



# **EVOLVING STANDARDS: INTELLECTUAL PROPERTY RIGHTS IN PHARMACEUTICALS**

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A vertical line of five glowing yellow light bulbs is positioned on the left side of the slide. The bulbs are of varying heights and are connected to a thin vertical wire. The background is dark, making the glowing bulbs stand out.

# OVERVIEW

- **Patents**
  - **Unauthorized use- Compulsory Licenses**
- **Undisclosed Information**



# **HISTORICAL PERSPECTIVE: EVOLVING STANDARDS**

## **Why include Patents and Undisclosed Information in Newer Bilateral and Multilateral Trade and Investment Agreements?**

- **Over a decade since TRIPs Agreement**
- **Rise in global trading**
- **Increased reliance on IP protection**
- **Build on TRIPs standards and norms**
- **Keeping pace with technology**

A vertical string of five glowing light bulbs is positioned on the left side of the image. The bulbs are illuminated, casting a warm yellow glow. They are suspended by thin white cords. The background is solid black.

# PATENTS

A vertical column of five glowing yellow lightbulbs is positioned on the left side of the slide. The bulbs are of varying heights and are connected to a thin vertical wire. The background is dark, making the lightbulbs stand out.

# **PATENTABLE SUBJECT MATTER**

## **TRIPs--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: EVOLVING STANDARDS

- Minimize permissible exclusions from patentability
  - Plants
  - Animals
  - New uses
  - Diagnostic/therapeutic/surgical methods





US006365201B1

(12) **United States Patent**  
**Wambebe et al.**

(10) **Patent No.:** **US 6,365,201 B1**  
(45) **Date of Patent:** **Apr. 2, 2002**

(54) **PHYTODRUG FOR MANAGEMENT OF  
PEPTIC ULCER AND METHODS OF  
PREPARING AND USING SAME**

(75) **Inventors:** **Charles O. N. Wambebe; Shingu K. Gamaniel**, both of Abuja; **Peter Akah**, Nsukka; **Dogara S. Fumen**, Kaduna State; **Hafsatu Shittu**, Abuja, all of (NG)

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(\* ) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.:** **09/606,305**

(22) **Filed:** **Jun. 29, 2000**

**Related U.S. Application Data**

(60) Continuation of application No. 09/228,107, filed on Jan. 11, 1999, now Pat. No. 6,083,509, which is a division of application No. 08/906,937, filed on Aug. 6, 1997, now Pat. No. 6,086,882.

(51) **Int. Cl.**<sup>7</sup> ..... **A61K 35/78; A61K 9/48; A61K 9/20**

(52) **U.S. Cl.** ..... **424/774; 514/925; 514/926; 514/927; 424/465; 424/451**

(58) **Field of Search** ..... **424/195.1, 451, 424/464, 465, 774; 514/925, 926, 927**

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

5,124,360 A	6/1992	Larner et al.	514/738
5,130,133 A	7/1992	Rajagopalan et al.	
5,219,574 A	6/1993	Wehling et al.	424/464
5,277,910 A	1/1994	Hidvegi	
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Nyarko et al., *Phytotherapy Research*, vol. 7, pp. 1-4, 1993.  
Addy, et al. *Phytotherapy Research*, vol. 6, pp. 25-28, 1992.  
Addy, et al. *Phytotherapy Research*, vol. 2, pp. 192-195, 1988.

*Primary Examiner*—Christopher R. Tate

(74) *Attorney, Agent, or Firm*—Shook, Hardy & Bacon L.L.P.

(57) **ABSTRACT**

A phytochemical composition for management of peptic ulcer conditions in humans is provided. The composition is a hot water extract of powdered *Indigofera arrecta* plant leaves. The extract may be prepared by contacting the powdered leaves with hot water for a period of time, filtering the extraction mixture, concentrating the filtrate in vacuo and freeze drying the concentrated filtrate. The extract is admixed with magnesium carbonate, dried maize starch, talc and magnesium stearate to form a homogenous mass which is filled into capsules. The capsules are ingested orally to provide an analgesic effect. Also described are methods for making the extract and the methodology for using the extract.

