
History of Compulsory Licensing Statutes and Legislation in the United States

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Types of U.S. Compulsory Licenses

- Government use
- Federally-funded research and development
- Industry specific
- War & national security
- Anti-trust
- *eBay*

Reasons & Contexts for Compulsory Licensing Proposals

- Non-use of patents and competition (early 1900s)
 - Following 1883 Paris Convention for the Protection of Industrial Property, Sherman Antitrust Act, and industrialization
- National security and defense (World Wars)
- Government-funded research & development
- Drug prices

Paris Convention for the Protection of Industrial Property Article 5.A.

(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

Paris Convention for the Protection of Industrial Property Article 5.A.

4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

(5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.

Government Use

28 U.S.C. § 1498(a)

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

...

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Government Use

Schillinger v. U.S., 155 U.S. 163 (1894).

“The United States cannot be used in their courts without their consent, and in granting such consent congress has an absolute discretion to specify the cases and contingencies in which the liability of the government is submitted to the courts for judicial determination. ... Under neither of these statutes [establishing the jurisdiction of the federal Court of Claims] had or has the court of claims any jurisdiction of claims against the government for mere torts. Some element of contractual liability must lie at the foundation of every action.”

Government Use

Russell v. U.S., 182 U.S. 516 (1901)

“[I]t is the prerogative of a sovereign not to be sued at all without its consent or upon such causes of action as it chooses. It has not chosen to be sued in an action sounding in tort.”

Government Use

- 1910: Congress passes legislation. Pub. L. 61-305, 36 Stat. 851-2 (1910).
 - Allows for infringement suit against U.S. government for recovery of reasonable compensation.
- *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28 (1918).
 - Supreme Court rules that government contractor can be sued for infringement, not covered by 1910 legislation.

Government Use

- FDR writes to Congress about *William Cramp* case:
 - “[M]anufacturers are exposed to expensive litigation, involving the possibilities of prohibitive injunction payment of royalties, rendering of accounts, and payment of punitive damages, and they are reluctant to take contracts that may bring such severe consequences. The situation promised serious disadvantage to the public interests, and in order that vital activities of this department may not be restricted unduly at this time, ... I have the honor to request that the act be amended by the insertion of a proper provision therefore in the pending naval appropriation bill.”
- 1918: Congress amends law to cover infringement by contractors. Pub. L. 65-132, 40 Stat. 704, 705 (1918).

Other Government Use Provisions

- USAID
- Tennessee Valley Authority
- Research and development

1912 Oldfield Hearings

- Omnibus patent law legislation by the Wilson administration (Patent Commissioner Edward B. Moore) proposed a remedy for the “suppression” or “withholding” of patents.
- Hearings April to May of 1912, led by Rep. William Allan Oldfield’s (D-Okla.) House Committee on Patents.
- Bill addressed various issues: independence of Patent Office, patent exhaustion, and the patent bar.

1912 Oldfield Hearings

- Allows any person to request a license from the patent holder if the patent has not been adequately used after four years from the start of the patent term.
- Any person “demanding it shall be entitled to a license from the owner of the patent, ... unless the owner shall show sufficient cause for such inaction.”
- Allows for appeal to District Court if the patent holder denies a license request.

1912 Oldfield Hearings

- Requires the court to grant a license “if the court is satisfied that the reasonable requirements of the public in reference to the invention have not been satisfied by reason of the neglect or the refusal of the patentee, his legal representatives, or those authorized” by the patentee to “make, use, or vend the invention, or to grant licenses to others on reasonable terms to make, use, or vend the same.”
- Requires the patentee to set terms that the court deems “just.”
- Provides exception for foreign patent holders.

1912 Oldfield Hearings

- Most of the hearings focused on the compulsory licensing provision.
- Debate over the proper remedy to non-use of patents.
 - Compulsory license provision or revocation of patents.
- Some witnesses proposed alternative compulsory licensing provisions.

