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Issue 146

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GLOBAL DOSSIER²

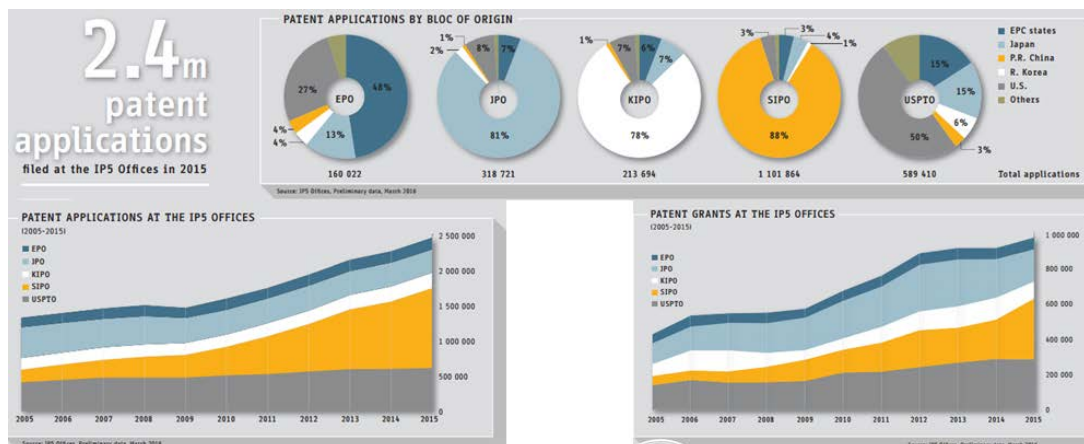
The five IP offices (IP5)³ is the name given to a forum of the five largest intellectual property offices in the world that was set up to improve the efficiency of the examination process for patents worldwide. The members of IP5 are:

1. [The European Patent Office \(EPO\)](#)⁴
2. [The Japan Patent Office \(JPO\)](#)⁵
3. [The Korean Intellectual Property Office \(KIPO\)](#)⁶
4. [The State Intellectual Property Office of the People's Republic of China \(SIPO\)](#)⁷ and
5. [The United States Patent and Trademark Office \(USPTO\)](#)⁸

The IP5 Offices together handle about 80% of the world's patent applications, and 95% of all work carried out under the Patent Cooperation Treaty (PCT). The vision of IP5 co-operation is the elimination of unnecessary duplication of work among the offices, enhancement of patent examination efficiency and quality, and guarantee of the stability of patent right.

The IP5 Offices, which started their cooperation in 2007, have been expanding the area of cooperation

from work-sharing among the IP5 Offices to harmonization of patent practices and quality management. Through their cooperation, the IP5 Offices have produced many concrete results. Major results



include Common Application Format (CAF), Common Citation Document (CCD), Global Dossier (GD) and Global Dossier Task Force (GDTF), IP5 Patent Information Policy, IP5 Patent Prosecution Highway (PPH)⁹ and IP5 website¹⁰.

The GD is an IP5 project being developed to provide services for monitoring and managing related cases filed in multiple international offices, by modernizing the global patent system. The Global Dossier

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provides a single, secure point of access for the management of dossier and examination information; increases efficiency and predictability of global patent family prosecution; time and cost savings for patent applicants by reducing applicant burden; enables and encourages streamlining of Office procedures among different IP Offices; and improves worldwide patent quality, resulting in higher value patents.

In January 2015, the **Global Dossier Task Force** meeting where IP5 Industry identified five short-term goals for the Offices to explore in an agreement that each Office would define the scope of a particular topic identified by Industry Groups as short-term goals:

- 1) Proof-of-Concept for Inter-Office Exchange – sharing documents between offices, e.g. prior art exchanges, supporting documents, bibliographic data updates, etc.
- 2) Alerting Functionality – an automated mechanism that alerts other offices, applicants, and/or representatives when there is a change in the status of an application
- 3) XML Document Provision – enabling the ability to download application content in XML format
- 4) Applicant Name Standardization – an automated mechanism that will assign a single, unique name to entities with applications pending in multiple offices
- 5) Legal Status – a mechanism to allow users to view the legal status of an application in another Office

The IP5 Offices are continuing to evaluate these short-term goals to determine which of these will be the next service to deliver.

