye

### **Documents**

# **TOTAL DOCUMENTS: 3**

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
20240521_RespNFOA.pdf		7	v	141 KB
20240521_RespNFOA- Apdf	(1-1)	open.	Amendment/Request for Reconsideration-After Non- Final Rejection	93 KB
20240521_RespNFOA- CLM.pdf	(2-5)	4	Claims	109 KB
20240521_RespNFOA- REM.pdf	(6-7)	2	Applicant Arguments/Remarks Made in an Amendment	118 KB

# **Digest**

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20240521_RespNFOA-CLM.pdf	6F8AB396C63D25C31DFD7BF47B46F987C474ECD9607DAD33 F9CD5D11278468C7FE3C940E3286DC8DD14E3A6082557320D 940729F96AEB58EEAD2269DD513D409
20240521_RespNFOA-REM.pdf	C68E41B56FFDBF12116E7912342505AFD52117B4395199B062 764F09ED8A1E26F43688A5AF0BF5F89C1BF8304A80A8D9A3C 27660B627733F5675E9C0760309AB

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#### New Applications Under 35 U.S.C. 111

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#### National Stage of an International Application under 35 U.S.C. 371

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#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

#### UNITED STATES PATENT AND TRADEMARK OFFICE



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28977 7590 07/01/2024		EXAN	MINER
Morgan, Lewis & Bockius LLP (PH)		MCKNIGH	T, CIARA A
2222 Market Street Philadelphia, PA 19103	Γ	ART UNIT	PAPER NUMBER
• /	_	1656	
	DA	ATE MAILED: 07/01/202	24

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 18/068,418
 12/19/2022
 Ge Wei
 063995-01-5105-US10
 5769

TITLE OF INVENTION: PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	10/01/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