1912 Oldfield Hearings

“Nearly all countries except the United States have provisions of law requiring the working of a patented invention, and in the event of failure to adequately work the invention that the patent shall either be revoked or that the owner thereof shall be required to grant a license to others to manufacture, use, and sell the same. ... In the amendment which I have prepared to this section it is provided that if the patented invention is not worked to an adequate extent after the expiration of the first four years any person may demand a license to manufacture and sell the same, and upon refusal of the patentee to grant such license shall have the right to apply to the court of the district in which the owner of the patent resides or has an established place of business and to demand an order from the judge requiring that the owner of the patent shall grant to him a license to manufacture, use, and sell the invention upon such terms, conditions, security, etc., as in the opinion of the court will be just. It is believed that such a measure will have the effect of placing all valuable inventions in public use within a reasonable time, and will also encourage the establishment in the United States of manufactories for the production of patented machines devices, etc., which have been patented by persons who are not citizens of the United States.”

1912 Oldfield Hearings

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1912 Oldfield Hearings

- Rep. Oldfield presented amended bill after the hearing, providing that licensee must prove that the patent holder has “withheld or suppressed” the invention “for the purpose or with the result of preventing any other person” from practicing the invention.
- From 1912 to 1915, other members of the House proposed alternative mechanisms to address non-use or suppression of patents.

1912 Oldfield Hearings

Francis Burston Harrison (D-N.Y.) 1912 eminent domain bill:

Allows for the taking of a “subordinate property in the grant, right, and property covered by every patent ... for public use, by exploitation, through proceedings in equity” in District Court, by the U.S. government, “the owner of a basic patent covering a correlated invention or discovery, or by the owner of a patent covering an improvement thereon.”

Also proposed a version that instead requires cross-licensing.

1922 Committee on Patents Hearings

- Proposed by U.S. Department of War.
- Provides that any patent issued to any person under the act shall contain a proviso to the effect that if the patent is not worked or put in operation so as to result in actual production in the United States of the article embodied in such patent in reasonable quantities within a reasonable time from the date of its issue — no less than two years nor more than five years — the United States reserves the right to license the patent to any person to manufacture, use, and sell the subject matter.
- Requires the payment of a reasonable royalty, to be fixed on an equitable basis according to the circumstances in each case, of not less than 0.5% and not more than 10% of the cost of manufacture of each article. Requires the royalties to be deposited into a special fund in the Treasury, to be paid to the patentee or other specified party.

1922 Committee on Patents Hearings

- U.S. Department of War feared that foreign-controlled patents would hinder U.S. industry before next war.
 - Before World War I, Germans controlled coal tar, optical glass, wireless telegraphy, and magneto patents.
 - After War, Germans obtained patents “embodying the subject matter of practically our whole system of railroad artillery which we had developed during the war.”

1922 Committee on Patents Hearings

- During the War, Congress had temporarily remedied the situation through the Trading with the Enemies Act in 1917.
 - Congress seized all enemy patents and issued compulsory licenses on them to U.S. industry.
 - Patents were returned, with royalties, after the war.
- After the war, Congress contemplated this new solution.

1922 Committee on Patents Hearings

- U.S. Army justified the bill in terms of national defense and build-up of essential U.S. industries.
- The Army took an expansive view of an essential industry – including everything from car manufacturing to the making of dyes for clothing.
- Large industry groups – including National Association of Manufacturers and American Institute of Chemical Engineers – opposed the bill.

1938 Subcommittee on Compulsory License Hearings

- Rep. W. D. McFarlane (D-Texas) and Rep. William P. Connery (D-Mass.) introduced legislation.
- Followed hearings on use of cross-licensing and patent pools to limit competition in industries.
- McFarlane legislation similar to earlier non-use of patents legislation.
- Connery legislation required compulsory licenses on patent pools that create a restraint on trade.

