PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	:	Patent Term Extension Application for U.S. Patent No 7,799,754
Filed	:	November 2, 2015

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as Priority Mail Express with sufficient postage addressed to: Commissioner for Patents, Mail Stop – Hatch Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450, on

August 12, 2016

Priority Mail Express No.:

EK283384173US

Hilary Bort Lang, Reg. No. 51,917

RESPONSE TO ORDER TO SHOW CAUSE OF JUNE 14, 2016

Deputy Commissioner for Patents
Mail Stop – Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Senior Legal Advisor Till:

BioMimetic Therapeutics, LLC ("Applicant") submits the following in response to the Order to Show Cause of June 14, 2016 ("Order"). Applicant respectfully requests that the United States Patent and Trademark Office ("PTO") consider this Response and find that Applicant's patent term extension application of November 2, 2015, was timely filed pursuant to the requirements set forth in 35 U.S.C. § 156(d).

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I. PRELIMINARY REMARKS

35 U.S.C. § 156(d)(1) provides patent term extension applicants a full "sixty-day period" during which they may file their patent term extension applications. The PTO acknowledges this statutory period, as the Order itself quotes both 35 U.S.C. § 156(d)(1) ("an application may only be submitted within the sixty-day period . . .") as well as the PTO implementing regulations, Rule 1.720(f) ("The application is submitted **within the sixty day period** . . ." (emphasis in the Order). Notably, the statute and implementing regulations *do not* provide applicants fifty-nine days plus some fraction of a day to file a patent term extension application. Instead, they provide applicants a full sixty-day period. Because the PTO's interpretation of the statute would deprive Applicant of the full sixty days to which it is entitled, that interpretation must be amended.

The date on which the sixty-day period *begins* is not dispositive here. Whether the trigger date is the date of the PMA approval letter (as asserted by the PTO in the Order) or the following day, the outcome is the same: Applicant's PTE application was timely filed.

At issue is whether the *end* of the sixty-day period may be calculated in a manner that deprives applicants of the full sixty days accorded by the statute. It may not. Such a calculation is not only precluded by the plain language of the statute; it would also contravene the settled principle that remedial statutes such as Section 156(d)(1) should be construed liberally.

II. BACKGROUND

Applicant developed Augment® Bone Graft, an FDA approved device that is indicated for use as an alternative to autograft in arthrodesis (*i.e.*, surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congential defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material. Augment® Bone Graft includes a composition of platelet derived growth factor solution and a biocompatible matrix. The Augment® Bone Graft technology is covered by U.S. Patent No. 7,799,754 (the '754 patent), which issued on September 21, 2010.

On September 1, 2015, nearly five years after the '754 patent issued, Applicant received notification from the FDA that Applicant's premarket approval application for its Augment® Bone Graft was approved. The FDA notification was sent by email and had a timestamp of 8:06 am. Ex. 1. Applicant filed an application for patent term extension to extend the term of the '754 patent on November 2, 2015.

III. ARGUMENT

Applicant's filing was timely because it was filed during the sixty-day period provided by 35 U.S.C. § 156(d)(1) and automatically extended by 35 U.S.C. § 21(b). The sixty-day period began when Applicant received notice of the FDA's approval (*i.e.*, no earlier than 8:06 am on September 1, 2015) and ended no earlier than a full 60 days later (*i.e.*, 8:06 am on Saturday, October 31, 2015). Furthermore because the deadline for filing (*i.e.*, the end of the sixty-day period) fell on a Saturday, the deadline was extended to the next succeeding secular or business

day (*i.e.*, Monday, November 2, 2015). Applicant filed its patent term extension application on Monday, November 2, 2015, and therefore, Applicant's filing was timely.

The plain meaning of section 156(d)(1) provides applicants with a full sixty-day period during which they may file their patent term extension applications. But even if section 156(d)(1) were ambiguous, Applicant's filing would still be timely because providing a full sixty-day period comports with both the Supreme Court's command to give remedial statutes liberal interpretations and with federal law.

