PATENT AND DATA PROTECTION: TRIPS STANDARDS AND U.S. IMPLEMENTATION

Office of IP Policy and Enforcement
US Patent and Trademark Office

OVERVIEW

- TRIPs Agreement
  - Patents – US Practice
  - Data Protection – US Practice

PATENTS

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Director of the United States Patent and Trademark Office

PATENTABLE SUBJECT MATTER

TRIPs Art. 27--Patentable Subject Matter

- Patents shall be available for any invention, whether products or processes, in all areas of technology provided that they are **new**, involve an **inventive step**, and are capable of **industrial application**.
- This general rule regarding eligibility is subject to specific exceptions set forth in the TRIPs Agreement.

PATENTABLE SUBJECT MATTER: UNITED STATES PRACTICE

Patentability

- **Novelty: In determining whether an invention is new and involves an inventive step, public disclosure by the applicant less than one year prior to filing is not a bar to patentability.**

- **Obviousness (Inventive Step): A four-part test was established in Graham v. John Deere Co. (1966)**
  - **The scope and content of the prior art**
  - **Differences between the prior art and the claims**
  - **Level of ordinary skill in the art**
  - **Secondary considerations**

- **Utility (Industrial Applicability): A claimed invention is industrially applicable if it has a specific, substantial, and credible utility.**

PATENTABLE SUBJECT MATTER: TRIPS Art. 27

Permissive Exclusions

1. Diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.
2. Plants and animals, other than micro-organisms, and essentially biological processes for the production of plants and animals other than nonbiological and microbiological processes.

PATENTABLE SUBJECT MATTER: U.S. PRACTICE

- Patentable subject matter includes:
  - Plants
  - Animals
  - Biotechnology
  - New methods of use
  - Diagnostic/therapeutic/surgical methods

DISCLOSURE REQUIREMENTS

TRIPs Art. 29--Disclosure Requirement

Patent applications must disclose the invention in a sufficiently clear and complete fashion.

U.S. Practice – Enablement and Written Description (35 U.S.C., 112, first para.)

- **The disclosure is sufficiently clear and complete if:**
  - **it provides information that allows the invention to be carried out by a person skilled in the art, without undue experimentation, as of the filing date.**
  - **The disclosure must provide adequate description of the invention to prove possession of the invention at the time application was filed.**

EXCEPTIONS TO PATENT RIGHTS: TRIPS Art. 30

Exceptions to Patent Rights

Permits exceptions provided that:

1. **such exceptions do not unreasonably conflict with normal exploitation of the patent and**
2. **do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.**

EXCEPTIONS TO PATENT RIGHTS: U.S. PRACTICE

"Bolar" Amendment (35 U.S.C. 271 (e)(1)):

- **Permits third parties to make and use patented technology solely for uses reasonably related to development and submission of information for marketing approval after patent expires.**
- **Provides generic drug manufacturers with the ability to enter the market immediately after patent expires!**

UNAUTHORIZED USE: TRIPS Art. 31

- The TRIPs Agreement sets forth conditions when nonvoluntary licenses (compulsory licenses) may be granted by a government.
- These conditions are safeguards to ensure that a patent owner's rights are not abrogated unjustifiably or unnecessarily.
- Members that grant compulsory licenses must comply with the terms and conditions specified in Article 31 of the TRIPs Agreement.

UNAUTHORIZED USE

Terms & Conditions in Article 31 of TRIPs

1. **Application must be considered individually.**
2. **Must demonstrate reasonable efforts to obtain authorization from the patentee on reasonable terms. [May be waived in cases of national emergency & nonpublic commercial use.]**
3. **Limited to authorized purposes.**
4. **Shall be nonexclusive & nonassignable.**
5. **Primarily for the supply of the domestic market.**
6. **Terminated if circumstances that led to issuance cease to exist and are unlikely to recur.**
7. **Requires adequate remuneration.**
8. **All decisions relating to the unauthorized use shall be reviewable.**

- What's new?

TERM OF PROTECTION: TRIPS Art. 33

Patent Term

- **Provides that the term of protection shall not end before the expiration of a period of 20 years counted from the filing date.**
- **Leaves open the possibility of patent term extensions in instances when circumstances warrant patent extension.**

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. 156

Patent No. :

Dated :

Inventor(s) :

Patent Owner :