#### PART B - FEE(S) TRANSMITTAL

CFR 1.363).  Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.  The Address indication (or "Fee Address" indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.  3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)  PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filling an assignment.  (A) NAME OF ASSIGNEE  (B) RESIDENCE: (CITY and STATE OR COUNTRY)  Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government  4a. Fees submitted: Issue Fee Publication Fee (if required)  4b. Method of Payment: (Please first reapply any previously paid fee shown above)  Electronic Payment via the USPTO patent electronic filling system  Electronic Payment via the USPTO patent electronic filling system  Electronic Payment via the USPTO patent electronic filling system  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No.  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue	All further correspondence correspondence address; a	e will be mailed to the cu nd/or (b) indicating a sepa	rrent correspondence a				
Feedy Transmissing. This certificate carbon to used for any other accompanying person of the present of crown drowing, nu 189777 790 070012034 Morgan, Lewis & Bockius LLP (PH) 2222 Market Street Philadelphia, PA 19103	ree payment, any desired		should preferably be	nddress as indicated unles for maintenance fee notinated from the filed prior to payment o	s corrected below o fications. <b>Because e</b> l <b>f this issue fee in or</b>	r directed otherwise in Bloc ectronic patent issuance n der not to jeopardize cope	ck 1, by (a) specifying a ne nay occur shortly after issundency.
APPLICATION NO.   FILING DATE	CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change 28977 7590 07/01/2024 Morgan, Lewis & Bockius LLP (PH) 2222 Market Street		e of address) Fed paj hav I h Std add US	e(s) Transmittal. Thi pers. Each additiona we its own certificate Cer ereby certify that th ttes Postal Service w dressed to the Mail Si PTO via the USPTO	s certificate cannot be used I paper, such as an assigna- of mailing or transmission. tificate of Mailing or Tran is Fee(s) Transmittal is bein rith sufficient postage for fi top ISSUE FEE address abood patent electronic filing sy-	for any other accompanyir ent or formal drawing, mu asmission ng deposited with the Unite rst class mail in an envelop ve, or being transmitted to the	
APPLICATION NO.				<u> </u>			
18/068,418 12/19/2022							
18/068,418 12/19/2022 Ge Wei 063995-01-5105-US10 5769  TITLE OF INVENTION: PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF  APPLN. TYPE ENTITY STATUS ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(s) DUE DATE DUE aconprovisional UNDISCOUNTED \$1200 \$0.00 \$0.00 \$1200 \$10/01/2024  EXAMINER ART UNIT CLASS SUBCLASS  MCKNIGHT, CLARA A 1656 424-094620  1. Change of correspondence address or indication of "Fee Address" (3) (1) The names of up to 3 registered patent attorneys or agents of the patent front page, list (1) The names of up to 3 registered patent attorneys or agents of a first front page and the names of up to 2 registered attorney or agents of a first front page. In the patent attorney or agents of the patent attorney or agents of a first front page. In the patent attorney or agents of the patent attorney or agents of the patent attorney or agents of the patent attorney or agents. If no name is 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MCKNIGHT, CIARA A 1656 424-094620  1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.365).  1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.365).  2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively. (2) The name of a single firm theying as a member a regular printed.  3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)  PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previousl recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE  (B) RESIDENCE: (CITY and STATE OR COUNTRY)  Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government 4a. Fees submitted: Issue Fee Publication Fee (if required)  4b. Method of Payment: (Please first reapply any previously paid fee shown above)    Electronic Payment via the USPTO patent electronic filing system   Enclosed check   Non-electronic payment by credit card (Attach form PTO-2038)    The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No.   NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity status. See 37 CFR 1.29    Applicant cartifying small entity status. See 37 CFR 1.27    Applicant changing to regular undiscounted fee status.   NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity status, certification abandoment on the patent of the payment o					7	\$1200	10/01/2024
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PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.  (A) NAME OF ASSIGNE  (B) RESIDENCE: (CITY and STATE OR COUNTRY)  Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government  4a. Fees submitted: Issue Fee Publication Fee (if required)  4b. Method of Payment: (Please first reapply any previously paid fee shown above)  I Electronic Payment via the USPTO patent electronic filing system Enclosed check Non-electronic payment by credit card (Attach form PTO-2038)  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No.  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.  NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.  Date  Date	Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).      Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.      "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. Use of a		(1) The names of up or agents OR, alternal (2) The name of a sin registered attorney or 2 registered patent att	to 3 registered patentively, gle firm (having as a agent) and the name orneys or agents. If	t attorneys  member a es of up to no name is		
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Page 2 of 3 OMB 0651-0033

PTOL-85 Part B (11/23) Approved for use through 03/31/2026

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

# United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/068,418	12/19/2022	Ge Wei	063995-01-5105-US10	5769
28977 75	90 07/01/2024		EXAM	IINER
•	Bockius LLP (PH)		MCKNIGHT	Γ, CIARA A
2222 Market Street Philadelphia, PA 1			ART UNIT	PAPER NUMBER
Filliaucipilia, FA 1	9103		1656	
			DATE MAILED: 07/01/202	4

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

#### **OMB Clearance and PRA Burden Statement for PTOL-85 Part B**

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

#### **Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record:
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