On November, 20, 2015, the USPTO launched the first service for the GD, [the Dossier Access](#)¹¹, a user-friendly online interface, which will make it easier for patent applicants to quickly and easily view, monitor, and manage intellectual property (IP) protection around the world by providing access to the dossiers of related applications filed at participating offices. modernizing the global patent system and delivering benefits. The Global Dossier, similar to the PAIR, shows the entire prosecution history and documents, and provides a secure, online access to the file histories of related applications from participating IP5.

PATENT APPLICATION INFORMATION RETRIEVAL (PAIR)

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GLOBAL DOSSIER

Global Dossier is a project being delivered by the **IP5 Offices**, provides Patent Family Service, Dossier Content Service and Classification & Citation Service. While the USPTO provides 24/7 service for these three services, the other members of IP5 have outage hours, when the data will not be available, everyday.

A **Global Dossier Task Force**¹² made up of the IP5 Offices, the **World Intellectual Property Organization** (WIPO), and IP5 Industry Groups: American Intellectual Property Law Association (AIPLA), Intellectual Property Owners Association (IPO), Business Europe (BE), Japan Intellectual Property Association (JIPA), Korea Intellectual Property Association (KINPA), and Patent Protection Association of China (PPAC), was created to ensure that the services developed align with the needs of all stakeholders. The IP5 Offices recognized the following three initiatives to be advanced, on June 2, 2016, at the IP5 Heads Meeting held in Tokyo: (1) Enhance the relationship with users, (2) Continue providing high-quality and reliable examination results, and (3) Explore readiness to respond to emerging technologies.

The USPTO has been modernizing the PAIR system and one of the latest projects is called eMod (eCommerce Modernization). eMod is a project to improve the electronic patent application process by modernizing its filing and viewing systems involving: Updated infrastructure to enable more efficient system integration; Increased functionality and overall system usefulness; Enhanced user experience through improved interface; Improved processes for patent submission, review, and management; Revamped authentication process; and Increased accuracy of application processing and publication. This

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project includes replacement of the current web-based patent application and document submission tool - Electronic Filing System-Web (EFS-Web); and the current web-based solution to retrieve and download information regarding patent application status - the Patent Application Information Retrieval (PAIR) system. The USPTO has scheduled eMod Text Pilot Program Training/Workshops in June and in Summer 2016: [eMod Text Pilot Program](#). Participants will be testing the new patent electronic filing and management system in development, Patent Center¹³.

Another project implemented was the e-Office Action program¹⁴, a USPTO initiative that is designed to notify applicants, via e-Mail, that new Office communication is available for secure viewing and downloading in Private PAIR. Applicants who opt-in to the program will receive a daily e-Mail notification that will replace the paper mailed delivery of correspondence. In addition, a record of the electronic notification will be placed in the IFW when an e-Office Action notice is sent.

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THE FINANCIAL MANAGER

Yet another improvement at the USPTO is [the Financial Manager](#)¹⁵, the new online fee payment management tool. Financial Manager allows you to do more business with the USPTO online, providing faster and easier access to the services and information needed to protect intellectual property.

[The Financial Manager](#) is for storing and managing electronic payment methods, including credit/debit cards, deposit accounts, and EFT accounts online. Financial Manager provides an easy and secure way for customers to replenish deposit account funds, view current balance, generate transaction reports, and download monthly statements online. For guidance, review the [Quick Start Guide](#)¹⁶ and [User Guide](#)¹⁷ and get started by 1) creating an account, 2) storing payment methods, and 3) adding users with different levels of permissions, allowing selected Financial Manager users to access, use, and/or help manage stored payment methods, check out quickly without entering detailed payment method information, and generate, view, and download reports, including transaction history and monthly statements as Excel, PDF, or CSV files.

The deadline to move existing USPTO deposit accounts and electronic funds transfer (EFT) accounts to [Financial Manager](#) has been extended through July. A new date will be announced later, and by that deadline all deposit accounts and EFT accounts must be stored in Financial Manager in order to be used for payments.