A. **Applicant's filing was timely because the plain meaning of section 156(d)(1) allows applicants to file applications for patent term extension within a full sixty-day period.**

"The starting point in interpreting any act of Congress is the text of the statute." *Genentech, Inc. v. Eli Lilly &Co.*, 998 F.2d 931, 941 (Fed. Cir. 1993). Furthermore, "[a]bsent a clearly expressed legislative intention to the contrary, that [text] . . . [is] conclusive." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980).

Section 156(d)(1) defines a period during which an application for patent term extension may be submitted. Section 156(d)(1) explains, "Such an application may only be submitted within the sixty-day period beginning on the date the product received [FDA approval] . . . ." The plain meaning of this language is to grant applicants sixty full days to file a patent term extension application.

The sixty-day period begins only once applicants are deemed to have received notice of the FDA approval. Indeed, as the Eastern District of Virginia has explained, "[T]he phrase day period does not start until applicants are deemed to have received notice of the FDA's approval . . ." *The Medicines Co. v. Kappos*, 731 F. Supp. 2d 470 at 481 (E.D. Va. 2010).

Applicant received notification from the FDA that Applicant's premarket approval application for its Augment® Bone Graft was approved on September 1, 2015. The FDA notification was sent by email and had a timestamp of 8:06 am. Ex. 1. Therefore, Applicant did not receive (and could not have received) notice of the FDA approval earlier than 8:06 am on September 1, 2015. Consequently, the sixty-day period for filing a patent term extension application did not begin (and could not have begun) any earlier than 8:06 am on September 1, 2015.

It is common knowledge that a day includes 24 hours. Therefore, the end of the first day of the sixty-day period could not have been any earlier than 8:06 am on September 2, 2015. Indeed, if someone is given an assignment at 8:06 am and is told that they have one day to complete it, there would be no doubt that the recipient of the assignment has until 8:06 am the following day to complete it. Similarly, the end of the sixtieth day of the sixty-day period was not (and could not have been) any earlier than 8:06 am on Saturday, October 31, 2015.

Furthermore, 35 U.S.C. § 21(b) explains:

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a Federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

Because the sixty-day period ended on (and thus, the last day for taking the action of filing a patent term extension application fell on) a Saturday, the last day for filing the patent term extension application of the '754 patent was automatically extended to the next succeeding secular or business day, *i.e.*, Monday, November 2, 2015. Furthermore, 35 U.S.C. § 21 does not specify a deadline or period with respect to particular triggering event. Therefore, 35 U.S.C. § permits action to be taken at any time on the next succeeding secular or business day. Applicant

filed a patent term extension application to extend the term of the '754 patent on Monday November 2, 2015; therefore, the patent term extension application was timely filed.

However, for FDA approvals received prior to 4:30 pm Eastern time, the Order indicates that the PTO appears to consider midnight of the FDA approval date as the end of the first day. Order, pp. 1-2 ("In other words, the first day of the sixty-day period within which an applicant must submit a PTE application is the day of FDA approval. The day after FDA approval is considered to be the second day in the sixty-day application window", "Here, Applicant received FDA approval on September 1, 2015, triggering the start of the sixty-day period for filing its PTE application and making its PTE application due on or before October 30, 2015.").

Considering midnight of the date of approval as the end of the first day improperly provides applicants with less than the full 60-day period provided under 35 U.S.C. § 156(d)(1). For example, if an applicant were to receive notice of an FDA approval at 4:00 pm Eastern Time on a business day, the PTO appears to consider the eight-hour period from 4:00 pm to midnight as the first day of the sixty-day period. However, an eight-hour period is not a day; instead, it is merely a fraction of a day.

At least one federal court has recognized that the plain meaning of a "sixty day period" is sixty full days, and not merely fifty-nine plus a fraction of a day. Indeed, in interpreting a similarly worded federal statute[1], the Second Circuit explained:

> The date of issuance of the FLRA's order should not be counted.[2] The statute provides for a "60-day period," not 59 days plus some

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[1] *Compare* 35 U.S.C. 156(d)(1) ("within the sixty-day period beginning on the date the product received permission") *with* 5 U.S.C. 7123(a) ("during the 60-day period beginning on the date on which the order was issued").