1938 Subcommittee on Compulsory License Hearings

McFarlane bill:

Allows any qualified application to request that the Commissioner of Patents grant a compulsory license on a patent, after at least three years from the grant of the patent, with proof that the patent has not been used for at least one year prior to the date of application, that the public interest will be served by the compulsory license, and with the proposal of specific terms and conditions for the license.

1938 Subcommittee on Compulsory License Hearings

Connery bill:

Allows any person to file a suit in district court for a nontransferable license under reasonable terms and conditions in cases where two or more persons have each brought one or more of their own patents “within a single control whereby industry and trade are dominated and interstate commerce is substantially restrained to the detriment of the public.”

1938 Subcommittee on Compulsory License Hearings

- Opposition from small manufacturers and patent attorneys, on the grounds that large corporations would use the compulsory licensing mechanism to force them to grant licenses.

Post-World War II

- Atomic Energy Act
 - “If atomic energy is important enough to justify complete governmental control, no aspect of its use should be determined by private monopoly.” - Harold D. Smith, Director of Bureau of Budget
- Marshall Plan & USAID
 - Special government use provisions for rebuilding the European economy and security.
 - USAID has a carve-out preventing government use of patented pharmaceuticals.

Clean Air Act

- 1970 Clean Air Act amendments
 - Special compulsory licensing scheme for compliance with requirements of Clean Air Act.
 - Passed with no discussion.
- 2000 Kucinich amendments and Unocal patent dispute.
 - Proposed adding clean gas technologies to the existing regime.
 - Followed dispute between Unocal and top U.S. oil corporations

Government Funded R&D: Standard Provision

No research [or other projects, etc.] shall be [carried out, contracted for, sponsored, co-sponsored, or authorized, etc.] unless all [information, uses, products, processes, patents, and other developments, etc.], with exceptions and limitations, if any, to be determined by the relevant authority, be available to the general public.

Government-Funded R&D: Standard Provision

- Helium Act Amendments of 1960
- Coal Research and Development Act of 1960
- Arms Control and Disarmament Act of 1961
- Saline Water Conservation Program (1971)
- Black Lung Benefits Act of 1972
- Consumer Product Safety Act of 1972
- Surface Mining and Reclamation Act of 1977
- Federal Mine Safety and Health Act of 1977

Government-Funded R&D: National Science Foundation

- Founded in 1950 to coordinate federal R&D efforts.
- Debate in Congress over patent issues.
- Contracts or “other arrangement[s] ... shall contain provisions governing the disposition of inventions produced thereunder in a manner calculated to protect the public interest and the equities of the individual or organization with which the contract or other arrangement is executed.”

Bayh-Dole Act (35 U.S.C. § 203)

- March-in Rights allow for government to issue compulsory licenses in four cases:
 1. action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
 2. action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
 3. action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
 4. action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.
- Practical application requires the subject invention to be “available to the public on reasonable terms.” 35 U.S.C. § 201(f).

Bayh-Dole Act

- Kennedy 1963 Government Patent Policy:

Where the principal or exclusive (except as against the government) rights to an invention are acquired by the contractor, the government shall have the right to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract.

- Nixon 1971 patent policy requires that inventions be “reasonably accessible to the public.”

Kefauver Drug-Industry Antitrust Hearings

- Sen. Estes Kefauver (D-Tenn.) wanted to reform the pharmaceutical industry, including high drug prices.
- Started hearings in 1959 on a range of issues.
- Proposed legislation in 1961 with a compulsory licensing provision.
 - Also contained additional antitrust provisions that would have declared certain industry practices to be in restraint of trade (e.g., favorable licensing terms and payments to withdraw patent applications).