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PATENT TERM ADJUSTMENT AND PATENT TERM EXTENSION

The Uruguay Rounds Agreements Act (Public Law 103-465), which became effective on June 8, 1995, changed the patent term in the United States. Before June 8, 1995, patents typically had 17 years of patent life from the date the patent was issued. Patents granted after the June 8, 1995 date now have a 20-year patent life from the date of the first filing of the patent application. However, the effective patent term is frequently less than 20 years because patents are often obtained before products are actually marketed.

Patent Term Adjustment (PTA) and Patent Term Extension (PTE) are two different arrangements regarding the patent term of a particular patent. PTA is to mitigate the loss of rights and term of patent life due to the USPTO prosecutorial delays under the doctrine of *prosecution history laches for unreasonable and undue delay in prosecution*, while PTE may result due to any number of reasons including Regulatory Agencies' approval and/or review processes, other than the USPTO prosecutorial delay.

PATENT TERM ADJUSTMENT (PTA)

PTA is Patent Term Adjustment to compensate for the loss of life of the a patent due to USPTO delays in prosecution beyond the allowed three-year period from the filing date of the application.

We had a 17-year term for patents from the grant date, until the law of American Inventors Protection Act took effect in 1999. Subtitle D - The "Patent Term Guarantee Act of 1999"¹⁸ guaranteed *diligent applicants a minimum 17-year patent term* within the 20-year term from the filing date¹⁹.

If prosecution takes more than 3 years, the effective term of the patent grant from the issue date would be less than 17 years. To maintain the 17-year term under the 20-year term regime, the USPTO allows the adjustment to the term due to any delays on the USPTO part, not due to *the sloppiness of the applicant*, which is called the Patent Term Adjustment (PTA). It also includes adjustments for delays due to Interferences, Secrecy Orders, and Appeals (35 USC 154²⁰ (b)(1) (C) GUARANTEE)

- interference proceedings²¹; and/or
- the application being placed under a secrecy order²²; and/or
- a successful appellate review by the Board of Patent Appeals and Interferences or by a Federal court under patentability and if the patent is not subject to a terminal disclaimer.

With respect to an interference proceeding, the PTE value is the number of days calculated by subtracting the date that the interference was declared from the date that the interference was terminated.

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With respect to a secrecy order, the PTE value is calculated from the sum of the number of days that the application was maintained in a sealed condition under 35 USC 181 and the number of days beginning on the date of the notification under 37 CFR 5.3(c) and ending on the date of mailing of the notice of allowance under 37 CFR 1.311²³.

With respect to appellate review, the PTA value is calculated by taking the date of the final decision and subtracting the later of either the date of the notice of appeal or the three year date (the three year date is calculate by taking the filing date or the earliest effective filing date claimed and adding three years to it).

PATENT TERM EXTENSION (PTE)

Many factors influence the length of the effective patent term, including the requirements in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act that certain products receive FDA approval before marketing. New human drug products generally must undergo extensive testing in animals and humans to show that the drugs are both safe and effective before FDA will approve the product for marketing.

Consequently, in order to stimulate product development and innovation, Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417)²⁴ to extend patent life to compensate patent holders for marketing time lost while developing the product and awaiting government approval. Title II of the Act created a program whereby patent holders whose patents claim a human drug product, medical device, food additive or color additive could recoup some of the lost patent time. In 1988, Congress enacted the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) which contained provisions for patent restoration to animal drug products. FDA's primary responsibility is to assist the Patent Trademark Office (PTO) in determining a product's eligibility for patent term restoration and to provide information to PTO regarding a product's regulatory review period.

Patent Term Extension (PTE)²⁵ reflects extension added to the patent term wherein marketing of the patented product was delayed due to regulatory delays, under 35 USC 156 Extension of Patent Term²⁶. The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if- (4) the product has been subject to a regulatory review period²⁷ before its commercial marketing or use.