[2] Applicant neither challenges nor agrees with the PTO's assertions regarding when the sixty-day period begins, as the beginning date is not dispositive to the outcome of this matter. However, the Second Circuit has clearly held that the date of a triggering event should not be counted as the first day of a sixty-day period within which an action would be deemed timely. Indeed, in *AFL-CIO* the Second Circuit held that 5 U.S.C. § 7123(a)'s clock started on the

> portion of the date of issuance. If, hypothetically, section 7123(a) provided for a 1-day period, it seems clear that a filing on the next day after issuance would be timely.

American Federation of Government Employees, AFL-CIO v. Federal Labor Relations Authority, 802 F.2d 47–48 (2d Cir. 1986) (interpreting 5 U.S.C. § 7123(a)).

The PTO should follow the Second Circuit's conclusion that sixty days does not mean fifty-nine days plus some portion of a triggering event date (in this case, the date of FDA approval). Sixty days means sixty full days.

The Order relies on *Unimed v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989) in support of its interpretation of the sixty-day period. However, the Court in *Unimed* did not decide when a sixty-day period begins or ends. Rather, the *Unimed* court only decided whether FDA approval or DEA rescheduling established the triggering date for section 156(d)(1)'s sixty-day period. *Id.* The Order states:

> The phrases used in section 156(d)(1) and Rule 1.720 to define the time period for submitting a patent term extension application, *i.e.*, "within" and "beginning on," are clear. *See Unimed, Inc. v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989) (characterizing the language used in section 156(d)(1) as "crystal clear"). Thus, under both section 156(d)(1) and Rule 1.720(f), a PTE applicant has sixty days to submit a PTE application; the first day of that sixty day period begins on the date granted permission for commercial marketing or use of the product which was subject to the applicable regulatory review period.

However, the Order's reliance on *Unimed* is misplaced. In discussing the language of section 1.56(d)(1) as being "crystal clear," the Court was specifically referring to whether FDA approval or DEA rescheduling corresponds to "the provision of law under which the applicable regulatory review period occurred." The Court's discussion of "crystal clear" language has

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day after the FLRA issued its order because it recognized that "the 60-day *period* begins on the date the order is issued, but does not direct that the *date of issuance* be counted as part of that period." *Id.*

absolutely nothing to do with whether the phrases "within" and "beginning on" are clear, as set forth in the Order. The *Unimed* court explained:

> According to section 156(d)(1), the sixty-day period begins "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." *Read in light of the definition of the "regulatory review period" in section 156(g)(1)(B), this language [i.e., the language "the provision of law under which the applicable regulatory review period occurred"] is crystal clear.* In this case, "the provision of law under which the applicable regulatory review period occurred" is section 505 of the FFDCA, which governs the approval of new drugs by the FDA. There is no mention of DEA rescheduling or of 21 U.S.C. § 811(a), the statute under which rescheduling takes place. Therefore, section 156(d) (1) admits of no other meaning than that the sixty-day period begins on the FDA approval date.

Id. at 828 (emphasis added). There is simply no support for the PTO's contention that an applicant must file for an extension within a period that is no more than 59 days plus a fraction of a day.

The plain meaning of section 156(d)(1) allows applicants to file for patent term extensions within a full sixty-day period. In this case, the sixty-day period (and the deadline for filing a patent term extension application) ended no earlier than 8:06 am on Saturday, October 31, 2015. Because the deadline fell on a Saturday, it was automatically extended to the next succeeding secular or business day (*i.e.*, Monday, November 2, 2015). Applicant filed its patent term extension application on Monday, November 2, 2015, and therefore, Applicant's filing was timely.

