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Overview of US Patent Regime

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Title 35 USC – Patents

- Part I – USPTO
- Part II – Patentability of Inventions and Grant of Patents
- Part III – Patents and protection of patent rights
- Part IV – Patent Cooperation Treaty

USPTO

Examines applications and grants patents; publishes and disseminates patent information; records assignments of patents; maintains search files of U.S. and foreign patents; supplies copies of patents and official records to the public; provides training to practitioners; publishes the Manual of Patent Examining Procedure to elucidate these.

Patent

- Property right granted to the inventor
- Term of 20 years from date of application in US
- Effective within US territories and possessions
- Patent term extensions and adjustments are available

§101. Inventions patentable - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



MPEP

Manual of Patent Examining Procedure
Latest Revision June 2020 [R-10.2019]

§101 – statutory requirements

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
 - One invention, one patent
 - Specific, substantial, credible utility
- Only to person who engages in the act of inventing. First-inventor-to-file applies to applications filed after March 16, 2013. Any application filed prior to March 16 will be examined under the previous first-to-invent rules.
- Patent applicants still must sign an oath asserting that they are the true inventor of the invention claimed in their application. Only a true inventor (or an agent or attorney acting on the true inventor's behalf) can file for patent protection on the claimed invention.



Statutory subject matter 35 USC 100(b)

- **Not patentable: Laws of nature, natural phenomena, abstract ideas – mental processes, mathematical algorithms, scientific tools/principles**
- "are the basic tools of scientific and technological work" & monopolizing these tools may impede innovation rather than promote it.
 - Process – act or series of steps
 - Machine – concrete: consisting of parts, devices, combination
 - Manufacture – article produced from raw materials to give new forms, qualities, properties, combinations by labour or machinery
 - Composition of matter – composition of 2 or more substances, composite articles, chemical union or mechanical mixture, whether gases, fluids, powders or solids.



Patentability - §102. Novelty; Prior Art.

Inventor is entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date ; – grace period

To reject a claim under 35 U.S.C. 102 as anticipated by a reference, the disclosure must teach every element required by the claim under its broadest reasonable interpretation. Normally, only one reference should be used in making a rejection; however, rejection over multiple references has been held to be proper when the extra references are cited to:

- (A) Prove the primary reference contains an "enabled disclosure;"
- (B) Explain the meaning of a term used in the primary reference; or
- (C) Show that a characteristic not disclosed in the reference is inherent.



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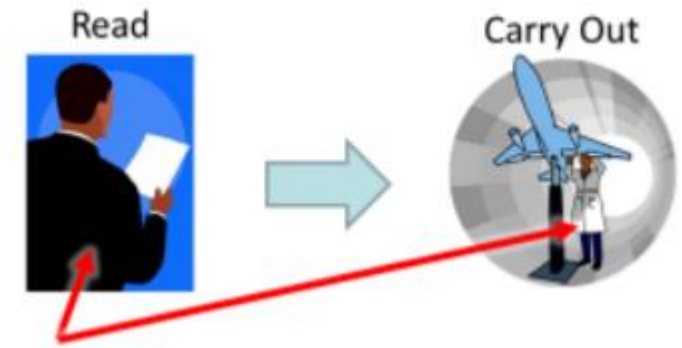
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§ 103. Non-obvious subject matter

- Even if the invention is not identically disclosed under §102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the filing date to a person having ordinary skill in the art to which the claimed invention pertains, a patent may not be obtained.
- "[T]he test for obviousness is what the combined teachings of the references would have suggested to [a PHOSITA]."



