DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2013–0062]

Grant of Interim Extension of the Term of U.S. Patent No. 5,496,801: Recombinant Human Parathyroid Hormone


ACTION: Notice of interim patent term extension.


FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention at Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; or by electronic mail: Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On December 6, 2013, NPS Pharmaceuticals, Inc., timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,496,801. The patent claims the human biological product recombinant human parathyroid hormone. The application indicates that Biologics License Application 125511 for the drug product, recombinant human parathyroid hormone, was filed on October 24, 2013, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period has continued beyond the original expiration date of the patent, December 23, 2013, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,496,801 is granted for a period of one year from the original expiration date of the patent.

Dated: December 20, 2013.

Andrew Hirshfeld,
Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO–C–2013–0060]

National Medal of Technology and Innovation Call for 2014 Nominations


ACTION: Notice and request for nominations.

SUMMARY: The Department of Commerce (United States Patent and Trademark Office) is accepting nominations for the National Medal of Technology and Innovation (NMTI). Since establishment by Congress in the Stevenson-Wydler Technology Innovation Act of 1980, the President of the United States has awarded the annual National Medal of Technology and Innovation (initially known as the National Medal of Technology) to our nation’s leading innovators. If you know of a candidate who has made an outstanding contribution to the nation’s economic, environmental or social well-being through the promotion of technology, technological innovation, or the development of technological manpower, you may obtain a nomination form from: http://www.uspto.gov/about/nmti/index.jsp.

ADDRESSES: The NMTI nomination form for the year 2014 may be obtained by visiting the USPTO Web site at http://www.uspto.gov/about/nmti/index.jsp. Nomination applications should be submitted to John Palafoutas, Program Manager, National Medal of Technology and Innovation Program, by electronic mail to NMTI@uspto.gov or by mail to: John Palafoutas, NMTI Program Manager, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia 22313–1450.

DATES: The deadline for submission of a nomination is 5 p.m. ET, April 1, 2014.

FOR FURTHER INFORMATION CONTACT: John Palafoutas, Program Manager, National Medal of Technology and Innovation Program, United States Patent and Trademark Office, 600 Dulany Street, Alexandria, VA 22314; telephone (571) 272–9821 or by electronic mail: nmti@uspto.gov.

SUPPLEMENTARY INFORMATION:

Background

As provided by Congress in the Stevenson-Wydler Technology Innovation Act of 1980, the National Medal of Technology was first awarded in 1985. On August 9, 2007, the President signed the America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act of 2007. The Act amended Section 16 of the Stevenson-Wydler Technology Innovation Act of 1980, changing the name of the Medal to the “National Medal of Technology and Innovation.” The NMTI is the highest honor awarded by the President of the United States to America’s leading innovators in the field of technology and is given annually to individuals, teams, or companies/non-profits who have made outstanding contributions to the promotion of technology or technological innovation, or to the development of technological manpower, for the improvement of the economic, environmental or social well-being of the United States. The primary purpose of the NMTI is to recognize American innovators whose vision, creativity, and brilliance in moving ideas to market or in developing of the nation’s technological manpower has had a profound and significant impact on our economy and way of life. The NMTI highlights the national importance of fostering technological innovation based upon solid science, resulting in commercially successful products and services.

Eligibility and Nomination Criteria

Nomination Guidelines containing information on eligibility and nomination criteria are at http://www.uspto.gov/about/nmti/guidelines.jsp.
I. Introduction

On July 26, 2013, the Commission published in the Federal Register its “Interpretive Guidance and Policy Statement Regarding Compliance with Certain Swap Regulations” (the “Guidance”).1 In the Guidance, the Commission set forth its interpretation of the manner in which it believes that section 2(i) of the Commodity Exchange Act (“CEA”) applies Title VII’s swap provisions to activities outside the U.S. and informed the public of some of the policies that it expects to follow, generally speaking, in applying Title VII and certain Commission regulations in contexts covered by section 2(i). Among other matters, the Guidance generally described the policy and procedural framework under which the Commission would consider a substituted compliance program with respect to Commission regulations applicable to entities located outside the U.S. Specifically, the Commission addressed a recognition program where compliance with a comparable regulatory requirement of a foreign jurisdiction would serve as a reasonable substitute for compliance with the attendant requirements of the CEA and the Commission’s regulations promulgated thereunder.

In addition to the Guidance, on July 22, 2013, the Commission issued the Exemptive Order Regarding Compliance with Certain Swap Regulations (the “Exemptive Order”).2 Among other things, the Exemptive Order provided time for the Commission to consider substituted compliance with respect to six jurisdictions where non-U.S. SDs are currently organized. In this regard, the Exemptive Order generally provided non-U.S. SDs and MSPs in the six jurisdictions with conditional relief from certain requirements of Commission regulations (those referred to as “Entity-Level Requirements” in the Guidance) until the earlier of December 21, 2013, or 30 days following the issuance of a substituted compliance determination.3

On May 13, 2013, the CBA, five individual Canadian banks provisionally registered with the Commission as SDs, and OSFI (collectively hereinafter, the “applicant”) submitted a request that the Commission determine that laws and regulations applicable in Canada provide a sufficient basis for an affirmative finding of comparability with respect to certain Entity-Level Requirements, including the Internal Business Conduct Requirements.4 The applicants provided Commission staff with a supplemental submission from the Ontario Securities Commission (“OSC”) dated June 7, 2013. The following is the Commission’s analysis and determination regarding the Internal Business Conduct Requirements, as detailed below.5

II. Background

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act6 (“Dodd-Frank Act” or “Dodd-Frank”), which, in Title VII, established a new regulatory framework for swaps. Section 722(d) of the Dodd-Frank Act amended the CEA by adding section 2(i), which provides that the swap provisions of the CEA (including any CEA rules or regulations) apply to cross-border activities when certain conditions are met, namely, when such activities have a “direct and significant connection with activities in, or effect on, commerce of the United States” or when they contravene Commission rules or regulations as are necessary or appropriate to prevent evasion of the swap provisions of the CEA enacted under Title VII of the Dodd-Frank Act.7

In the three years since its enactment, the Commission has finalized 68 rules and orders to implement Title VII of the Dodd-Frank Act. The finalized rules include those promulgated under section 4s of the CEA, which address registration of SDs and MSPs and other substantive requirements applicable to SDs and MSPs. With few exceptions, the delayed compliance dates for the Commission’s regulations implementing such section 4s requirements applicable to SDs and MSPs have passed and new SDs and MSPs are now required to be in full compliance with such regulations upon registration with the

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2 78 FR 43785 (July 22, 2013).
3 The Entity-Level Requirements under the Exemptive Order consist of 17 CFR 1.31, 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and parts 45 and 46 of the Commission’s regulations.
4 For purposes of this notice, the Internal Business Conduct Requirements consist of 17 CFR 3.3, 23.201, 23.203, 23.600, 23.601, 23.602, 23.603, 23.605, and 23.606.
5 This notice does not address swap data repository reporting (“SDR Reporting”). The Commission may provide a comparability determination with respect to the SDR Reporting requirement in a separate notice.
7 7 U.S.C. 2(i).