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

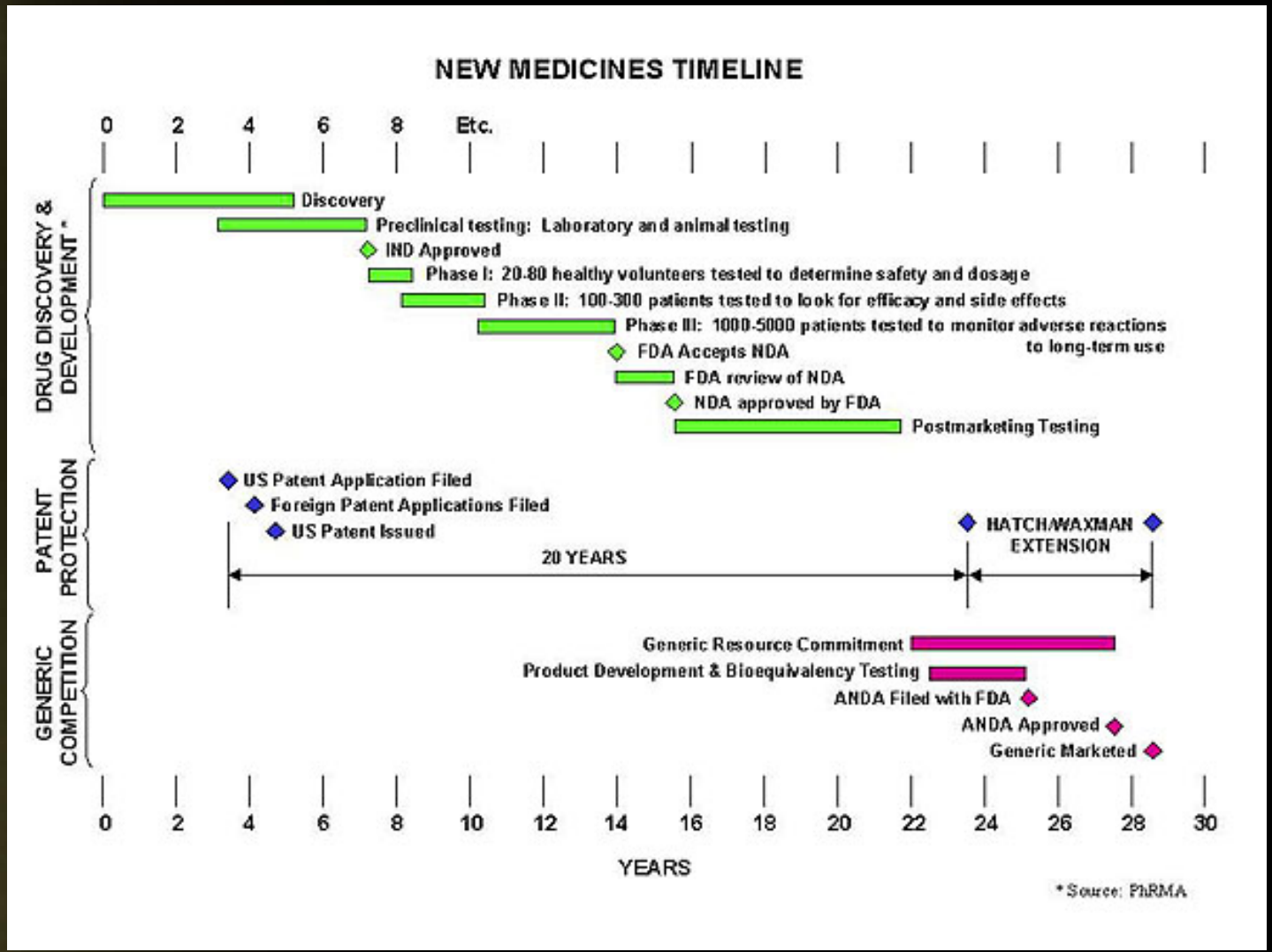
1,128 DAYS

with all rights pertaining thereto as provided by 35 U.S.C. 156 (b).

I have caused the seal of the Patent and Trademark Office to be affixed this 25th day of July, 1991.

Harry F. Manbeck, Jr.

Harry F. Manbeck, Jr.
Assistant Secretary and Commissioner
of Patents and Trademarks


NEW MEDICINES TIMELINE
0
2
4
6
8
Etc.
DRUG DISCOVERY & DEVELOPMENT *
Discovery
Preclinical testing: Laboratory and animal testing
IND Approved
Phase I: 20-80 healthy volunteers tested to determine safety and dosage
Phase II: 100-300 patients tested to look for efficacy and side effects
Phase III: 1000-5000 patients tested to monitor adverse reactions to long-term use
FDA Accepts NDA
FDA review of NDA
NDA approved by FDA
Postmarketing Testing
PATENT PROTECTION
US Patent Application Filed
Foreign Patent Applications Filed
US Patent Issued
20 YEARS
HATCH/WAXMAN EXTENSION
GENERIC COMPETITION
Generic Resource Commitment
Product Development & Bioequivalency Testing
ANDA Filed with FDA
ANDA Approved
Generic Marketed
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
YEARS
* Source: PhRMA

TERM OF PROTECTION: U.S. PRACTICE

Term Adjustments

- Adjust patent term to compensate for delays in granting a patent. Compensation granted when it takes more than three years from filing to obtain a patent due to office delays (35 U.S.C. 154).
- Compensate for unreasonable curtailment of patent term as a result of the marketing approval process related to the first permitted commercial marketing of a drug product (35 U.S.C. 156).