Rutherford's Gold Foil Experiment

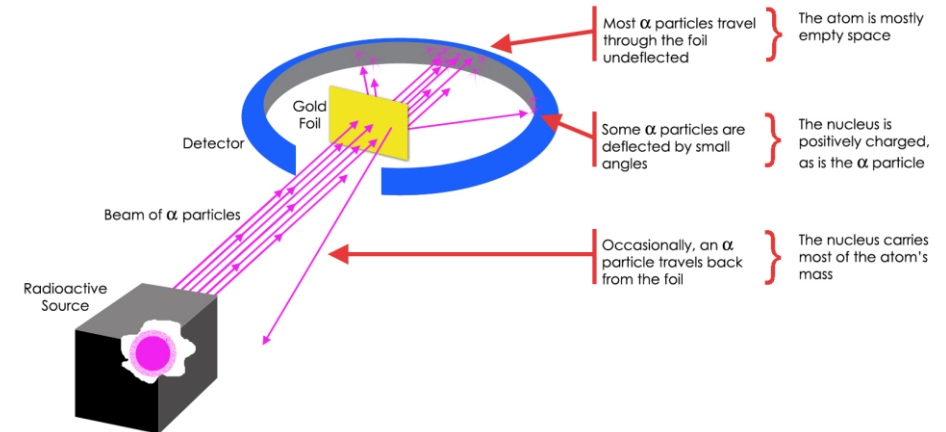
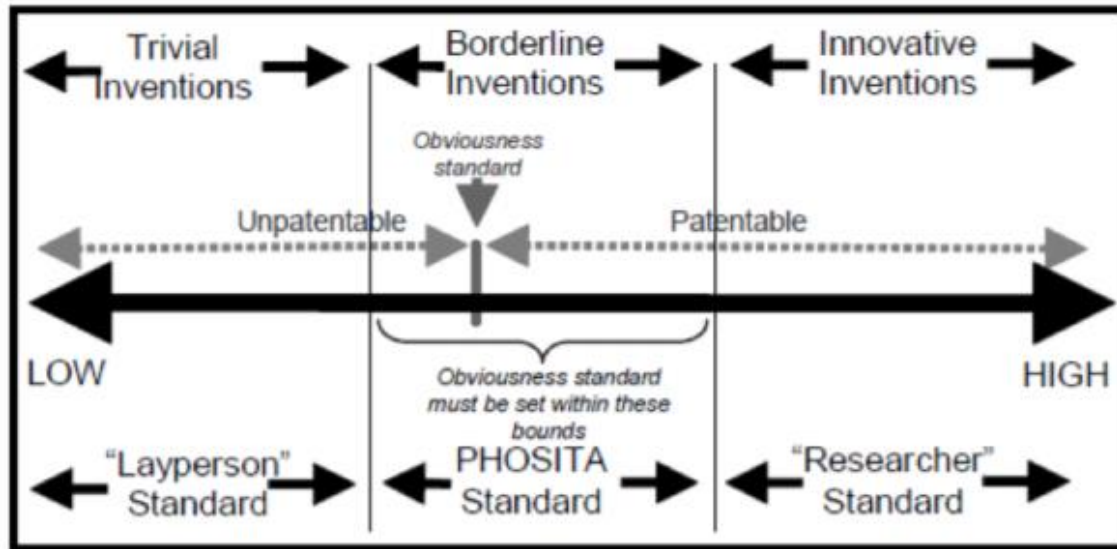


Figure 1: PHOSITA Standard as a Collar on the Obviousness Standard



Source: Jonathan J. Darrow, *The Neglected Dimensions of Patent Law's PHOSITA Standards*, Harvard Law Journal of Law and Technology⁷²

In the case of *Graham v. John Deere*,⁷³ the Supreme Court of the U.S. obtained from 35 U.S.C § 103, four factors that formed an essential test to determine non-obviousness, the foremost of which was the 'level of ordinary skill in the art.'⁷⁴ However, the role of Secondary Factors in determining non-obviousness acquired great importance after Graham's Case, diminishing the role of PHOSITA till the advent of K.S.R Judgment which revived the importance of PHOSITA.

The case of *Environment Designs, Ltd. v. Union Oil Co.*,⁷⁵ provided a list of non-exhaustive factors which may be considered in determining the level of ordinary skill in the art of the person, which are:

- a. The educational level of the inventor;
- b. Type of problems encountered in the art;
- c. Prior art solutions to those problems;
- d. Rapidly with which inventions are made;
- e. Sophistication of the technology
- f. Education level of active workers in the field.

