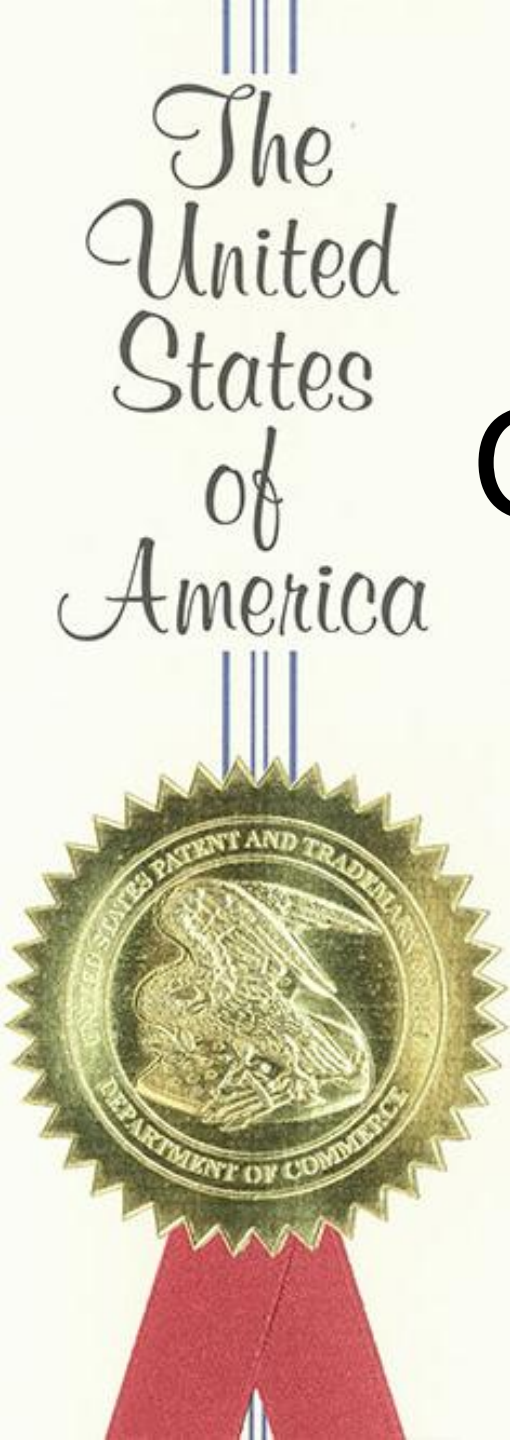


Overview of US Patent Regime

Swapna Sundar



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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.

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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.

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§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
- Process, machine, manufacture, composition of matter
- Only to person who engages in the act of inventing

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Statutory subject matter

- **Not patentable:** Laws of nature, natural phenomena, abstract ideas – mental processes, mathematical algorithms, scientific tools/principles
- 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.

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Patentability

§102. Novelty; Prior Art.

A person shall be entitled to a patent unless—

1. 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 of the claimed invention;

Exception – a disclosure made 1 year or less before the effective filing date by the inventor or jt. Inventor

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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.
- PHOSITA

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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.
- Filing date is when appln is received at USPTO
- SPEC – written description of the invention; the manner and process of making and using it, in full, clear, concise and exact terms as to enable PHOSITA to make and use the same, and shall set forth the best mode contemplated by the inventor
- §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

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§ 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.

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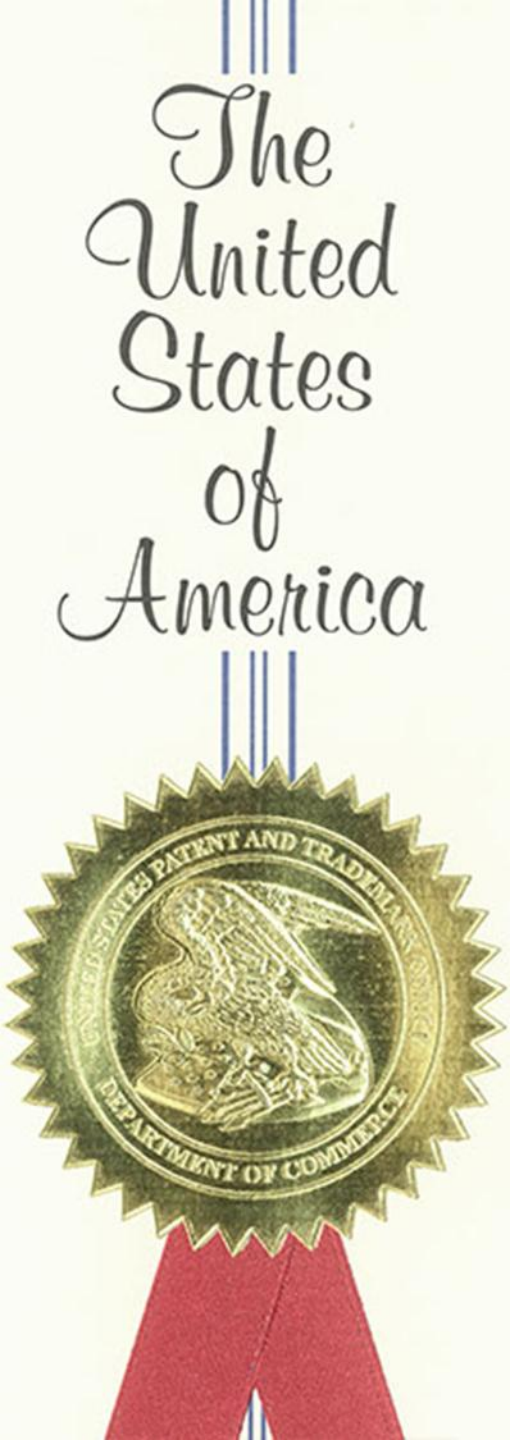