**6 Claims, No Drawings**



# **DISCLOSURE REQUIREMENTS: EVOLVING STANDARDS**

## **TRIPs--Disclosure Requirement**

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

## **Newer Standard--Enabling Disclosure**

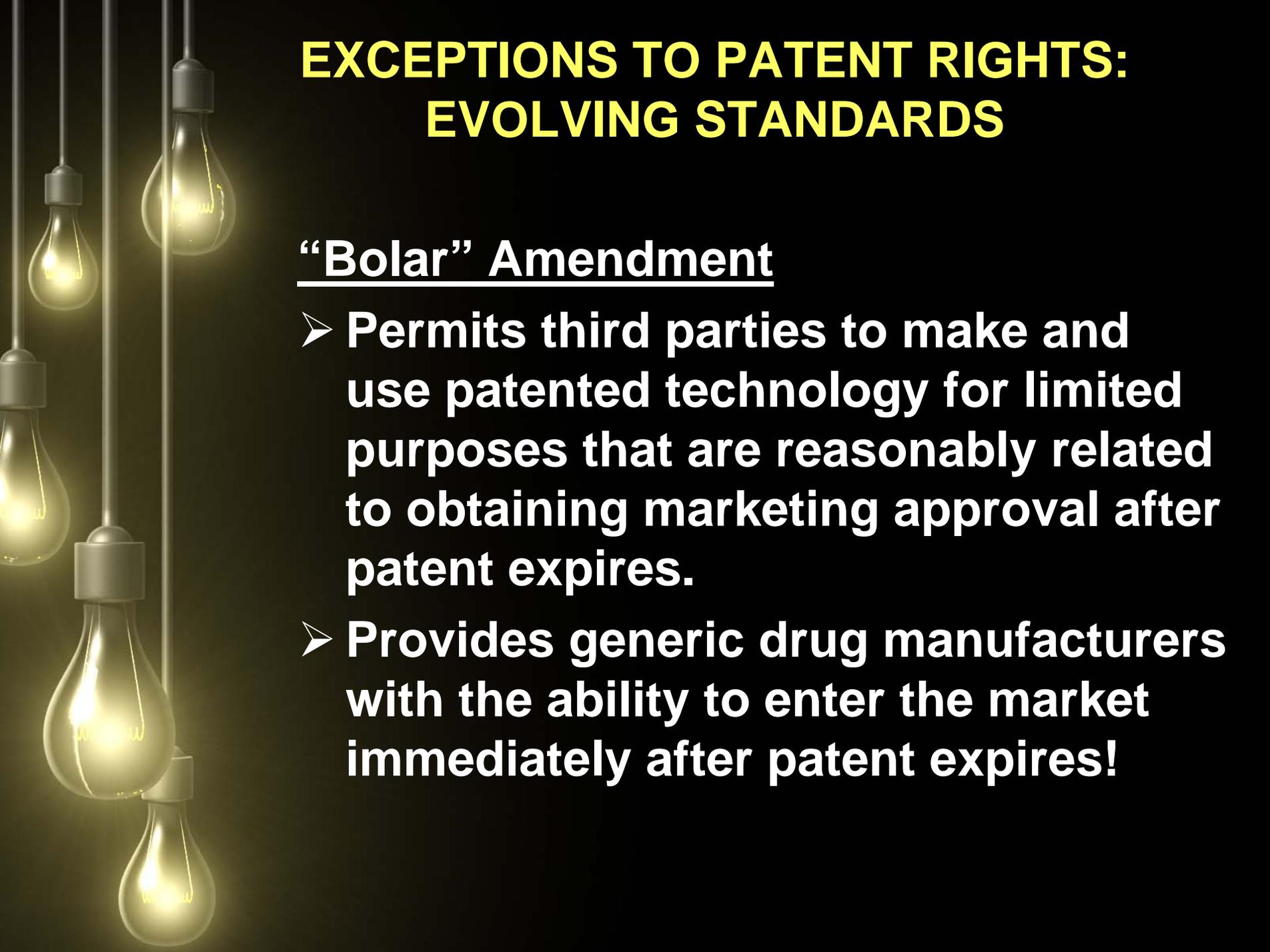
**The disclosure is sufficiently clear and complete if it provides information that allows the invention to be carried out by a person skilled in the art, without undue experimentation, as of the filing date.**

# EXCEPTIONS TO PATENT RIGHTS

## TRIPs--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.

A decorative background on the left side of the slide features several glowing yellow light bulbs hanging from thin black cords. The bulbs are arranged in a vertical line, with some slightly offset to the left or right, creating a modern, minimalist aesthetic. The background is a solid dark color, likely black or dark grey.