The expression "ordinary skill" is intended to exclude the "best" expert that can be found. It is intended that the person be limited to one having the average level of skill reached in the field in the country concerned.

The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date.

PHOSITA being close to an "ordinary inventor" than its original meaning of "ordinary mechanic."

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Application for Patent

§ 111. written application containing spec under §112; drawing under §113; and oath/declaration under §115. and one or more claims.

(a) IN GENERAL.—

(1) WRITTEN APPLICATION.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Director.

(2) CONTENTS.—Such application shall include—

(A) a specification as prescribed by section 112;

(B) a drawing as prescribed by section 113; and

(C) an oath or declaration as prescribed by section 115.

(3) FEE, OATH OR DECLARATION, AND CLAIMS.—The application shall be accompanied by the fee required by law. The fee, oath or declaration, and 1 or more claims may be submitted after the filing date of the application, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Director. Upon failure to submit the fee, oath or declaration, and 1 or more claims within such prescribed period, the application shall be regarded as abandoned.

(4) FILING DATE.—The filing date of an application shall be the date on which a specification, with or without claims, is received in the United States Patent and Trademark Office. §113 drawings – where necessary, w/i2m of notice from Dir. – not to overcome insufficiency in spec or supplement original disclosure.

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Claims

- SPEC shall conclude with CLAIM/S
- **Independent** -
- **Dependent** – contain a ref to a previous claim and specify limitation of the subject matter claimed
- **Multiple Dependent** – ref in the alternative only to more than one claim previously set forth
- **Combination** – expressed as a means or step for performing a specified function without the recital of structure, material or acts – construe to cover corresponding...and equivalents thereof.
- Dir. May require **Models/specimen** for inspection or experiment or exhibit advantageously parts of the invention

Prior to writing claim(s) answer these questions:

- What is the invention?
- What are the elements that make up the invention?
- How do the elements relate to one another?
- Do you have more than one invention?
- Tangible: Apparatus, machine, composition
- Method: Making or Using
- Are there multiple embodiments of the same invention?

§ 115, 116 & 117 Inventor's Oath/Declaration/Inventor



- Every inventor is named
- Oath statements – application was authorised to be made by declarant; individual believes herself to be the original inventor
- Substitute statement
- **Joint inventor** – even if they did not work together, did not make same type/amount of contribution; did not contribute to every claim
- **Omitted inventor** – may join subsequently
- **Death or incapacity** – Legal representatives
- **Assignment** – person having proprietary interest

§116 Inventors



US 6285999B1

Inventor: Lawrence Page

Current Assignee: Leland
Stanford Junior University,
Google LLC

**Method for node ranking in a
linked database**

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§119, 120, 121 Priority

- PCT priority with fee, 12m period, certified copy, inventor
- Amendment
- **Divisional** – if 2 or more independent or distinct inventions are claimed in one appln, Dir. May require the application to be restricted to one invention. Other invention is made subject of a divisional application.

§122 Confidentiality and publication

- Applications will be confidential until publication
- 18m complete spec - publication
- Secrecy order under §181

§131, 132 Examination/rejection; reexamination

- If on examination it appears that applicant is entitled to a patent, the Dir. shall issue a patent
- Notice of rejection shall be given
- If applicant persists in his claim with or without amendment, it shall be re-examined. No amendment shall introduce new matter to the disclosure.

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§134 appeal to Patent Trial and Appeal Board

- An applicant whose claim has been twice rejected, or rejected in re-examination may appeal with fee

§135. Derivation proceedings

A derivation proceeding is a trial proceeding conducted at the Board to determine whether (i) an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application, and (ii) the earlier application claiming such invention was filed without authorization. An applicant subject to the first-inventor-to-file provisions may file a petition to institute a derivation proceeding only within 1 year of the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention. Came into effect 2013