Kefauver Drug-Industry Antitrust Hearings

- Limits the period of exclusivity for a patented drug to a period of three years, with an additional 14 year period during which the patent holder shall “[grant] to each qualified applicant an unrestricted license to make, use, and sell that drug.”
- Requires the patent holder to report refusal of such a license within 90 days to the Commissioner of Patents. Also allows the Commissioner to make a determination of the non-grant of a license “on his own motion” or to make such a determination based upon a complaint of any person. Requires the Commissioner to cancel the patent upon refusal of a grant of a license.

Kefauver Drug-Industry Antitrust Hearings

“One fundamental fact disclosed by our drug hearings, at least in my opinion, is that by any test and under any standard, prices and profits in the ethical drug industry are excessive and unreasonable. The problem is all the more serious because it concerns the health and happiness of every citizen in our country. Our hearings have made it patently clear that Congress must pass new legislation to meet this problem. There are two alternatives: Federal Government price control of ethical drugs or legislation providing for freer competition in this field. We have chosen to retain and preserve our private enterprise system in this vital industry, and thus our bill is designed to stimulate price competition among more sellers and dissipate presently existing monopolistic controls, so that prices may seek competitive levels as a result of normal economic forces.”

Kefauver Drug-Industry Antitrust Hearings

- Opposition from Pharmaceutical Manufacturers Association and Kennedy Administration.
- Kefauver-Harris amendments to the Food & Drug Act passed without antitrust provisions.
- Kefauver reintroduced compulsory licensing provisions, with modifications.

Kefauver Compulsory Licensing Bill Version 2.0

- Allows any qualified applicant to request a license on a patented drug for which the patents have been issued at least three years prior to the date of the application for license and when the price of the drug is 500-percent the cost of production.
- Allows the applicant to request the Federal Trade Commission to grant a compulsory license if the patent holder declines

Gaylord Nelson Hearings, 1970s

- Sen. Gaylord Nelson, D-Wisc., proposed a compulsory licensing bill in his attempt to reform the pharmaceutical industry.
- Follows expansion of compulsory licensing provision in Canada in 1969.
- Public Health Price Protection Act contained a complex compulsory licensing scheme involving the rulemaking process at the FTC.

Gaylord Nelson Hearings, 1970s

- Requires the Surgeon General or the Federal Trade Commission to issue a certification or initiate a public rulemaking procedure, respectively, if there is evidence that a drug has a high price and other criteria are met.

Gaylord Nelson Hearings, 1970s

- Surgeon General (later changed to Secretary of Health, Education & Welfare) certification criteria:
 1. (a) continued availability of a drug would be in the public interest, or (b) a drug is the drug of choice for particular clinical uses;
 2. the drug has a “substantial market;” and
 3. there are either (a) fewer than four producers in the United States or (b) the average price of the drug is higher than five times the cost of manufacture or higher than the average price of any foreign country.

Gaylord Nelson Hearings, 1970s

- Federal Trade Commission rulemaking procedure trigger:
 1. (a) the average price of the drug is either higher than five times the cost of manufacture or higher than the average price of any foreign country; (b) annual sales exceeded \$1 million for three or more years; and (c) the existence of a patent contributed to the high price of the drug;
 2. mandatory licensing of a drug on reasonable terms and conditions would contribute to lower prices; and
 3. a mandatory license would be in the public interest.
- FTC may rely upon the HEW certification instead.

Gaylord Nelson Hearings, 1970s

- Federal Trade Commission Rulemaking Procedure:
 1. Issue a rule stating that the opportunity for a mandatory license on the patents would be in the public interest.
 2. Issue a rule declaring the reasonable terms and conditions on the mandatory license, including a reasonable royalty rate.
 - a. The FTC would have been allowed to issue an interim rule if the public interest would be served by an immediate mandatory license.
 - b. Requires FTC to account for price and R&D investment.
 - c. Allows the FTC to require firms to share technical know-how as a condition for collecting remuneration.

Gaylord Nelson Hearings, 1970s

- Support came from Public Citizen and Ralph Nader.
- Opposition from PMA and other industry groups.