# **EXCEPTIONS TO PATENT RIGHTS: EVOLVING STANDARDS**

## **“Bolar” Amendment**

- **Permits third parties to make and use patented technology for limited purposes that are reasonably related to obtaining marketing approval after patent expires.**
- **Provides generic drug manufacturers with the ability to enter the market immediately after patent expires!**

# Introduction: Compulsory Licenses

- **What are they?**
- **What is the U.S. experience with compulsory licenses?**
- **What is § 1498?**

# What is a Compulsory License?

## Definition

- **Government-allowed use of a patented invention by a third party without the authorization of the right holder**



# UNAUTHORIZED USE

- The Paris Convention
  - Article 5(A): rights and obligations incorporated into TRIPs
    - Permissible to:
      - Prevent abuses which might result from the exercise of exclusive rights
        - » Failure to work (or insufficient working)  
-conditions

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# UNAUTHORIZED USE

- **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.**

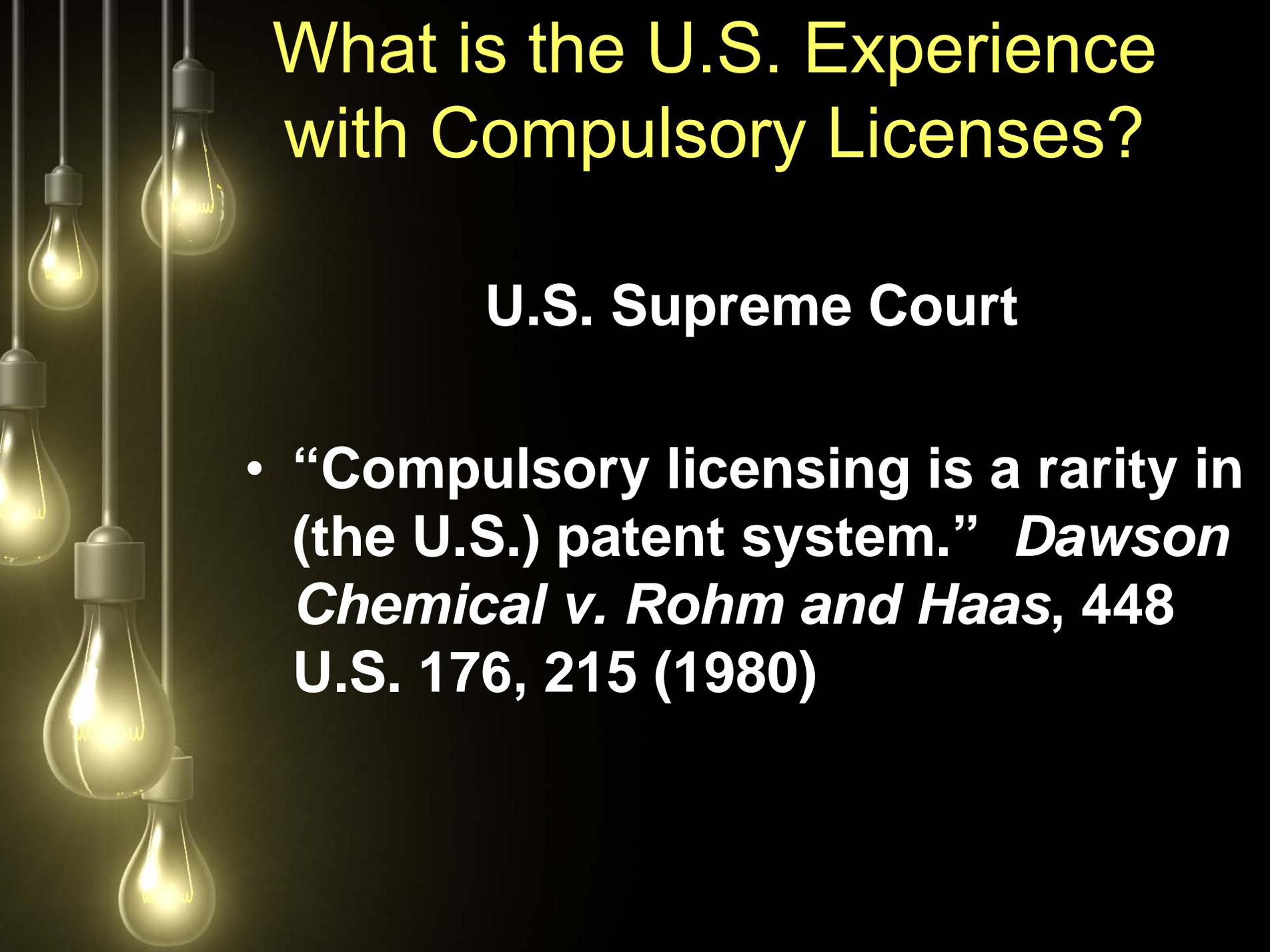
# UNAUTHORIZED USE

## 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.



# U.S. Experience with Compulsory Licensing

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# What is the U.S. Experience with Compulsory Licenses?

## U.S. Supreme Court

- **“Compulsory licensing is a rarity in (the U.S.) patent system.” *Dawson Chemical v. Rohm and Haas*, 448 U.S. 176, 215 (1980)**



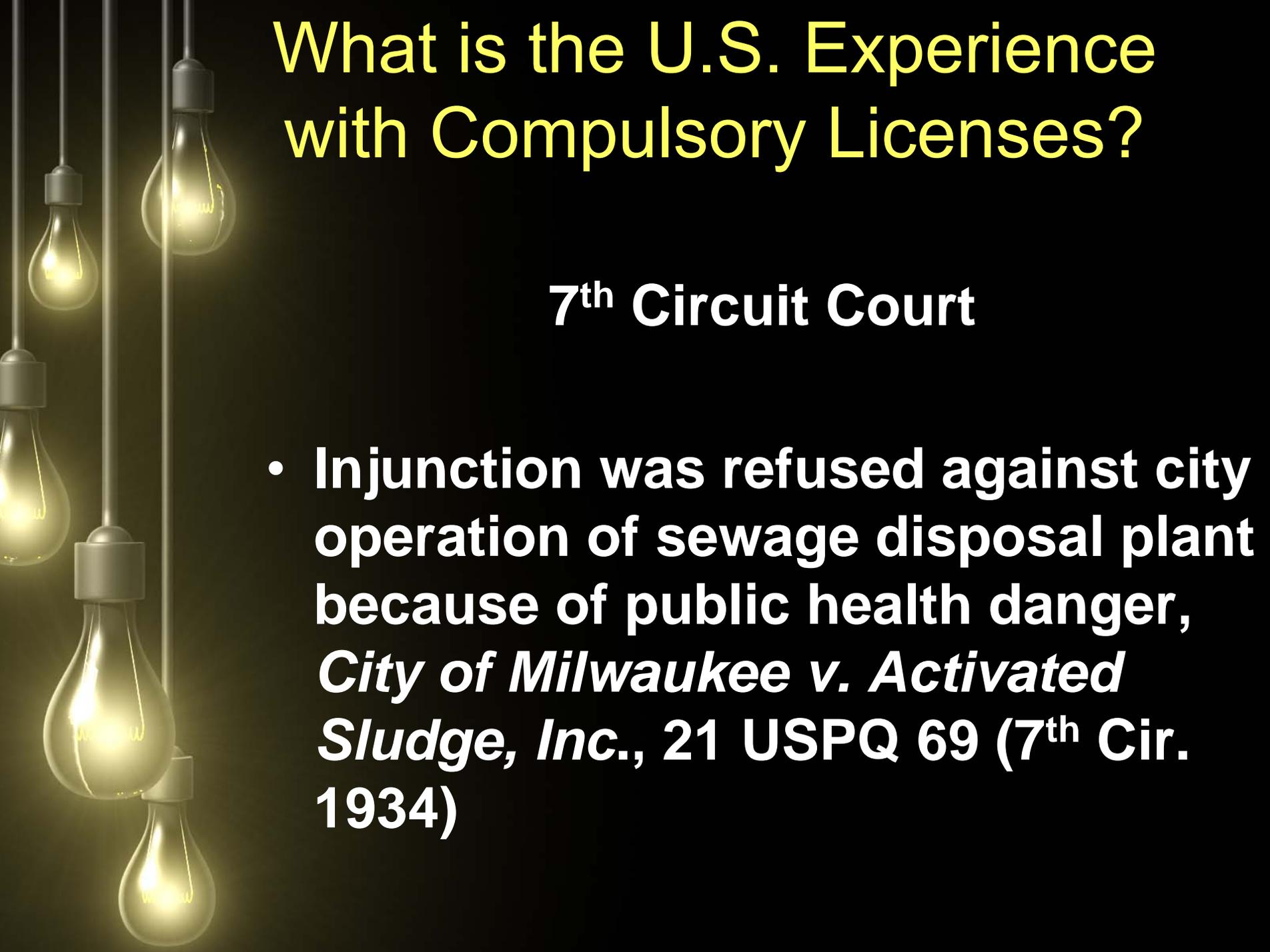
# What is the U.S. Experience with Compulsory Licenses?