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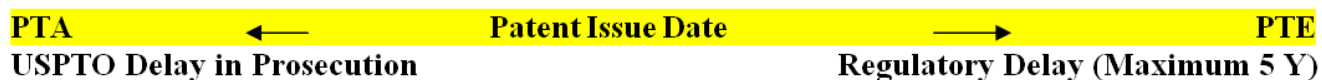
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The owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency.

Products covered by 35 USC 271²⁸(e) and provided that it shall not be an act of infringement, for example, to make and test a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA)²⁹.

The term of a patent eligible for extension under subsection 35 USC 156 (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued. The period of extension determined on the basis of the regulatory review period determined under any 35 USC 156 paragraphs may not exceed five years.

PTE IS DISTINCT FROM PTA³⁰



The PTE is different from the PTA and the criteria for PTE differ from those for PTA in the following aspects:

1. PTA can be granted for any US utility patent during the prosecution of which the USPTO unreasonably delayed the grant resulting in less than 17-year term.
2. PTE is limited to only US utility patents covering products requiring regulatory approval for marketing through a regulatory approval process, and is limited to the delay in marketing due to the regulatory approval delay after the grant of the patent.
3. The amount of PTA has no specific fixed limit other than the total delay due to the USPTO failure to prosecute diligently, while PTE is limited to a fixed maximum of five years, and the total term of an extended patent is limited to 14 years following regulatory approval.
4. One patent covering a new product may be extended as there is no need for all related patents to be covered by the PTE.
5. PTE is not limited by a terminal disclaimer, which has no relevance to the loss due to the regulatory approval process, whereas the PTA is limited by the TD.
6. The USPTO calculates and grants the PTA automatically.

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7. A PTE request must be submitted in a timely fashion. Failure to submit a request for PTE within the statutory timeframe will automatically result loss of any PTE available due to regulatory delays. A PTE request must be submitted within 60 days of FDA approval for the first permitted commercial marketing or use of the product or method covered by the claims of a patent before such commercialization or use and before expiration of the patent, by the owner of record or the owner's agent (the approval for the first permitted commercial marketing or use, i.e., for a patent that was previously extended by PTE for regulatory process for commercial marketing or use of the same).

Total Patent Term = Standard Term + PTA + PTE

The patent grant includes notification of the PTA³¹, whereas the PTE cannot be calculated until after the issue of the patent. However, the PTE can be estimated and projected³², based on the average time required for such approval process, until the approval process is completed. Only then, you can calculate exactly “the delay in marketing due to the regulatory approval process³³ for the PTE”. Therefore, PTE cannot be calculated at the time of the patent grant, at which time it is “zero.” If the approval process has completed before the grant, there is no ground for PTE. If the regulatory approval has not completed by the time of the grant, there is no way of knowing the PTE at that time. So, in either case, the PTE is “zero” on the date of the grant of the patent.

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REFERENCES AND NOTES³⁴

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<http://www.avvo.com/profile/dashboard>.

² Global Dossier: <http://globaldossier.uspto.gov/#/> ;

Global Dossier at IP5: <http://www.fiveipoffices.org/activities/globaldossier.html>

Global Dossier at Espacenet: https://worldwide.espacenet.com/help?topic=globaldossier&method=handleHelpTopic&locale=en_EP

<https://www.epo.org/service-support/updates/2014/20141024a.html>

³ Five IP Offices: www.fiveipoffices.org

⁴ The European Patent Office (EPO): <https://www.epo.org/index.html>

⁵ The Japan Patent Office (JPO): <https://www.jpo.go.jp/>

⁶ The Korean Intellectual Property Office (KIPO): <http://www.kipo.go.kr/kpo/user.tdf?a=user.english.main.BoardApp&c=1001>

⁷ The State Intellectual Property Office of the People's Republic of China (SIPO): <http://english.sipo.gov.cn/>

⁸ [The United States Patent and Trademark Office \(USPTO\)](#)

⁹ IP5 Patent Prosecution Highway: <http://www.fiveipoffices.org/activities/ws/ip5pph.html>