§122 Confidentiality and publication

- 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.



§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.

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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.

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§154. Patent term adjustment

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.

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§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 Director.

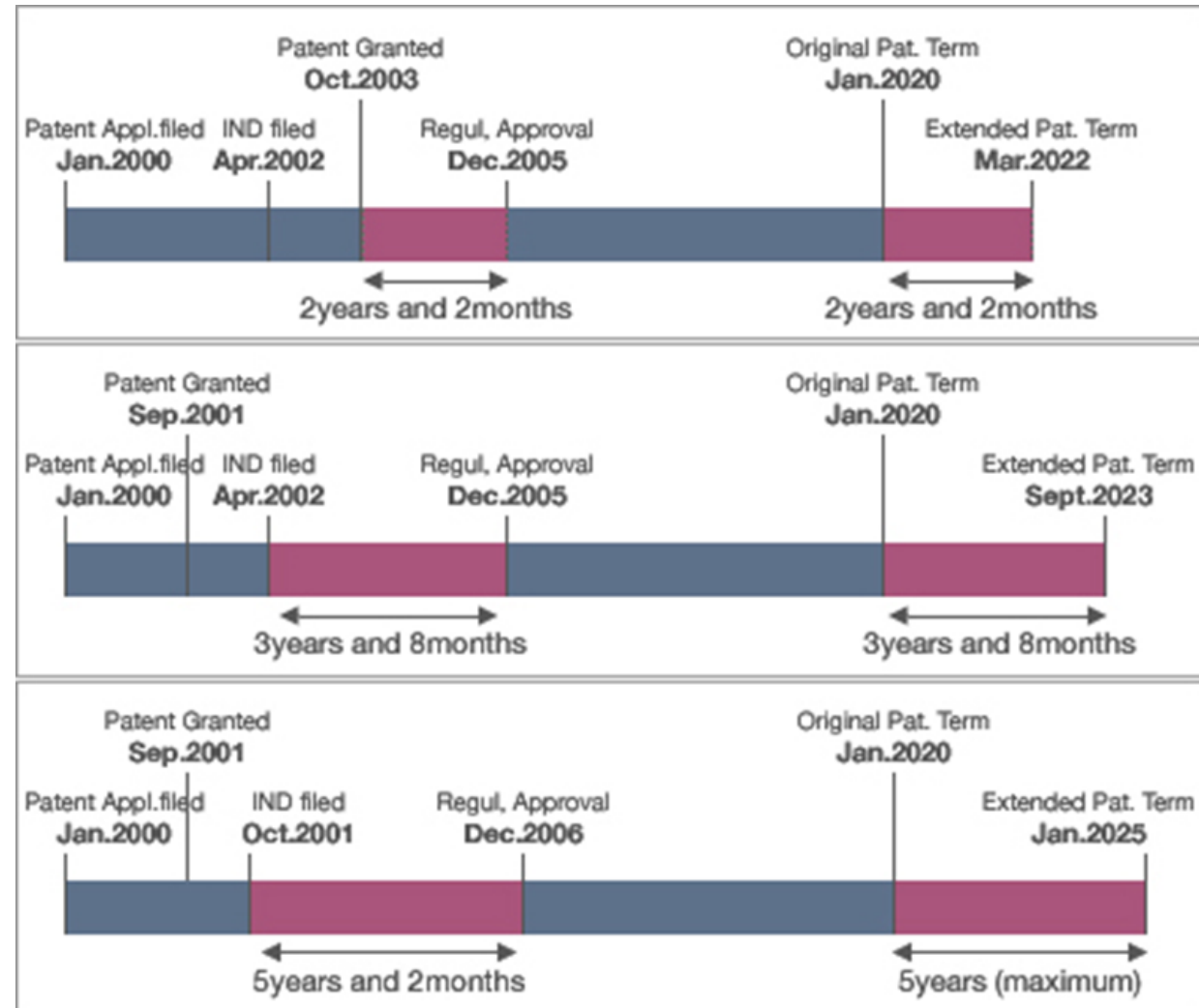
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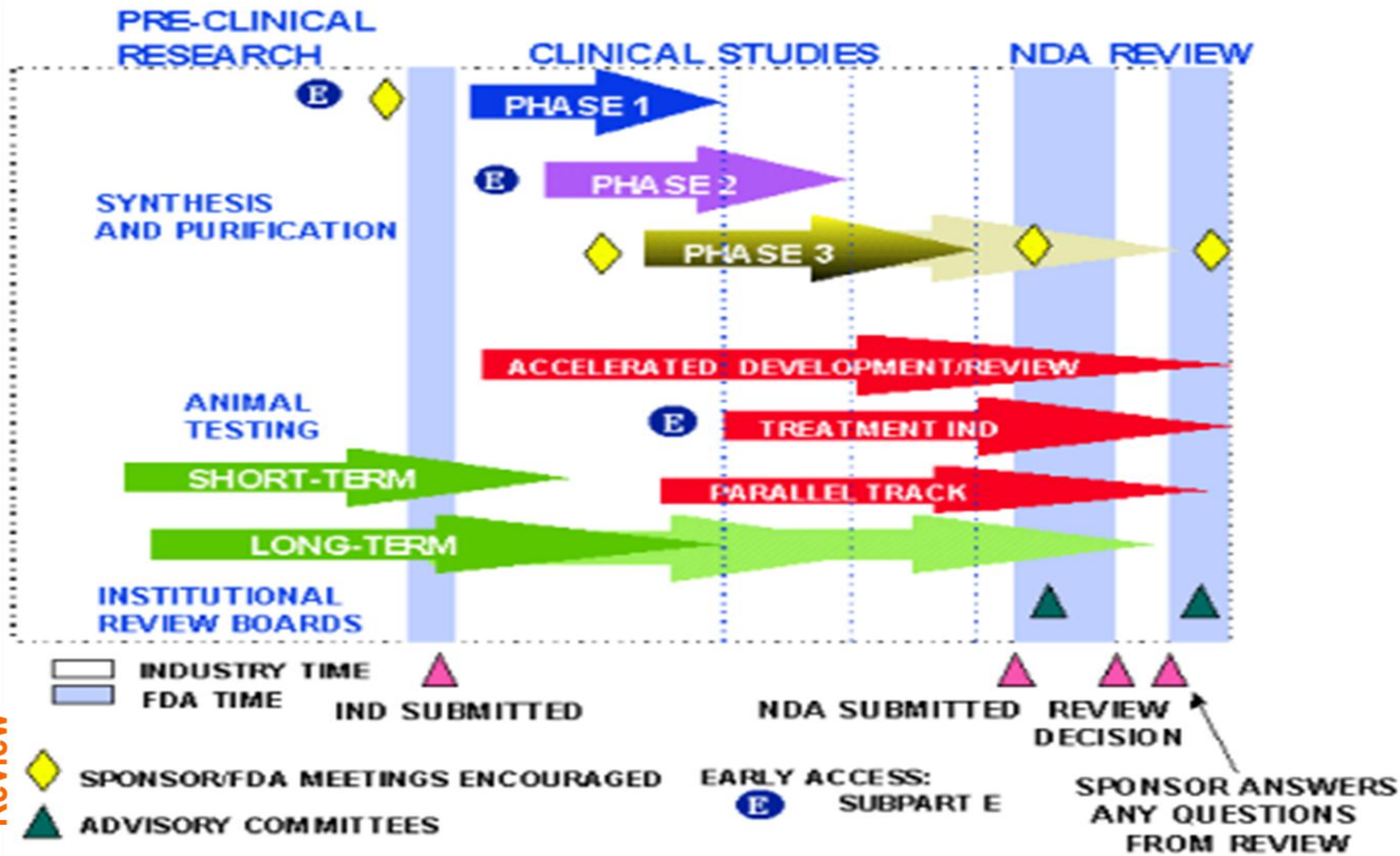
Half of the time in the testing phase, plus all the time in the review phase