Inter Partes Review

- Inter partes review is a trial proceeding conducted at the Board to review the patentability of one or more claims in a patent only on a ground that could be raised under §§ 102 or 103, and only on the basis of prior art consisting of patents or printed publications. For first-inventor-to-file patents, inter partes review process begins with a third party (a person who is not the owner of the patent) filing a petition after the later of either: (1) 9 months after the grant of the patent or issuance of a reissue patent; or (2) if a post grant review is instituted, the termination of the post grant review.
- The procedure for conducting inter partes review took effect on September 16, 2012
- Large technology firms, like Apple, Google, Intel and Amazon, support the system and have used the inter partes review process to challenge uncertain patents held by those who they perceive to be patent trolls and to fend off challenges to their own patents from other firms. For example, Apple had sought an inter partes review of patents owned by VirnetX



The patent dispute between VirnetX and [Apple dates back to 2010](#) when VirnetX accused Apple's [FaceTime](#) feature of infringing on its intellectual property, and there are multiple lawsuits involved.

In this particular case, Apple was ordered to [pay \\$302 million](#) in October 2016, but with interest and other costs included, the judgement was [increased to \\$440 million](#). Though Apple appealed the \$440 million award many times, courts have continually [ruled in VirnetX's favor](#).

Most recently, Apple attempted to get the U.S. Supreme Court to [hear its appeal](#), but the Supreme Court in February 2020 declined to intervene.

Review of USPTO decisions

- §141 – Appeal against board decision to Federal Circuit – examination, post-grant or inter partes review/derivation proceedings
- Appellant shall file written notice to Dir. §142
- §145 – in the alternative, remedy by civil action against the DIR. in the District Court for the Eastern Distt. Of Virginia.

Issue of Patent

§151. A written notice of allowance – with issue fee, publication fee to be paid within 3 months. Upon payment, the patent will issue. Issue under seal of Dir.; may issue to assignee on request of inventor.

Patent Trial and Appeal Board

The Patent Trial and Appeal Board (PTAB) conducts trials, including inter partes, post-grant, and covered business method patent reviews and derivation proceedings, hears appeals from adverse examiner decisions in patent applications and reexamination proceedings, and renders decisions in interferences.

§154. Patent term adjustment – 37 CFR

37 CFR 1.705 Patent term adjustment determination.

(a) The patent will include notification of any patent term adjustment under 35 U.S.C. 154(b).

• A – Delay

• B – Delay

• C – Delay

• Applicant Delay

• Overlap Delay



Patent term guarantee: Guarantee of no more than 3-yr appln pendency - if issue of patent is delayed due to failure of the USPTO to

- provide a notice of rejection/re-examination/notice of allowance within 14 m
- To respond to reply within 4m
- Act on appln within 4m after decision by PTAB
- Issue patent w/i 4m from payment of issue fee

Term to be extended by 1 day for each day of delay – appeal to civil court from reconsideration of Dir. USPTO performs PTA calculation with notice of allowance, and prior to issue.

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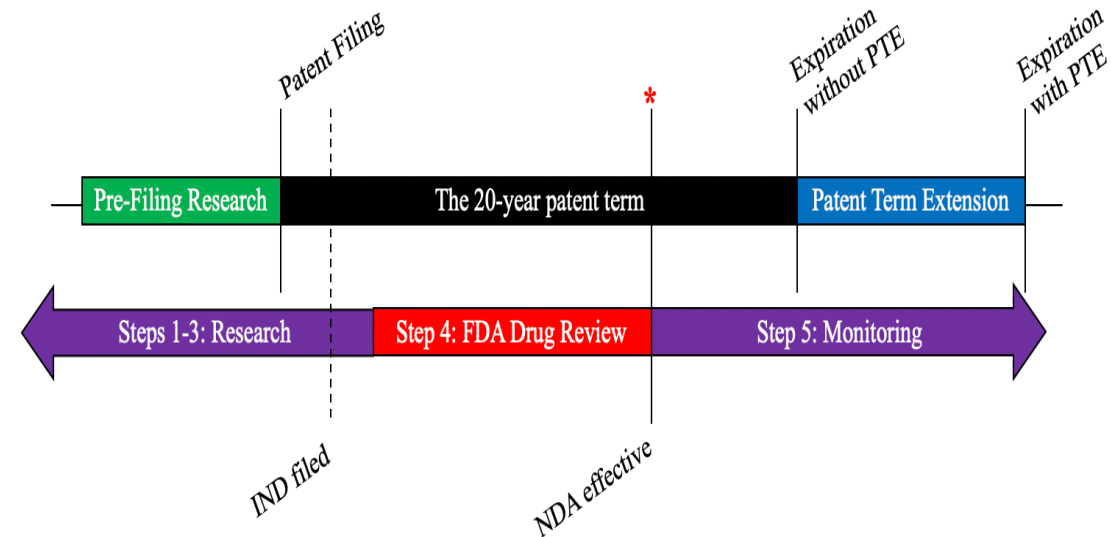