<http://www.uspto.gov/patents-getting-started/international-protection/patent-prosecution-highway-pph-fast-track>

http://www.wipo.int/pct/en/filing/pct_pph.html

¹⁰ Five IP Offices: www.fiveipoffices.org

¹¹ [The Dossier Access](#): <http://globaldossier.uspto.gov/#/>

¹² [Global Dossier Task Force](#): <http://www.fiveipoffices.org/industry-consultation/gdtf2015.html>

¹³ eMod: <http://www.uspto.gov/patent/emod> ; http://www.alanet.org/events/blc/handouts/LI01_New_Strategies_from_the_USPTO.pdf

¹⁴ The e-Office Action http://www.uspto.gov/sites/default/files/documents/e-oa_quick_start_guide_Mar2015.pdf

¹⁵ [the Financial Manager](#): [http://www.uspto.gov/learning-and-resources/fees-and-payment/financial-manager-information.html?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=](http://www.uspto.gov/learning-and-resources/fees-and-payment/financial-manager-information.html?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=Store_and_manage_electronic_payment_methods)

[Store and manage electronic payment methods](#), including credit/debit cards, deposit accounts, and EFT accounts online,

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[Check out quickly](#) without entering detailed payment method information, and
[Generate, view, and download reports](#), including transaction history and monthly statements as Excel, PDF, or CSV files.

¹⁶ [Quick Start Guide](#)

¹⁷ [User Guide](#)

¹⁸ American Inventors' Protection Act – Summary: <http://www.uspto.gov/patent/laws-and-regulations/american-inventors-protection-act-1999/american-inventors-protection-a-2>

¹⁹ under 35 USC 154 (B)(1) (B) Guarantee of No More Than 3-Year Application Pendency.

²⁰ 35 USC154 (pre-AIA) Contents and term of patent; provisional rights.

(b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

(I) the date on which an application was filed under section 111(a) ; or

(II) the date of commencement of the national stage under section 371 in an international application;

(ii) respond to a reply under section 132 , or to an appeal taken under section 134 , within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141 , 145 , or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b) ;

(ii) any time consumed by a proceeding under section 135(a) , any time consumed by the imposition of an order under section 181 , or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a) ;

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, or review, as the case may be.

²¹ Under 35 USC 135(a)

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²² 35 USC181 Secrecy of certain inventions and withholding of patent. Whenever publication or disclosure by the publication of an application or by the grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be kept secret and shall withhold the publication of an application or the grant of a patent therefor under the conditions set forth hereinafter. Whenever the publication or disclosure of an invention by the publication of an application or by the granting of a patent, in which the Government does not have a property interest, might, in the opinion of the Commissioner of Patents, be detrimental to the national security, he shall make the application for patent in which such invention is disclosed available for inspection to the Atomic Energy Commission, the Secretary of Defense, and the chief officer of any other department or agency of the Government designated by the President as a defense agency of the United States. Each individual to whom the application is disclosed shall sign a dated acknowledgment thereof, which acknowledgment shall be entered in the file of the application. If, in the opinion of the Atomic Energy Commission, the Secretary of a Defense Department, or the chief officer of another department or agency so designated, the publication or disclosure of the invention by the publication of an application or by the granting of a patent therefore would be detrimental to the national security, the Atomic Energy Commission, the Secretary of a Defense Department, or such other chief officer shall notify the Commissioner of Patents and the Commissioner of Patents shall order that the invention be kept secret and shall withhold the publication of the application or the grant of a patent for such period as the national interest requires, and notify the applicant thereof. Upon proper showing by the head of the department or agency who caused the secrecy order to be issued that the examination of the application might jeopardize the national interest, the Commissioner of Patents shall thereupon maintain the application in a sealed condition and notify the applicant thereof. The owner of an application which has been placed under a secrecy order shall have a right to appeal from the order to the Secretary of Commerce under rules prescribed by him. An invention shall not be ordered kept secret and the publication of an application or the grant of a patent withheld for a period of more than one year. The Commissioner of Patents shall renew the order at the end thereof, or at the end of any renewal period, for additional periods of one year upon notification by the head of the department or the chief officer of the agency who caused the order to be issued that an affirmative determination has been made that the national interest continues to so require. An order in effect, or issued, during a time when the United States is at war, shall remain in effect for the duration of hostilities and one year following cessation of hostilities. An order in effect, or issued, during a national emergency declared by the President shall remain in effect for the duration of the national emergency and six months thereafter. The Commissioner of Patents may rescind any order upon notification by the heads of the departments and the chief officers of the agencies who caused the order to be issued that the publication or disclosure of the invention is no longer deemed detrimental to the national security..