**Compulsory licenses are provided for in the Clean Air Act and are sometimes used to remedy anticompetitive practices**

# What is the U.S. Experience with Compulsory Licenses?

## U.S. Supreme Court

- The general rule is that a patent owner may refuse to issue licenses or to make or sell the patented invention (*Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908))

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# What is the U.S. Experience with Compulsory Licenses?

## 7<sup>th</sup> Circuit Court

- Injunction was refused against city operation of sewage disposal plant because of public health danger, *City of Milwaukee v. Activated Sludge, Inc.*, 21 USPQ 69 (7<sup>th</sup> Cir. 1934)

# What is § 1498?

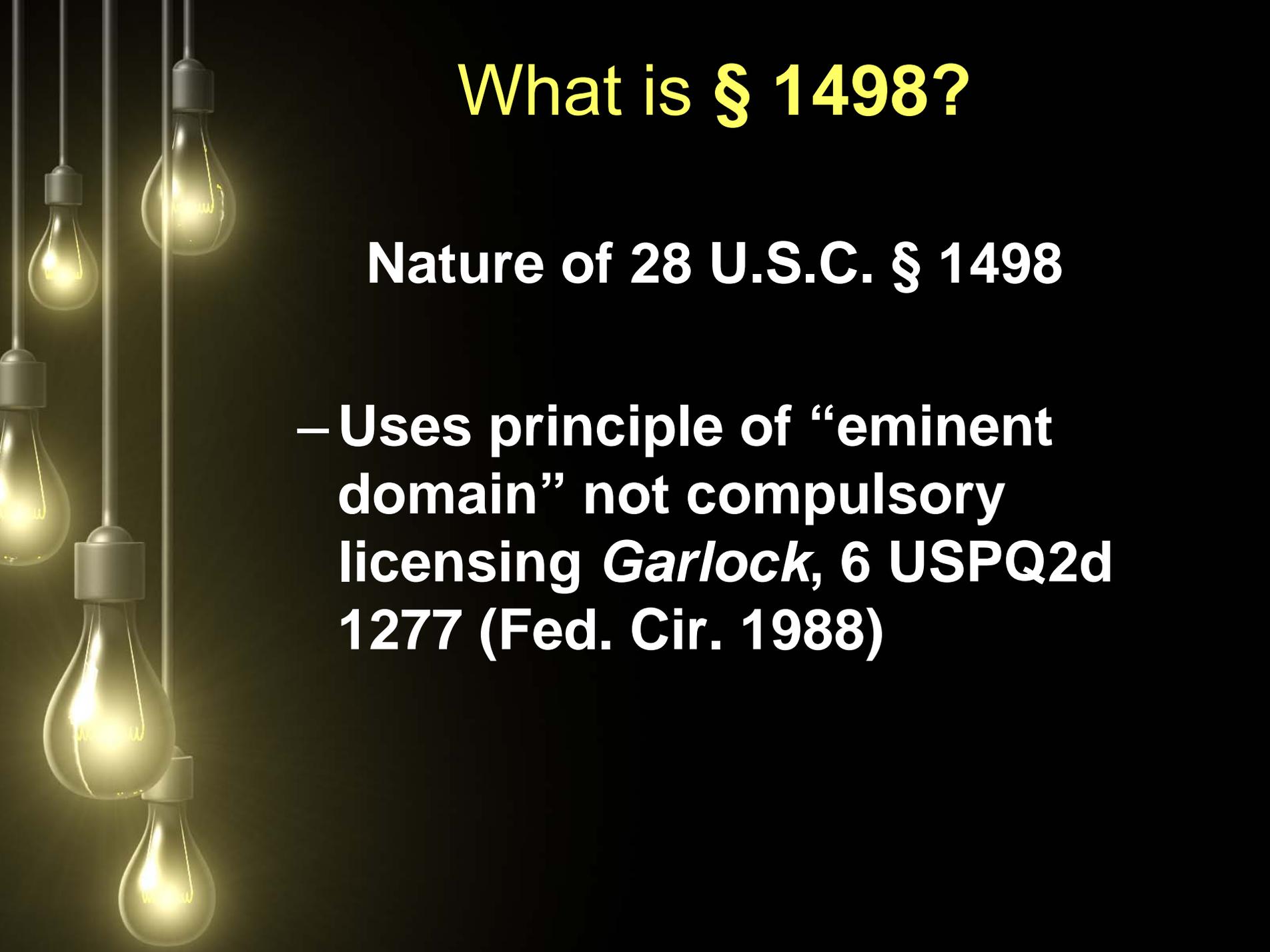