A patent shall include to right to obtain
reasonable royalty from anyone who

- makes, uses, offers for sale, or sells or imports such an invention into the United States; or
- if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process
- Had notice of the published patent or of international appln.

§156. Patent Term Extension

- Term has not expired; never been extended; filing of appln for extn by patentee; Drug or veterinary product not covered by claims which have been extended
- Product has been subject to regulatory review before commercial marketing or use
- The term of a patent eligible for extension shall be extended by the time equal to the regulatory review period
- reduced by any period during which the applicant did not act with due diligence during regulatory review period.
- owner of record of the patent or its agent shall submit an application to the PTO.



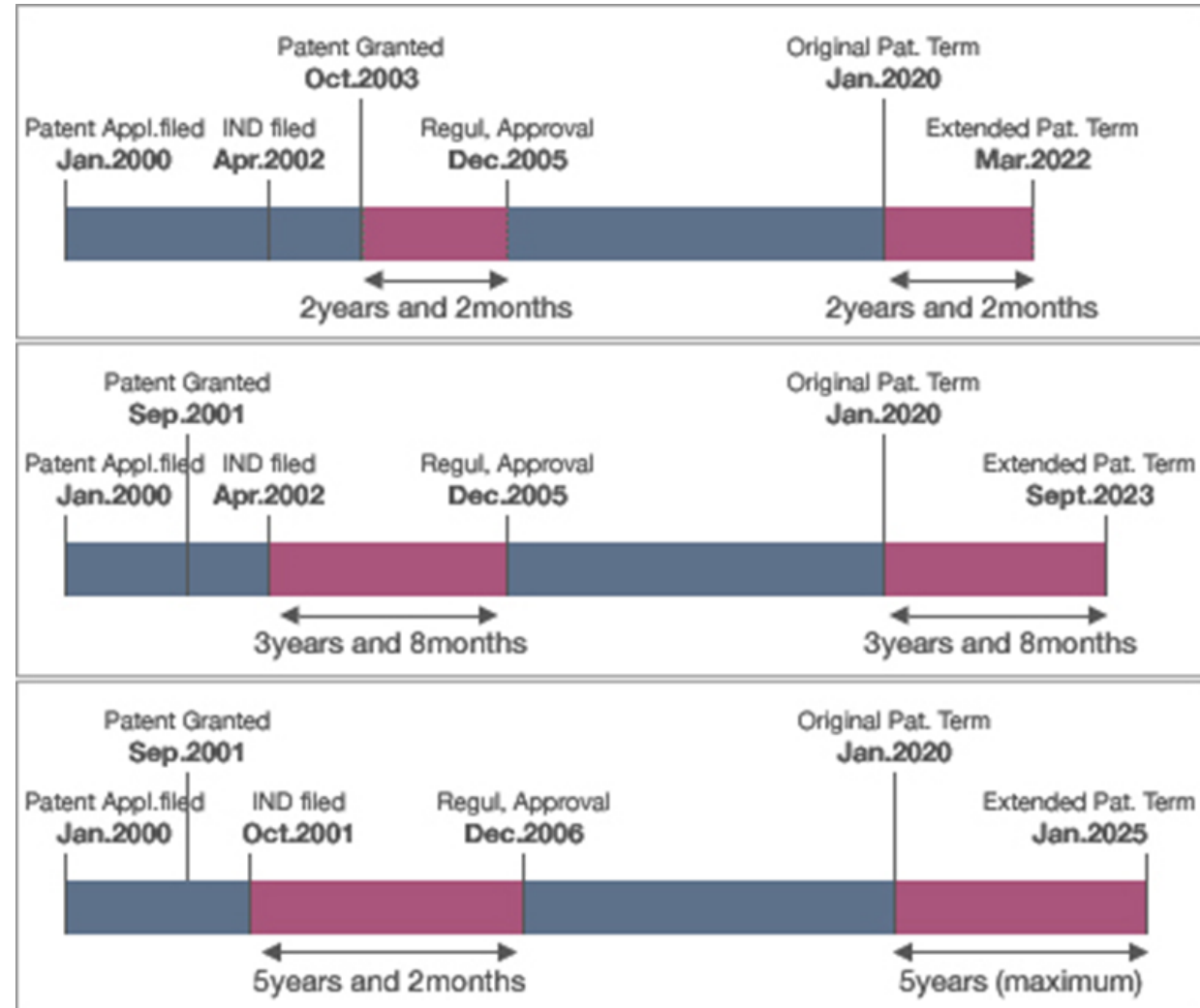
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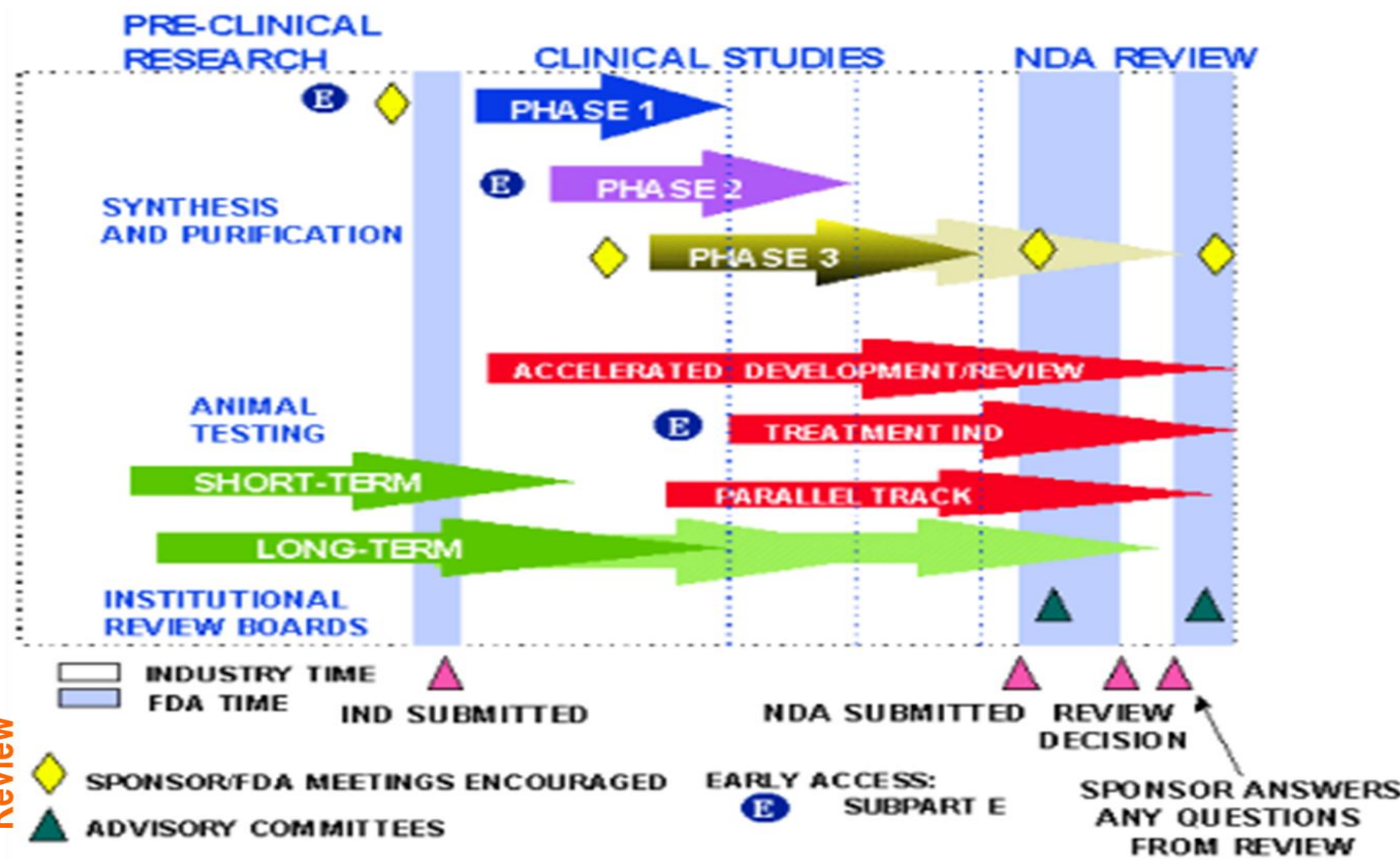
Half of the time in the testing phase,
plus all the time in the review phase