35 USC 5.2 Secrecy order

- When notified by the chief officer of a defense agency that publication or disclosure of the invention by the granting of a patent would be detrimental to the national security, an order that the invention be kept secret will be issued by the Commissioner for Patents.
- Any request for compensation as provided in 35 USC183 must not be made to the Patent and Trademark Office, but directly to the department or agency which caused the secrecy order to be issued.
- An application disclosing any significant part of the subject matter of an application under a secrecy order pursuant to paragraph (a) of this section also falls within the scope of such secrecy order. Any such application that is pending before the Office must be promptly brought to the attention of Licensing and Review, unless such application is itself under a secrecy order pursuant to paragraph (a) of this section. Any subsequently filed application containing any significant part of the subject matter of an application under a secrecy order pursuant to paragraph (a) of this section must either be hand-carried to Licensing and Review or mailed to the Office in compliance with § 5.1(a)

5.3 Prosecution of application under secrecy orders; withholding patent.

Unless specifically ordered otherwise, action on the application by the Office and prosecution by the applicant will proceed during the time an application is under secrecy order to the point indicated in this section:

- National applications under secrecy order which come to a final rejection must be appealed or otherwise prosecuted to avoid abandonment. Appeals in such cases must be completed by the applicant but unless otherwise specifically ordered by the Commissioner for Patents will not be set for hearing until the secrecy order is removed.
- An interference or derivation will not be instituted involving a national application under secrecy order. An applicant whose application is under secrecy order may suggest an interference (§ 41.202(a) of this title), but the Office will not act on the request while the application remains under a secrecy order.
- When the national application is found to be in condition for allowance except for the secrecy order the applicant and the agency which caused the secrecy order to be issued will be notified. This notice (which is not a notice of allowance under § 1.311 of this chapter) does not require reply by the applicant and places the national application in a condition of suspension until the secrecy order is removed. When the secrecy order is removed the Patent and Trademark Office will issue a notice of allowance under § 1.311 of this chapter, or take such other action as may then be warranted.

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(d) International applications and international design applications under secrecy order will not be mailed, delivered, or otherwise transmitted to the international authorities or the applicant. International applications under secrecy order will be processed up to the point where, if it were not for the secrecy order, record and search copies would be transmitted to the international authorities or the applicant.

²³ § 41.31 Appeal to Board

(a) Who may appeal and how to file an appeal.

An appeal is taken to the Board by filing a notice of appeal.

(1) Every applicant, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

²⁴ Upon written request from the U.S. Patent and Trademark Office, FDA will assist the U.S. Patent and Trademark Office in determining whether a patent related to a product is eligible for patent term restoration: [The regulations governing the Patent Term Restoration program are located in the Code of Federal Regulations, 21 CFR Part 60.](#)

²⁵ [Patent-Term Extension and the Pharmaceutical Industry, August 1981](#)

²⁶ **35 USC156 Extension of patent term**

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if —

- (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
- (2) the term of the patent has never been extended under subsection (e)(1) of this section;
- (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
- (4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which —

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the “approved product.”

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended —

(1) in the case of a patent which claims a product, be limited to any use approved for the product —

(A) before the expiration of the term of the patent —

- (i) under the provision of law under which the applicable regulatory review occurred, or
 - (ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and
- (B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product —

(A) before the expiration of the term of the patent —

- (i) under any provision of law under which an applicable regulatory review occurred, and
- (ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

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(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and
 (3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make —
 (A) the approved product, or
 (B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g).
 As used in this subsection, the term "product" includes an approved product.
 (c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—
 (1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;
 (2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);
 (3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years, and
 (4) in no event shall more than one patent be extended under subsection (e)(i) for the same regulatory review period for any product.
 (d) (1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning 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. The application shall contain—
 (A) the identity of the approved product and the Federal statute under which regulatory review occurred;
 (B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;
 (C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);
 (D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and
 (E) such patent or other information as the Director may require.
 For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.
 (2)(A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Director shall notify —
 (i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and
 (ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug and Cosmetic Act, of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Director, the Secretary reviewing the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination, and shall publish in the Federal Register a notice of such determination.
 (B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by the Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the

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Commissioner of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Director of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.