28 U.S.C. § 1498

- **Patent owner's exclusive remedy for "use or manufacture" by or for the United States without authority is a suit in the United States Court of Federal Claims for recovery of reasonable and entire compensation**

# What is § 1498?

## Purpose of 28 U.S.C. § 1498

- To allow government to procure products and services that it needs without injunction or delay
- Patent search would add cost and time
- Benefit to tax payers

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# What is § 1498?

## Nature of 28 U.S.C. § 1498

- Uses principle of “eminent domain” not compulsory licensing *Garlock*, 6 USPQ2d 1277 (Fed. Cir. 1988)

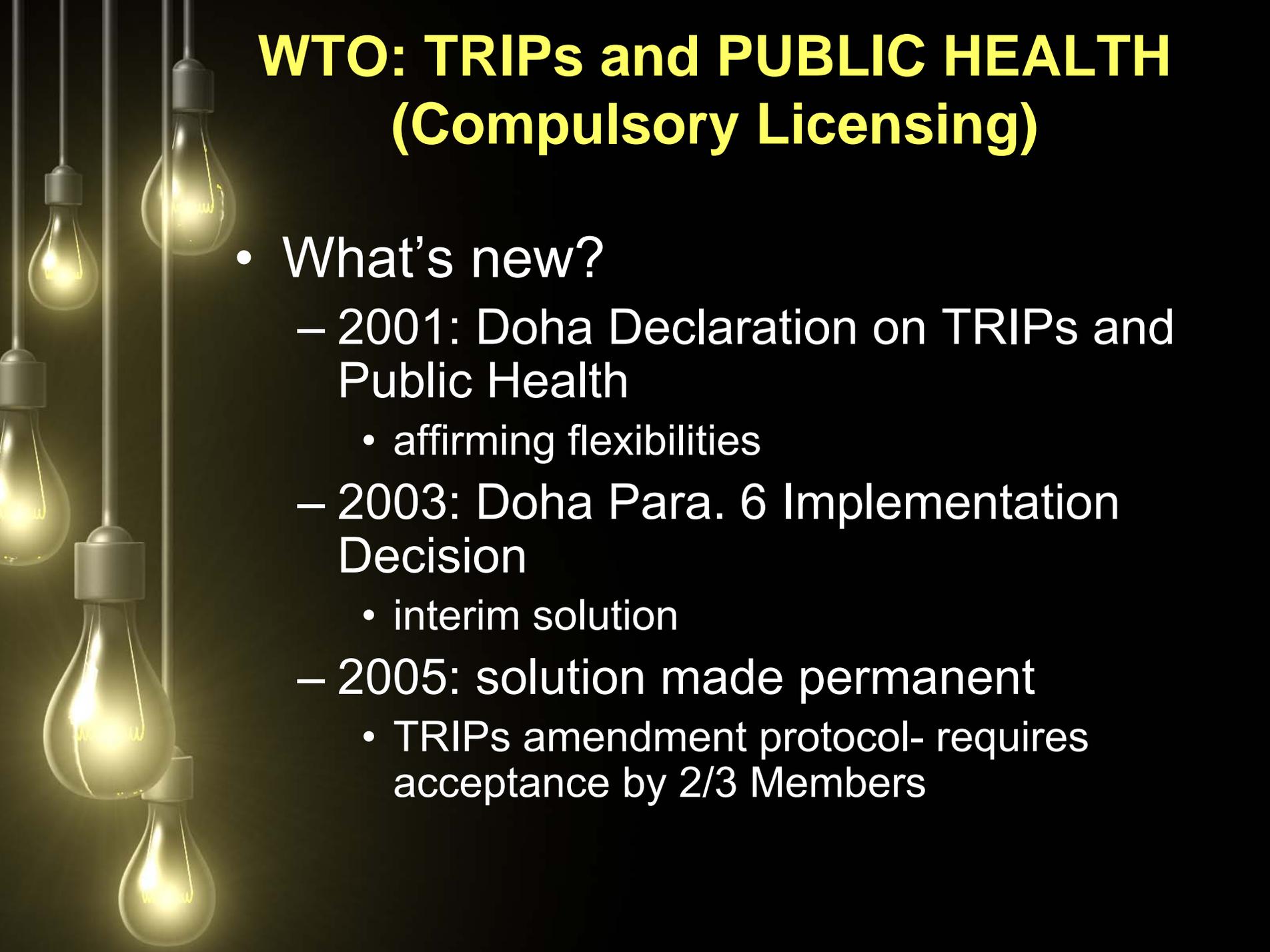
# What is § 1498?