	<b>Application</b> 18/068,41		Applicant(s) Wei et al.	
Notice of Allowability	Examiner		Art Unit 1656	AIA (FITF) Status No
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS (nerewith (or previously mailed), a Notice of Allowance (PTOL-85) (NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHT of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAI or other app IGHTS. This	INS) CLOSED in this appl propriate communication v application is subject to v	ication. If not i will be mailed i	ncluded n due course. <b>THIS</b>
1. This communication is responsive to claim amendments 05. A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was.		on		
2. An election was made by the applicant in response to a rest restriction requirement and election have been incorporated			ne interview on	; the
3. The allowed claim(s) is/are 1-35. As a result of the allowed Highway program at a participating intellectual property offinhttp://www.uspto.gov/patents/init_events/pph/index.jsp	ice for the c	orresponding application.	For more info	
4. Acknowledgment is made of a claim for foreign priority unde	er 35 U.S.C	. § 119(a)-(d) or (f).		
Certified copies:				
a) $\square$ All b) $\square$ Some* c) $\square$ None of the:				
<ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this national stage application from the</li> </ol>				
International Bureau (PCT Rule 17.2(a)).				
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	" of this com MENT of this	nmunication to file a reply application.	complying with	n the requirements
5. CORRECTED DRAWINGS (as "replacement sheets") must	t be submitte	ed.		
including changes required by the attached Examiner's Paper No./Mail Date	s Amendme	nt / Comment or in the Of	fice action of	
Identifying indicia such as the application number (see 37 CFR 1 sheet. Replacement sheet(s) should be labeled as such in the heat			gs in the front	(not the back) of each
6. DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT F				he
Attachment(s)				
1. Notice of References Cited (PTO-892)		5. Examiner's Amendr	ment/Commen	t
<ol> <li>Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date</li> </ol>		6. 🗹 Examiner's Stateme	ent of Reasons	s for Allowance
Examiner's Comment Regarding Requirement for Deposit of Biological Material		7. Other		
4. Interview Summary (PTO-413), Paper No./Mail Date				
/CIARA A MCKNIGHT/ Examiner, Art Unit 1656		SUZANNE M NOAKE Primary Examiner, Art		
Examinor, Art Offic 1000		minary Examiner, Art	CHIL 1000	

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20240625

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Art Unit: 1656

#### Notice of Allowance

1. The amendments to the claims filed 21 May 2024 are acknowledged and have been considered in their entireties. Claims 1-35 are under examination after rejoinder (See below).

#### Terminal Disclaimer

- The terminal disclaimer filed on 21 May 2024 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 10865400 has been reviewed and is accepted. The terminal disclaimer has been recorded.
- 3. The terminal disclaimer filed on 21 May 2024 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **U.S. Application No. 18/340,786** has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### Withdrawal of Previous Objections/Rejections

- 4. The objections to claims 1, 2, 8-10, 17, 22, and 29 for informalities are withdrawn, since the amended claims included the suggested change from the previous office action.
- 5. The objection to claim 7 for informalities is withdrawn, since the amended claim included the suggested change from the previous office action.
- 6. The objection to claim 15 for informalities are withdrawn, since the amended claims included the suggested change from the previous office action.
- 7. The 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, rejection of claim 17 as being indefinite for the utilization of the term "modifications" is withdrawn, since the

Application/Control Number: 18/068,418

Art Unit: 1656

amended claim 17 recites "post-translational modifications" as suggested in the previous office

action.

8. The 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, rejection of claim

34 as being indefinite for the utilization of the term "is modified" is withdrawn, since the

amended claim 34 recites "is further modified" as suggested in the previous office action.

9. The 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, rejection of claim

35 for indefiniteness for the term "Fe domain" is withdrawn, since the amended claim 35 recites

"Fc domain" as suggested in the previous office action.

10. The 35 U.S.C. 112(d) or 35 U.S.C. 112 (pre-AIA0, fourth paragraph, rejection of claim 8

for failing to further limit the subject matter for the recitation of "comprises" is withdrawn, since

the amended claims now recite "consists of."

11. The 35 U.S.C. 112(d) or 35 U.S.C. 112 (pre-AIA0, fourth paragraph, rejection of claim 15

for failing to further limit the subject matter for the recitation of "SEQ ID NO: 623 and 624" is

withdrawn, since the amended claims have deleted these SEQ ID NOs.

12. The double patenting rejection over **U.S. Patent 10865400** is withdrawn, since the

terminal disclaimer has been filed.

13. The double patenting rejection over **U.S. Application No. 18/338189** is withdrawn,

since the terminal disclaimer has been filed.