(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the day on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period, the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)(1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under

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seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 USC151 - 158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of —

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of —

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of —

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(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of —

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of —

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus- Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and —

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environment effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted, before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Director may establish such fees as the Director determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

²⁷ Patent Term Extension for Delays at other Agencies (2750 MPEP, under 35 USC156)

The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 USC355(b), (j), (l); 35 USC156, 271, 282)(Hatch-Waxman Act). The act sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669, 15 USPQ2d 1121, 1126 (1990). The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion occurred after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive FDA approval before patent expiration.

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The part of the act codified as 35 USC156 was designed to create new incentives for research and development of certain products subject to premarket government approval by a regulatory agency. The statute enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency. The rights derived from extension of the patent term under 35 USC156(a) are defined in 35 USC156(b), but are not limited to a claim-by-claim basis. Rather, subsection(a) of 156 indicates that “[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended.” See *Genetics Institute LLC v. Novartis Vaccines and Diagnostics Inc.*, 655 F.3d 1291, 99 USPQ2d 1713 (Fed. Cir. 2011). However, pursuant to 35 USC156(b), if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent.

In exchange for extension of the term of the patent, Congress legislatively overruled *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984) as to products covered by 35 USC271(e) and provided that it shall not be an act of infringement, for example, to make and test a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA). 35 USC271(e)(1). See Donald O. Beers et al., *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, Eighth Edition, Wolters Kluwer Law & Business, 2013, 4.05 for a discussion of the Hatch-Waxman Act and infringement litigation. Furthermore, Congress provided that an ANDA that the FDA will grant to the marketing applicant a period of 5 years of data exclusivity for any active ingredient or salt or ester of the active ingredient which had not been previously approved under section 505(b) of the Federal Food, Drug and Cosmetic Act. 21 USC355(j)(4)(D)(ii). See also Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 Food, Drug and Cosmetic L. J. 351, 353-60 (1985). See also Lourie, *Patent Term Restoration*, 66 J. Pat. Off. Soc’y 526 (1984).

On November 16, 1988, 35 USC156 was amended by Public Law 100-670, essentially to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products which are primarily manufactured through biotechnology are excluded from the provisions of patent term extension.

On December 3, 1993, 35 USC156 was further amended to provide for interim extension of a patent where a product claimed by the patent was expected to be approved, but not until after the original expiration date of the patent. Public Law 103-179, Section 5.

An application for the extension of the term of a patent under 35 USC156 must be submitted by the owner of record of the patent or its agent within the sixty-day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. See 35 USC156(d)(1). This language regarding the sixty-day period has been clarified by the America Invents Act where the Act provides that, “[f]or purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term ‘business day’ means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.” See Section 37 of the AIA and 35 USC156. The USPTO initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Director of the United States Patent and Trademark Office to notify the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with 35 USC156 within sixty days and to submit to the Secretary a copy of the application. Not later than thirty days after receipt of the application from the Director, the Secretary will determine the length of the applicable regulatory review period and notify the Director of the determination. If the Director determines that the patent is eligible for extension, the Director calculates the length of extension for which the patent is eligible under the appropriate statutory provision and issues an appropriate Certificate of Extension.

Patent term extensions provided by private relief legislation, public laws other than as enacted by 35 USC156, such as 35 USC155 and 155A, are not addressed herein.

²⁸ 35 U.S.C. 271 Infringement of patent.

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another

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without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit —

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151 - 158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C) (i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285 .