## Differences between 28 U.S.C. § 1498 and Compulsory Licensing

- Unlike compulsory licensing under Article 31, which implies knowledge, § 1498 generally applies where there is no prior knowledge
- § 1498 provides for “reasonable and entire compensation” rather than the “adequate remuneration” of Article 31.

# **U.S. Experience with Compulsory Licenses: Conclusion**

- A compulsory license is government allowed use of a patented invention by a third party without the authorization of the right holder**
- The United States seldom grants compulsory licenses**
- § 1498 is a retroactive compensation provision, rather than a compulsory license**

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# WTO: TRIPs and PUBLIC HEALTH (Compulsory Licensing)

- What's new?
  - 2001: Doha Declaration on TRIPs and Public Health
    - affirming flexibilities
  - 2003: Doha Para. 6 Implementation Decision
    - interim solution
  - 2005: solution made permanent
    - TRIPs amendment protocol- requires acceptance by 2/3 Members

# TRIPs and PUBLIC HEALTH (Compulsory Licensing)

- The Solution
  - Article 31(f) Waiver
    - Purpose: protection of public health
    - Art 31(f) provides that any compulsory licenses granted by a Member must be predominantly for the supply of its domestic market
      - Article 31(h)- adequate remuneration
      - Notifications and responsibilities- eligible importing members & exporting members

# TERM OF PATENT PROTECTION

## TRIPs--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.

# TERM OF PATENT PROTECTION: EVOLVING STANDARDS

## Term Adjustments

- Adjust patent term to compensate for delays in granting a patent. At minimum, must compensate when it takes more than four years after filing to obtain patent.
- Compensate for unreasonable curtailment of patent term as a result of marketing approval delays related to the first approval of a new drug product.

A vertical string of five glowing light bulbs is positioned on the left side of the image. The bulbs are illuminated, casting a warm yellow glow. The background is solid black. The text 'UNDISCLOSED INFORMATION' is centered in the middle of the image.

# 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: EVOLVING STANDARDS

## New Chemical Entities-

information and evidence of  
approval protected

- Pharmaceuticals- 5 years
- Agricultural chemicals- 10 years





# PROTECTION OF UNDISCLOSED INFORMATION: EVOLVING STANDARDS

Products containing a chemical entity which has been previously approved- information and evidence of approval protected:

## New Clinical Information

- Pharmaceuticals- 3 years

## New uses

- Agricultural chemicals

# PROTECTION OF UNDISCLOSED INFORMATION: EVOLVING STANDARDS

Independence of patent and data  
protections (undisclosed  
information)



# PROTECTION OF UNDISCLOSED INFORMATION: EVOLVING STANDARDS

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

# THE END

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**QUESTIONS???**