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

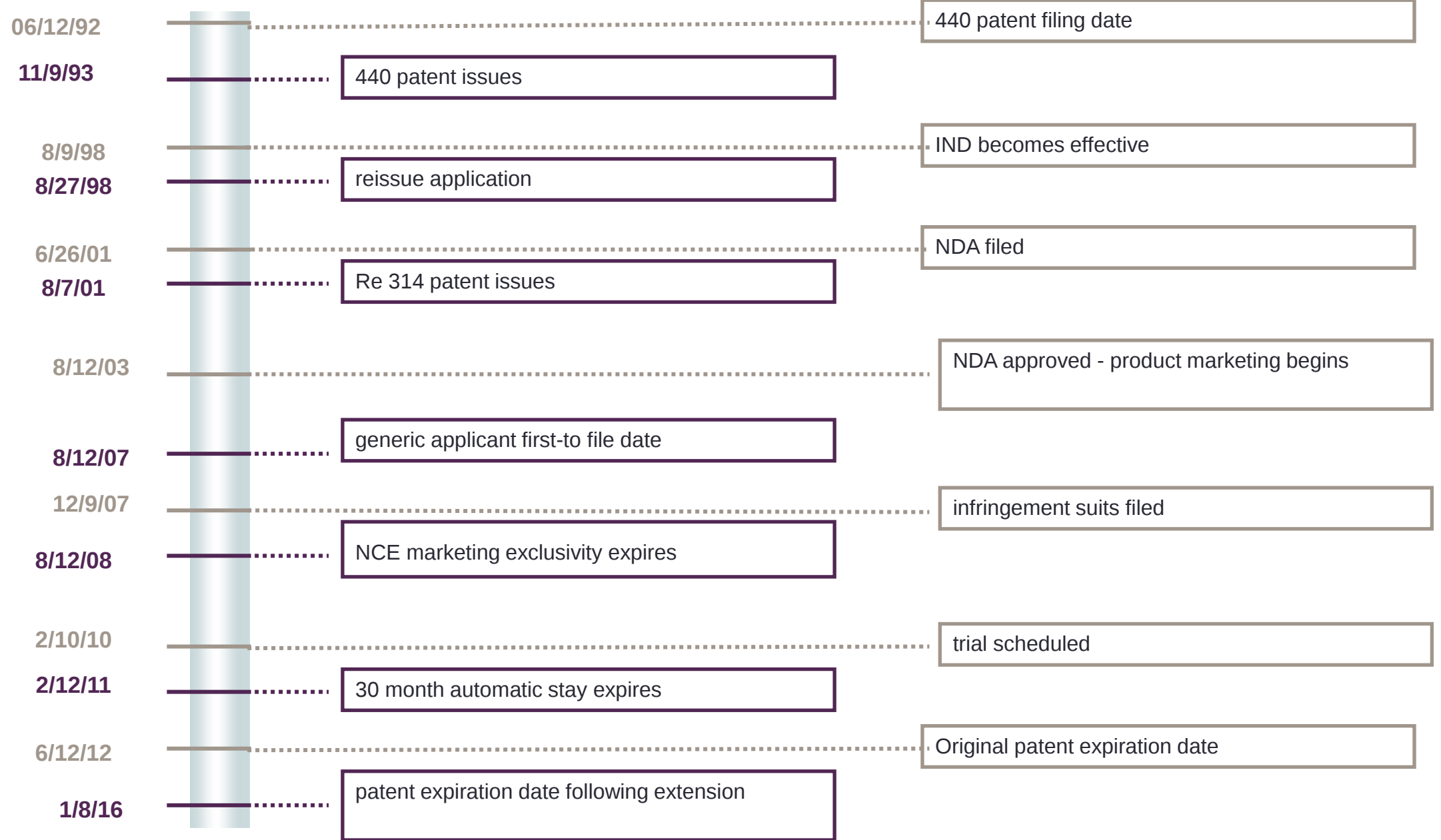
- Active ingredient of drug or biological product, medical device, food or colour additive subject to regulation under Fed. Food, Drug and Cosmetic Act.



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



Example timeline: rosuvastatin

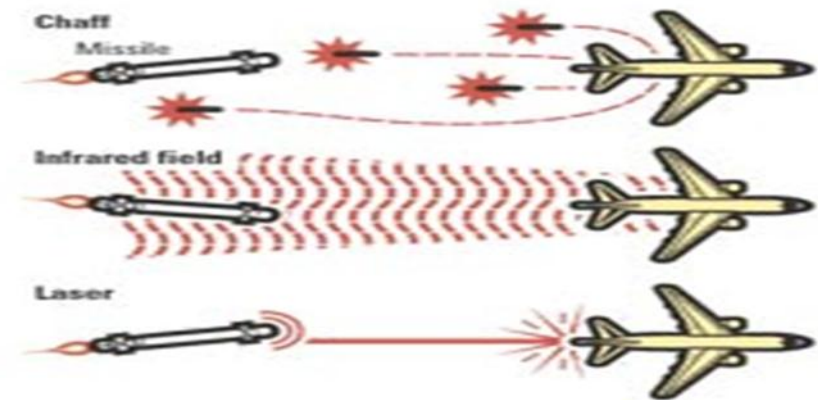


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§181 Secrecy

- 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.



Thank you

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