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j) (2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j) (2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6) (A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent-

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

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(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or
 (II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.
 (B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.
 (C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.
 (f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
 (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
 (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after —
 (1) it is materially changed by subsequent processes; or
 (2) it becomes a trivial and nonessential component of another product.
 (h) As used in this section, the term “whoever” includes any State, any instrumentality of a State, any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.
 (i) As used in this section, an “offer for sale” or an “offer to sell” by a person other than the patentee or any assignee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

²⁹ CAUGHT IN THE MIDDLE: REDUCING THE UNCERTAINTY CREATED BY THE FDA AND THE PATENT SYSTEM FOR GENETIC DIAGNOSTIC TEST MAKERS: http://www.uspto.gov/sites/default/files/aia_implementation/gene-comment-goswami.pdf

³⁰ Patent Term Adjustment and Patent Term Extension: Valuable Tools to Prolong Patent Protection Through Careful Vigilance: <https://www.wsg.com/publications/PDFSearch/life-sciences-report/Spring14/medical-device-biotechnology-companies.htm>

³¹ Patent Term Adjustment (PTA)
 – Governed by 35 U.S.C. § 154(b)
 – Meant to compensate for USPTO delays examining and issuing patent
 – Ensures that “no applicant diligently seeking to obtain a patent will receive a term of less than 17 years”

Patent Term Extension (PTE)
 – Governed by 35 U.S.C. § 156
 – Meant to compensate for delays in regulatory approval process for pharmaceutical and other products subject to pre-market approval

Total Patent Term = “Standard Term” + PTA + PTE
 35 USC 154 (b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

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(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—
(I) the date on which an application was filed under section 111(a) ; or
(II) the date of commencement of the national stage under section 371 in an international application;
(ii) respond to a reply under section 132 , or to an appeal taken under section 134 , within 4 months after the date on which the reply was filed or the appeal was taken;
(iii) act on an application within 4 months after the date of a decision by the Patent Trial and Appeal Board under section 134 or 135 or a decision by a Federal court under section 141 , 145 , or 146 in a case in which allowable claims remain in the application; or
(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied,
the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b) ;
(ii) any time consumed by a proceeding under section 135(a) , any time consumed by the imposition of an order under section 181 , or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or
(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),
the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, SECRECY ORDERS, AND APPEALS.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a) ;
(ii) the imposition of an order under section 181 ; or
(iii) appellate review by the Patent Trial and Appeal Board or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,
the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) LIMITATIONS.—

(A) IN GENERAL.— To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.— No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) PROCEDURES FOR PATENT TERM ADJUSTMENT DETERMINATION.—

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall—

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination no later than the date of issuance of the patent; and

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(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) APPEAL OF PATENT TERM ADJUSTMENT DETERMINATION.—

(A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.

³² [Making Estimates And Projections Using Distributions](#)

³³ PTE Relevant Regulatory Acts

Relevant Regulatory Review Periods

- Section 505 of Federal Food Drug and Cosmetic Act (new drugs).
- Section 351 of the Public Health Services Act (human biological products).
- Section 515 of the Federal Food Drug and Cosmetic Act (medical devices).
- Section 512 of the Federal Food Drug and Cosmetic Act (new animal drugs).
- The Virus-Serum Toxin Act, 21 U.S.C. §§ 151-159 (veterinary biological products).
- Section 409 of the Federal Food Drug and Cosmetic Act (food additives and color additives).

Life Science Lawyer Guide to PTA and PTE, by Mary Till, The Office of Patent Legal Administration:

https://view.officeapps.live.com/op/view.aspx?src=http://www.uspto.gov/patents/law/exam/presentation/pta_pte_27jan2011.ppt

³⁴ In addition to the primary sources cited above, additional references include:

[New York Times](#), [Washington Post](#), [Mercury News](#), [Bayarea.com](#), [Deccan Chronicle](#), [the Hindu](#), [Hindustan Times](#), [Times of India](#), [AP](#), [Reuters](#), [AFP](#), [The Guardian](#), [Pravda](#), [Spiegel](#), [Connexion](#), etc.

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“Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls.” [Rabindranath Tagore \(1861-1941\), Gitanjali, 1912.](#)

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