Election/Restrictions

Page 3

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14. Claims 1-30 and 34-35 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 31-33, directed to the process of using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement as set forth in the Office action mailed on 20 February 2024 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

#### Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the claims are drawn to a modified PH20 polypeptide with a mutation corresponding to position 324 in SEQ ID NO: 3 with at least 91% identity to a sequence selected from the group consisting of SEQ ID NOs: 3, 7, and 32-66. Prior to the priority date of 30 December 2011, the closest known art was Lin et al. (Lin et al., 1993, *PNAS*—cited on the Information Disclosure Statement dated 07 June 2021), which discloses a PH20 variant that is 99.7% identical to SEQ ID NO: 3 in the instant application (See Supplemental File, 20240201\_135928\_us-17-327-586-3.minpct90.rpr). Lin et al. does not suggest mutating site 324 or functionally study the PH20 variant in any manner to determine increased stability, solubility, or hyaluronidase activity. As such, the instant claims are deemed novel and non-obvious and claims 1-35 are allowed.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CIARA A MCKNIGHT whose telephone number is (703)756-4791. The examiner can normally be reached M-F 9:00am-5:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CIARA A MCKNIGHT/ Examiner, Art Unit 1656 Application/Control Number: 18/068,418

Art Unit: 1656

/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656

Petitioner Merck, Ex. 1002, p. 567

Page 6

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

CPC				
Symbol		Туре	Version	
C12N	/ 9	2474	F	2013-01-01
A61K	/ 38	/ 47	1	2013-01-01
A61K	/ 38	/ 28	I	2013-01-01
A61K	/ 45	/ 06	I	2013-01-01
C12Y	/ 302	/ 01035	I	2013-01-01
A61K	/ 9	/ 0019	1	2013-01-01
A61K	/ 47	/ 10	1	2013-01-01
C12Q	/ 1	/ 34	I	2013-01-01
A61P	/ 35	1 00	1	2018-01-01
C07K	/ 14	/ 47	1	2013-01-01
G01N	/ 2333	/ 926	A	2013-01-01
G01N	/ 2333	/ 928	А	2013-01-01
Y02A	/ 50	/ 30	А	2018-01-01
C07K	/ 2319	/ 30	А	2013-01-01
A61K	/ 38	1 00	А	2013-01-01

CPC Combination Sets						
Symbol			Туре	Set	Ranking	Version
A61K	/ 38	/ 28	1	1	1	2013-01-01
A61K	/ 2300	/ 00	I	1	2	2013-01-01
A61K	/ 38	47	1	2	1	2013-01-01
A61K	/ 2300	/ 00	I	2	2	2013-01-01

/CIARA A MCKNIGHT/ Examiner, Art Unit 1656	25 June 2024	Total Claim	s Allowed:
(Assistant Examiner)	(Date)	38	5
/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656	26 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none
U.S. Patent and Trademark Office		Р	art of Paper No.: 20240625

U.S. Patent and Trademark Office

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

INTERNATIONAL CLASSIFICATION						
CLAIMED						
C12N		9	1	26		
A61K	1	9	1	00		
A61K	1	38	1	28		
A61K		38	1	47		
A61K		45		06		
A61K		47		10		
A61P		35		00		
C07K		14		47		
C12Q	1	1	1	34		
A61K	1	38	1	00		

NON-CLAIMED	

US ORIGINAL CLASSIFICATION				
CLASS	SUBCLASS			

CROSS REFERENCES(S)						
CLASS	CLASS SUBCLASS (ONE SUBCLASS PER BLOCK)					

/CIARA A MCKNIGHT/ Examiner, Art Unit 1656	25 June 2024	Total Claims Allowed:	
(Assistant Examiner)	(Date)	35	
/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656	26 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

U.S. Patent and Trademark Office

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

☑ (	☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47														
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/CIARA A MCKNIGHT/ Examiner, Art Unit 1656	25 June 2024	Total Claims	s Allowed:
(Assistant Examiner)	(Date)	35	
/SUZANNE M NOAKES/ Primary Examiner, Art Unit 1656	26 June 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

U.S. Patent and Trademark Office

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

CPC - Searched*					
Symbol	Date	Examiner			
C12N9/2474, A61P35/00, A61K9/0019, A61K38/28, A61K38/47, A61K4506, A61K47/10, C07K14/47, C12Q1/34, C12Y302/01035, Y02A50/30, A61K38/00, C07K2319/30, G01N2333/926, G01N2333/928					