B. <u>The PTO should interpret section 156(d)(1) as providing applicant with a full sixty-day period because section 156 is a remedial statute that deserves liberal construction.</u>

As federal courts and this Office have recognized, section 156(d)(1) is a remedial statute. *See Genetics & IVF Institute v. Kappos*, 801 F.Supp.2d 497, 508 (E.D. Va. 2011) ("§ 156 is a remedial statute"); *The Medicines Co. v. Kappos*, 699 F.Supp.2d 804, 809 (E.D. Va. 2010) ("[t]he Court's review here is further shaped by the remedial nature of [section 156]"); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) ("the Hatch-Waxman Act provides the holders of patents . . . with an extended term of protection under the patent to compensate for the delay in obtaining FDA approval"); *In re Patent No. 4.146.*029 (Comm'r Pat. July 12, 1988) ("SynchroMed Decision") at 3. ("Since § 156 was intended to restore a part of the effective patent life of a patented product . . . § 156 can be viewed as remedial in nature").

The Supreme Court has instructed "[r]emedial legislation . . . is to be given a liberal construction consistent with [its] purpose." *U.S. v. Article of Drug . . . Bacto–Unidisk . . .* , 394 U.S. 784, 798 (1969). "A generous reading, in favor of those whom Congress intended to benefit from the law, is also appropriate when considering issues of time limits and deadlines." *Kelly v. Alamo*, 964 F.2d 747, 750 (8th Cir. 1992). Thus, section 156(d)(1) deserves a liberal construction consistent with its purpose. Furthermore, a reading of section 156(d)(1) that provides applicants with a full sixty-day period to file a patent term extension application is appropriate in view of the fact that section 156(d)(1)'s purpose is to benefit patent holders, like the Applicant in this case, who are seeking to recover lost patent term due to FDA delay.

IV. CONCLUSION

The plain meaning of section 156(d)(1) provides applicants with sixty—not fifty-nine and a fraction—days to file a patent term extension application. But even if section 156(d)(1) were ambiguous, Applicant's filing would still be timely because providing a full sixty-day period comports with both the Supreme Court's command to give remedial statutes liberal interpretations and with federal law.

A petition for a one month extension of time pursuant to 37 C.F.R. §1.136 is submitted herewith, along with a check for the $200.00 extension of time fee. Furthermore, the Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 230035.

Respectfully submitted,

Dated: August 12, 2016

By: _____
Hilary Dorr Lang, Ph.D.
Registration No. 51,917
Attorney of Record
Customer No. 100652

Application for Extension of Patent Term
U.S. Patent No. 7,799,754
Attorney Docket No. BMT04-0030

EXHIBIT 1

Hilary D. Lang

From: Hilary D. Lang
Sent: Friday, August 12, 2016 1:23 PM
To: Hilary D. Lang
Subject: AUGMENT approval
Attachments: P100006.Letter.APPR.FINAL[1].pdf; ATT00001.htm

From: Headlee, Donna [mailto:Donna.Headlee@fda.hhs.gov]
Sent: Tuesday, September 01, 2015 8:06 AM
To: Russ Pagano
Cc: 'hrhodes@mcra.com'; Russell Pagano
Subject: P100006 Approval Order

Dear Mr. Pagano,

A copy of your letter is attached to this email. Please note, this is your official copy; we are no longer sending hardcopy letters through the U.S. postal service. Please confirm receipt of this email.

If you have any questions regarding this submission, please contact the reviewer noted in the letter. Thank you.

Sincerely,

Donna Headlee, RN, BSN, CCRP
Consumer Safety Officer
FDA/CDRH/POS/PMA
Phone: 301-796-5649
email: donna.headlee@fda.hhs.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Biomimetic Therapeutics, LLC
Russ Pagano, Ph.D.
Vice President, Clinical and Regulatory Affairs
389 Nichol Mill Lane
Franklin, Tennessee 37067

September 1, 2015

Re: P100006
Trade/Device Name: Augment® Bone Graft
Filed: May 7, 2010
Amended: May 7, May 13, November 19, 2010; April 15, August 5, 2011; June 15, July 2, September 13, 2012; September 3, September 5, 2013; February 7, March 31, April 29, June 24, October 31, November 4, November 19, 2014; February 18, and April 9, 2015
Procode: NOX

Dear Dr. Pagano:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for Augment® Bone Graft. This device is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