1984 Drug Price
Competition and
Patent Restoration Act,
Hatch-Waxman Act

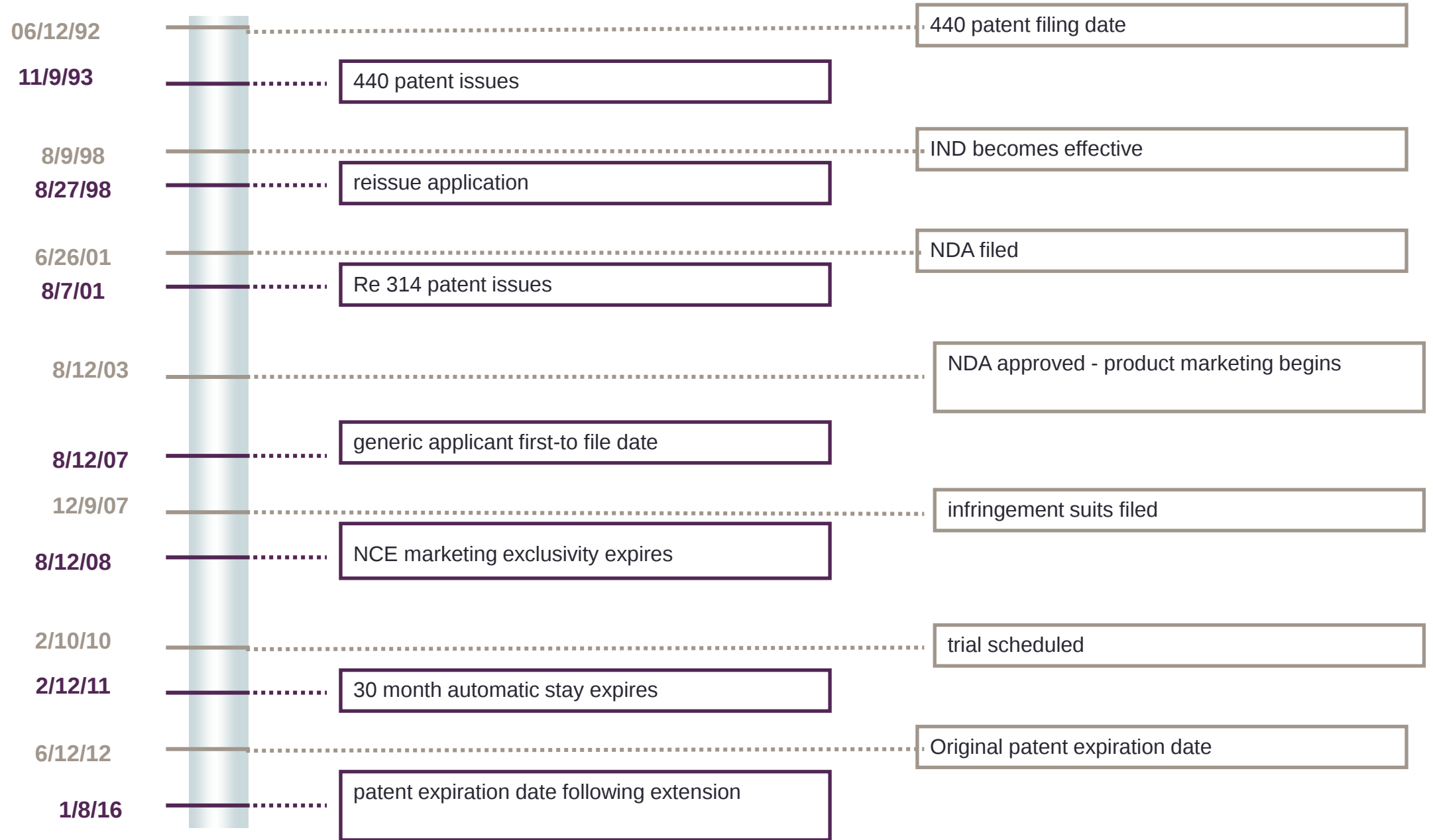
- Active ingredient of
drug or biological
product, medical
device, food or colour
additive subject to
regulation under Fed.
Food, Drug and
Cosmetic Act.