35 U.S.C. 156
Patent Term Extension (PTE) in the U.S.

- Provided for patent extension (restoration)
  - Recover half-a-day restoration for every day of investigational new drug testing
  - Recover day-for-day restoration while awaiting New Drug Application (NDA) FDA marketing approval
- Limitations on Term Extension
  - The total time restored is limited to no more than 5 years
  - The total market exclusivity time with extension cannot exceed 14 years from the approval date, regardless of how much time was lost to clinical testing and regulatory review
  - The marketing applicant must exercise due diligence in seeking approval of the NDA, or the period of lack of diligence is subtracted
- Maintained incentive for research-based companies to discover innovative medicines by recouping high cost of research and clinical trials

UNDISCLOSED INFORMATION

PROTECTION OF UNDISCLOSED INFORMATION

TRIPs- Article 39.3 (New Chemical Entities)

Members when requiring, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, the submission of undisclosed or other test data…shall protect such data against unfair commercial use…

PROTECTION OF UNDISCLOSED INFORMATION: U.S. DATA EXCLUSIVITY SYSTEM

New Chemical Entities- protection against reliance on innovator information:

- Pharmaceuticals - 5 years from approval
  - Drug that contains no active ingredient previously approved by FDA
  - FDA grants 5-years of data protection based on the active ingredient
  - Generally prohibits FDA from accepting a 505(b)(2) application or an Abbreviated New Drug Application (ANDA) for a drug product containing that active ingredient from 5-years of the date of approval of the first new drug application (NDA)

PROTECTION OF UNDISCLOSED INFORMATION: U.S. DATA EXCLUSIVITY SYSTEM

- **Products containing a chemical entity which has been previously approved -** protection against reliance on innovator information:
  - New Clinical Information (Pharmaceuticals) – 3 years from approval
    - Granted for certain changes in a drug product
    - Application or supplement must contain reports of new clinical (human) investigations essential to approval
    - Protection begins at the time of product approval and covers only the change in the product supported by the new clinical studies
    - FDA cannot approve a section 505(b)(2) application or an ANDA for the same product for 3-years.
    - FDA can accept and review application during this period

- Orphan Drug Exclusivity: 7 year protection on orphan drugs

- Pediatric Exclusivity: 6-month extension to protection innovator already has

PROTECTION OF UNDISCLOSED INFORMATION: U.S. PRACTICE

For pharmaceutical products, when another's safety and efficacy information or evidence of prior approval may be relied upon for marketing approval:

- Implementation of measures in the marketing approval process to prevent others from marketing a product covered by a patent claiming the product or its approved method of use during the term of the patent
- Patent owner notification if another requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product

U.S. Practice

- Consideration of Patents
  - New Drug Applications (NDAs) must include patent information and the FDA considers the existence of patents as part of the approval process for certain drugs.
  - If a patent exists, marketing approval will not be granted to a generic until the patent has expired, or is certified as invalid, not infringed, etc.

U.S. Practice

- How FDA becomes aware of patents
  - Requirement to list patents that cover the drug as part of NDA filing
  - Must submit signed declaration
  - FDA relies on innovator drug company's assertion
  - Patent information published in Orange Book

U.S. Practice

- Generic companies are aware of patents through the **Orange Book:**
  - Lists a wide variety of approved drug patents, as included in a New Drug Application
  - Opportunity for generic drug companies to inform FDA that a particular listed patent does not cover the FDA-approved drug product
  - FDA request evaluation of complaint by innovator company
  - Innovator company can request de-listing or respond with good-faith belief that listing is proper

U.S. Practice

- Generic Drug Company must certify when filing ANDA or 505(b)2 application

I) That patent information has not been filed;

II) That the patent has already expired;

III) The date on which the patent will expire, and the generic drug will not go on the market until that date passes; or

IV) That the patent is not infringed or is invalid

U.S. Practice

- Paragraph I, II, III certifications relatively straightforward
  - Existence of ANDA normally not known until approval date
- Paragraph IV certification more involved
  - ANDA applicant must notify manufacturer or patent owner of its filing; must describe reasons patent will not be infringed, is invalid, or unenforceable

U.S. Practice

- Paragraph IV certification
  - -30 month stay on FDA marketing approval for resolution of patent infringement action
  - -If patent is invalidated, approval is granted as of date of court decision
  - -If successful: 180-day generic drug exclusivity to first ANDA with a paragraph IV certification

Patent vs. Data Protection

Patent Protection and Undisclosed Information Protection are Separate IP Protections Under TRIPS and Protect Different Subject Matter

Patents

- Protect:
  - The pharmaceutical product; or
  - The method of making the pharmaceutical product; or
  - The method of using the pharmaceutical product

Data Protection

- Protects:
  - The test or other data generated by the innovator in clinical studies to prove safety and efficacy;
  - Does not provide protection for a competitor who produces their own phase I, II & III clinical data

THANK YOU!

QUESTIONS???