A 36-month shelf life has been established for each of the two components of Augment® Bone Graft, and the expiration date for the product as a whole has been established as that corresponding to the earlier of the two components. The total product must be stored at refrigerated temperature (2-8°C, 36-46°F). This is to advise you that the protocol you used to

establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Two (2) copies of each report, identified as an "ODE Lead PMA Post-Approval Study Report" or "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

1. ODE Lead PMA Post-Approval Study – Extended Follow-up of Premarket Cohort (Long-term PAS Study): The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The Extended Follow-up of Premarket Cohort (Long-term PAS Study) is a continued follow-up of the Augment Bone Graft and Autologous graft premarket IDE cohort. It is a prospective, controlled study within the US and Canada comparing Augment Bone Graft to Autograft (in a 2:1 ratio) in hind foot and ankle arthrodesis at 5 or more years post-treatment. The study will address the following objectives: (1) Can it be assessed and confirmed that bridging bone occurs in the long-term after Augment has been resorbed? (2) Are the improvements in clinical outcomes associated with the use of Augment sustained long-term? (3) Does the promotion of existing tumors from a nonmalignant to malignant state at longer time-points in patients treated with Augment exceed the expected rate of promotion in patients not treated with Augment or other growth factors used to promote fusion?

The primary effectiveness endpoints will consist of the following:

- Demonstration of bridging bone via CT
- Patient Function as determined by Pain on Weight Bearing (via VAS), AOFAS Score and Foot Function Index (FFI)

The primary safety endpoints will consist of the following:

- Presence of all adverse events (i.e., description, frequency, incidence, time to onset of first event, severity, duration, treatments administered, etc.)
- Presence of serious unanticipated adverse device effects (UADE)
- rhPDGF-BB antibody status
- At evaluation, subjects will be interviewed regarding significant medical conditions, including incidence of cancer
- Presence of clinically important events as defined below:
    - Musculoskeletal and connective tissue disorders (severe pain, swelling and/or arthralgia in the treated foot/ankle joint(s));
    - Additional surgery of the original treated joint due to non-union.
    - Neoplasms benign, malignant and unspecified (including cysts and polyps) (all lower level terms associated with neoplasms)
    - Complications related to bone graft harvest site

The study will require 150 subjects (100 Augment; 50 Autograft) to be evaluated at a single visit at 5 years or more after original treatment under BMTI-2006-01 study. Hypothesis testing for maintenance of improvements within the Augment group on pain on weight bearing, AOFOS and FFI will be conducted.

2. OSB Lead PMA Post-Approval Study – 2-year New Enrollment Study: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. The 2-year New Enrollment Study is a prospective, single arm, new enrollment study of patients with ankle and hind foot fusion procedures using Augment Bone Graft. The study will address the following objectives: (1) Can it be assessed and confirmed that bridging bone occurs after Augment has been resorbed? (2) Are the improvements in clinical outcomes associated with the use of Augment in the IDE study confirmed? (3) Does the promotion of existing tumors from a nonmalignant to malignant state in patients treated with Augment exceed the expected rate of promotion in patients not treated with Augment or other growth factors used to promote fusion?

   The primary effectiveness endpoints will consist of the following:

   - Pain on Weight Bearing (via VAS) (Pre-op, Week 12, Week 24, Year 1, Year 2)
   - Confirmation of bridging bone via CT (Year 1, Year 2)
   - Patient Function (Pre-op, Week 12, Week 24, Year 1, Year 2) as determined by AOFAS Score and Foot Function Index (FFI)

   The primary safety endpoints will consist of the following:

- Presence of all adverse events (i.e., description, frequency, incidence, time to onset of first event, severity, duration, treatments administered, etc.)
- Presence of serious unanticipated adverse device effects (UADE)
- rhPDGF-BB antibody status
- At evaluation, subjects will be interviewed regarding significant medical conditions, including incidence of cancer
- Presence of clinically important events as defined below:
    - Musculoskeletal and connective tissue disorders (severe pain, swelling and/or arthralgia in the treated foot/ankle joint(s));
    - Additional surgery of the original treated joint due to non-union.
    - Neoplasms benign, malignant and unspecified (including cysts and polyps) (all lower level terms associated with neoplasms)

The study will require 118 Augment subjects who will be followed through the 2-year time point and provide at least 100 evaluable subjects at the two year follow-up visit. The frequency of follow up will be as follows: Pre-op, Post-op, 12 weeks, 24 weeks, 1 year, and 2 years.