The New Drug Development Process:
Steps from Test Tube to New Drug Application
Review



Example timeline: rosuvastatin

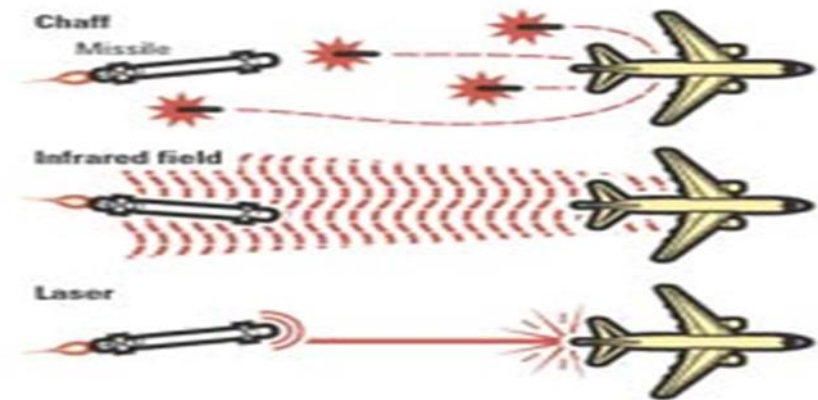


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§181 Secrecy

- Invention in which the government has a property interest, publication may be detrimental to the national security, commissioner of patents shall order the invention be kept secret.
- Secrecy orders 35 USC 120 – Compensation. US Patent 8925438, Damnjanovic – countermeasure technique using an appropriate fluid spray against infrared heat seeking missile.



Patent Dance

- Colloquially referred to as the “patent dance,” the [BPCIA](#) provides a framework that includes certain steps and a schedule during which the applicant and reference product sponsor exchange confidential information disclosed in the [aBLA](#).
- During the patent dance, the applicant and sponsor identify the patents that could be litigated in the future during two potential phases of litigation. In the first phase, the sponsor can allege infringement of a subset of the patents identified during the patent dance. The second phase begins after the sponsor receives the Notice of Commercial Marketing from the applicant.

Time and process

- Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) to provide an abbreviated pathway for biosimilars to gain FDA approval through submission of an abbreviated Biologics License Application (aBLA).
- If both the applicant and the sponsor engage in all of the steps set forth in the BPCIA and take the maximum allotted time, the patent dance can take up to 250 days (approximately eight months) to complete.
- Patent dance is not mandatory. In *Amgen v. Sandoz*, CITE, the Supreme Court held that the patent dance is not mandatory. Although the BPCIA requires that an applicant “must” provide its application and manufacturing information.
- If, however, the applicant eschews the dance, the decision of when and which patents to litigate shifts to the sponsor, who retains the right to immediately seek “a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

Thank you

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