CPC Combination Sets - Searched*				
Symbol	Date	Examiner		

US Classification - Searched*					
Class Subclass Date Examiner					

<sup>\*</sup> See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PALM inventor name search, all inventors searched	04/18/2024	/CAM/
SEARCH inventor name and assignee search, all inventors searched	04/18/2024	/CAM/
SEARCH keyword search, see attached printouts for search strategy and databases searched	04/18/2024	/CAM/
PUBMED keyword search, see attached printout for strategy	04/18/2024	/CAM/
STIC sequence search	04/18/2024	/CAM/
SEARCH inventor name and assignee, updated	06/25/2024	/CAM/
PUBMED keyword search, updated	06/25/2024	/CAM/

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/068,418	Wei et al.
	Examiner	Art Unit
	CIARA A MCKNIGHT	1656

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Part of Paper No.: 20240625

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## History and Search Details

Search

Search	Actions	Details	Query	Results	Time
#16	***		Search: PH20 hyaluronidase disease	22	15:38:00
#15	***		Search: PH20 hyaluronidase composition	3	15:37:44
#14	000		Search: <b>PH20 hyaluronidase soluble</b>	15	15:37:37
#13	000		Search: PH20 hyaluronidase 324	0	15:37:12
#12	* * *		Search: PH20 hyaluronidase 324 - Schema: all	0	15:37:12
#11	***		Search: PH20 hyaluronidase cancer	46	15:37:04
#10	000		Search: PH20 hyaluronidase stability	4	15:36:58
#9	000		Search: PH20 hyaluronidase solubility	15	15:36:54
#8	***		Search: PH20 hyaluronidase treatment	83	15:36:45
#7	***		Search: PH20 hyaluronidase glycosylation mutant	0	15:36:36
#6	***		Search: PH20 hyaluronidase glycosylation mutant - Schema: all	0	15:36:36
#5	000		Search: PH20 hyaluronidase glycosylation	20	15:36:30
#4	000		Search: PH20 hyaluronidase pharmaceutical	12	15:36:23
#3	***		Search: PH20 hyaluronidase mutant	7	15:36:16
#2	***		Search: <b>PH20 hyaluronidase</b>	178	15:36:12

Search		Details	Query	Results	Time
#1	***		Search: PH20	238	15:36:03

Showing 1 to 16 of 16 entries

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# PE2E SEARCH - Search History (Prior Art)

Ref#	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1484	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/02/02 02:56 PM
L2	66	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/02/02 02:57 PM
L3	53	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/02/02 02:57 PM
L4	55	((("HALOZYME") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2024/02/02 02:59 PM
L5	1505	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/25 03:35 PM
L6	68	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/25 03:35 PM
L7	55	((("WEI") near3 ("Ge")) OR (("SHEPARD") near3 ("H")) OR (("ZHAO") near3 ("Qiping")) OR (("CONNOR") near3 ("Robert"))).INV. AND PH20	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/06/25 03:35 PM
L8	57	((("HALOZYME") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2024/06/25 03:35 PM

06/25/2024 03:35:42 PM Workspace: 18068418 inventor Page 1 of 2 CM

# PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

06/25/2024 03:35:42 PM Workspace: 18068418 inventor





# **ELECTRONIC ACKNOWLEDGEMENT RECEIPT**

APPLICATION # 18/068,418

RECEIPT DATE / TIME

08/16/2024 09:12:20 PM Z ET

ATTORNEY DOCKET #

063995-01-5105-US10

### Title of Invention

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

# **Application Information**

APPLICATION TYPE Utility - N

Utility - Nonprovisional Application

under 35 USC 111(a)