There will be 3 comparators and are outlined as follows:

Comparator 1 Patients serve as own control: Baseline pain and function parameters will be used as comparators in analysis that demonstrates that clinical improvements observed at 2 years post-treatment are clinically meaningful (>20 point difference for Pain on weight bearing (VAS) and AOFAS and 10 point difference for Foot Function Index (FFI), as defined in the SSED.)

Comparator 2 Historical Comparator –Augment IDE Cohort –Will be used to compare success rates for fusion, pain and function endpoints in Augment arm of IDE study to success rates for these endpoints in the 2 year New Enrollment study participants treated with Augment .

Comparator 3 Historical Comparator –Autograft IDE Cohort –Will be used to compare success rates for pain and function in Autograft arm of IDE study to success rates for these endpoints in the 2 year New Enrollment study participants treated with Augment. Primary hypothesis testing for maintenance of improvements as outlined above in "Comparator 1" on pain on weight bearing, AOFOS and FFI will be conducted.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval

Studies Imposed by PMA Order"
(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes complete protocols of your post-approval studies described above. Your PMA supplements should be clearly labeled as an "ODE Lead PMA Post-Approval Study Protocol" or "OSB Lead PMA Post-Approval Study Protocol" as noted above and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at
http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Sarah Brittain at 240-402-3141 or Sarah.Brittain@fda.hhs.gov.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Charles E. Hart, et al.
Patent No.	7,799,754
Issue Date:	September 21, 2010
Serial No.:	11/704,685
Filed:	February 9, 2007
For:	Compositions and Methods for Treating Bone
Group Art Unit:	1646
Examiner:	Xiozhen Xie
Attorney's Docket No.:	BMT04-0030
Customer No.:	100652

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. 1.136, Applicant petitions for a one month extension of time to respond to the Order to Show Cause of June 14, 2016, thereby extending to the deadline to reply from July 14, 2016, to August 14, 2016. A check in the amount of $200.00 for the extension fee is submitted herewith. Please charge any deficiency or credit any overpayment to Deposit Account 230035.

Respectfully submitted,

August 12, 2016

Hilary Dorr Lang
Registration No. 51,917
ATTORNEY FOR APPLICANT

PATTERSON INTELLECTUAL PROPERTY LAW, PC
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1600 Division Street, Suite 500
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UNITED STATES PATENT AND TRADEMARK OFFICE

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

Food & Drug Administration
CDER, Office of Regulatory Policy
10903 New Hampshire Avenue,
Bldg. 51 Room 6250
Silver Spring MD 20993-0002

JUN 14 2016

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,799,754 was filed on November 02, 2015, under 35 U.S.C. § 156. Please note that patent term extension applications for U.S. Patent No. 8,106,008, and U.S. Patent No. 7,473,678 for P100006 for the medical device Augment® Bone Graft were filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, Augment® Bone Graft containing (1) β-TCP granules of 1-2 mm in size and (2) 0.3 mg/ml rhPDGF-BB, 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, provided that the previous approval of GEM 21S® medical device, contains β-TCP granules of 0.25 to 1 mm in size and (2) 0.3 mg/ml rhPDGF-BB, is not considered the first permitted marketing or use of the device, as required by 35 U.S.C. 156(a)(5)(A).

Inquiries regarding this communication should be directed to Ali Salimi at (571) 272-0909 (telephone) or (571) 273-0909 (facsimile) or by e-mail at ali.salimi@uspto.gov.

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

cc: Hilary Dorr Lang
Patterson Intellectual Property Law, PC
Roundabout Plaza
1600 Division Street, Suite 500
Nashville, TN 37203