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OCT 22 2014

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,612,109 was filed on September 19, 2013, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, INJECTAFER® (ferric carboxymaltose), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Burton A. Amernick  
c/o Novak Druce Connolly Bove + Quigg LLP  
1007 N. Orange St.  
Wilmington, DE 19801

Document code: WFEE

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Sales Receipt for Accounting Date: 10/22/2014

CKHLOK SALE #00000008 Mailroom Dt: 09/19/2013 032775 10531895  
01 FC : 1457 1,120.00 DA

<b>FEE TRANSMITTAL</b>	Complete if known	
	Application Number	Patent #: 7,612,109
	Filing Date	Issued: November 3, 2009
	First Named Inventor	Peter Geisser
	Examiner Name	N/A
<input type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27	Art Unit	N/A
<input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously	Practitioner Docket No.	17271-00007-US
TOTAL AMOUNT OF PAYMENT	(\$ ) 1,120.00	

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**PATENT EXTENSION  
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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)**

Application Type	FILING FEES			SEARCH FEES			EXAMINATION FEES			Fees Paid (\$)
	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	U (\$)	S (\$)	M (\$)	
Utility	280	140*	70	600	300	150	720	360	180	
Design	180	90	45	120	60	30	460	230	115	
Plant	180	90	45	380	190	95	580	290	145	
Reissue	280	140	70	600	300	150	2,160	1,080	540	
Provisional	260	130	65	0	0	0	0	0	0	

\* The \$140 small entity status filing fee for a utility application is further reduced to \$70 for a small entity status applicant who files the application via EFS-Web.

**2. EXCESS CLAIM FEES**

Fee Description	Undiscounted Fee (\$)	Small Entity Fee (\$)	Micro Entity Fee (\$)
Each claim over 20 (including Reissues)	80	40	20
Each independent claim over 3 (including Reissues)	420	210	105
Multiple dependent claims	780	390	195
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
_____ - 20 or HP = _____ x _____ = _____			
HP = highest number of total claims paid for, if greater than 20.			
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
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HP = highest number of independent claims paid for, if greater than 3.			

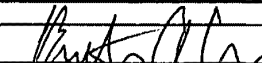
**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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**4. OTHER FEE(S)**

Other FEE(S)	Fees Paid (\$)
Non-English specification, \$130 fee (no small or micro entity discount)	_____
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, \$400 fee (\$200 small or micro entity)	_____
Other (e.g., late filing surcharge): 1457 Extension of term of patent	1,120.00

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	24,852
Name (Print/Type)	Burton A. Amernick	Telephone	(302) 658-9141
		Date	September 19, 2013

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Application No. 10/531,895	Application No.	Application No.	IDON Customer No.
Patent No. 7,612,109	Patent No.	Registration No.	
Attorney Docket No. 17271-00007-US		Identify or Describe Mark	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 7,612,109

ISSUED: November 3, 2009

INVENTORS: Peter Geisser, et al.

FOR: Aqueous Iron Carbohydrate Complexes, Their Production and Medicaments Containing Them

Office of Patent Legal Administration  
Mail Stop Hatch-Waxman PTE  
Room MDW 7D55  
600 Dulany Street (Madison Building)  
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PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. §156

Sir:

Pursuant to 35 U.S.C. §156 and 37 C.F.R. §1.710 *et seq.*, Vifor (International) AG, a corporation organized under the laws of Switzerland, hereby requests an extension of the patent term due to regulatory review of U.S. Patent No. 7,612,109, which was granted on November 3, 2009.

Applicant asserts that it is the owner of the entire right, title and interest in U.S. Patent No. 7,612,109 by virtue of the following chain of title. The invention was assigned by the inventors, Geisser, Philipp and Richle to Vifor (International) AG. This assignment was recorded in the U.S. Patent and Trademark Office (USPTO) at Reel 023066, Frame 0144 on August 7, 2009. A copy of the assignment is attached hereto as Appendix A.

A copy of the Power of Attorney evidencing that Vifor (International) AG, being the owner of the entire right, title and interest in and to U.S. Patent No. 7,612,109, appoints Novak Druce Connolly Bove + Quigg LLP as its agent to act in its interest in this matter is attached hereto as Appendix B.

10/22/2014 CXHLOK 00000000 032775 10531895  
01 FC:1457 1120.00 DA

The marketing applicant for the approved product upon which this application for extension is based is Luitpold Pharmaceuticals, Inc. Luitpold Pharmaceuticals, Inc. is a corporation organized under the laws of New York and is the licensee of U.S. Patent No. 7,612,109. Luitpold

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