PATENT# -

5769

FILED BY Collins Mba-Jonas

PATENT CENTER # 66821508

FILING DATE 1

12/19/2022

CUSTOMER # 28977

FIRST NAMED INVENTOR

Ge Wei

CORRESPONDENCE ADDRESS

CONFIRMATION #

AUTHORIZED BY

Kalpesh Upadhye

#### **Documents**

# **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
20240816_Issuefeepayment.	1	Issue Fee Payment (PTO-85B)	125 KB

# **Digest**

### **DOCUMENT**

### **MESSAGE DIGEST(SHA-512)**

20240816\_Issuefeepayment.pd

32A63ADA65DAF744B1138014DE977FE94B9DF7E1ADD5649B F7C6C44576FA816AB1C63956673F2A347A3A00BC156862E9C A4428C39315C950F767454D4CE56220

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#### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

#### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.





# **ELECTRONIC PAYMENT RECEIPT**

APPLICATION # 18/068.418 RECEIPT DATE / TIME

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ATTORNEY DOCKET #

063995-01-5105-US10

#### Title of Invention

PH20 POLYPEPTIDE VARIANTS, FORMULATIONS AND USES THEREOF

# Application Information

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

PATENT #

**CONFIRMATION #** 5769

FILED BY Collins Mba-Jonas

PATENT CENTER # 66821508 **AUTHORIZED BY** 

Kalpesh Upadhye

CUSTOMER# 28977 FILING DATE

12/19/2022

CORRESPONDENCE ADDRESS

FIRST NAMED

Ge Wei **INVENTOR** 

# **Payment Information**

**PAYMENT METHOD CARD / 5344** 

**PAYMENT TRANSACTION ID** E20248FL12528229

**PAYMENT AUTHORIZED BY** Kalpesh Upadhye

**FEE CODE** 

**DESCRIPTION** 

ITEM PRICE(\$)

QUANTITY

**ITEM TOTAL(\$)** 

1501

UTILITY ISSUE FEE

1200.00

1

1200.00

**TOTAL** AMOUNT:

\$1,200.00

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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTORN	IEY DOCKET NO.	CON	FIRMATION NO.
18/068,418	12/19/2022		Ge Wei		063995	-01-5105-US10		5769
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nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00		\$1200		10/01/2024
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(A) NAME OF ASSI Halozyme, Inc.		137 CFR 3.11 and 37 CF	(B) RESIDENCE: (CIT San Diego, CA				ment.	
Please check the approp	riate assignee category or o	categories (will not be pr	rinted on the patent) : 🗖	Individual 🏻 Corpo	oration or o	other private group of	entity [	Government
4a. Fees submitted:	Issue Fee Public (Please first reapply any p	ication Fee (if required)						
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Authorized Signature	e_/Kalpesh V. Upadhye/			Date August	16, 2024			
Typed or printed nam	<sub>ne</sub> Kalpesh V. Upadhye	Ph.D.		Registration N	No. 70,236	3		

Page 2 of 3 OMB 0651-0033

PTOL-85 Part B (11/23) Approved for use through 03/31/2026

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/068,418	10/08/2024	12110520	063995-01-5105-US10	5769

28977 7590 09/18/2024

Morgan, Lewis & Bockius LLP (PH) 2222 Market Street Philadelphia, PA 19103

### ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

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### Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (https://patentcenter.uspto.gov).

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IR103 (Rev. 10/09)

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Ge Wei, San Diego, CA; H. Michael Shepard, Eugene, OR; Qiping Zhao, San Diego, CA; Robert James Connor, Oceanside, CA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Halozyme, Inc., San Diego, CA;

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IR103 (Rev. 10/09)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/068,418	12/19/2022	Ge Wei	063995-01-5105-US10	5769
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Philadelphia, P.	A 19103		ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
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judith.troilo@morganlewis.com phpatentcorrespondence@morganlewis.com

APPLICATION NO.	ISSUE DATE	PATENT NO.
18/068,418	08-Oct-2024	12110520

Morgan, Lewis & Bockius LLP (PH) 2222 Market Street Philadelphia, PA 19103

# **EGRANT NOTIFICATION**

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