Rep. Jerrold Nadler & RU-486, 1994

Allows the Secretary of Health and Human Services to determine, after notice and an opportunity for an agency hearing, that (1) the owner of a patent claiming a product “has not taken all reasonable steps towards the commercial marketing or use of that product, if the product is not already so marketed or used, and (2) the availability of the product to the public is of vital importance to the public health or welfare.”

Requires the Secretary to notify the Commissioner of Patents of any determination and the Commissioner to provide for compulsory licenses.

Rep. Sherrod Brown Bills, 90s to 2000s

- 1999: Affordable Prescription Drugs Act
 - “This legislation is not designed to produce artificially low prescription drug prices, which could jeopardize the pipeline of new prescription drugs. This legislation is designed to correct unjustifiably high prices that (1) inflate private and public health care spending; and (2) undercut access for seniors.”
- 2001: Affordable Prescription Drugs and Medical Inventions Act
- 2001: Public Health Emergency Medicines Act
 - Post-9/11 and Anthrax scares.

Rep. Sherrod Brown Affordable Prescription Drug Act

Allows the Secretary of Health and Human Services to issue compulsory licenses on medicines if:

“(1) the patent holder, contractor, licensee, or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in a field of use;

“(2) such compulsory license is necessary to alleviate health or safety needs which are not adequately satisfied by the patent holder, contractor, licensee, or assignee; or

“(3) the patented material is priced higher than may be reasonably expected based on criteria developed by the Secretary of Commerce.”

Rep. Sherrod Brown Affordable Prescription Drug Act

The licensee must have sought a license prior to petitioning the Secretary (subject to waivers in the case of a national emergency, extreme urgency, or public non-commercial use), except in cases where the license is a remedy to anticompetitive practices.

Allows for termination of the license if and when the circumstances that led to the license cease to exist and are unlikely to recur.

Rep. Sherrod Brown Public Health Emergency Medicines Act

Allows the Secretary of Health and Human Services to authorize the use of a patented invention relating to health care without permission of the patent holder if the Secretary determines that the invention is needed to address a public health emergency.

Rep. Sherrod Brown Public Health Emergency Medicines Act

Remuneration standards:

“(1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;

“(2) evidence of the efficacy and innovative nature and importance to the public health of the invention or products using the invention;

“(3) the degree to which the invention benefited from publicly funded research;

“(4) the need for adequate incentives for the creation and commercialization of new inventions;

Rep. Sherrod Brown Public Health Emergency Medicines Act

“(5) the interests of the public as patients and payers for health care services;

“(6) the public health benefits of expanded access to the invention;

“(7) the benefits of making the invention available to working families and retired persons;

“(8) the need to correct anti-competitive practices; or

“(9) other public interest considerations.”

Sen. Bernie Sanders & Veterans Affairs, 2015

- Gilead launches Sovaldi (sofosbuvir) in 2013.
- VA blows its budget for the drug in 2015, and asks Congress to tap into \$400 million from another fund.
- Sanders asks VA to use section 1498, but the VA declines, citing issues with remuneration.
- Sanders offered an alternative to account for the budget constraints of the VA.

Sen. Bernie Sanders & Veterans Affairs, 2015

Allows the Secretary of Veterans Affairs to limit compensation for a patented medical technology to a reasonable royalty when the price is excessive or presents a barrier to care.

Defines the price of a medical technology as excessive or presenting a barrier to care, in cases where the Secretary so determines, and in cases where:

(1) the price of the technology is the primary factor prohibiting the Secretary from being able to provide access to the technology to all veterans for whom the technology is considered clinically appropriate; and

(2) there is no comparable and equally efficacious technology available to the Department at a reasonable and affordable price.

Sen. Bernie Sanders & Veterans Affairs, 2015

Requires the Secretary to set a reasonable and affordable royalty as entire compensation for the patented technology, considering the following:

“(1) The impact of paying the royalty on the budget of the Department for providing hospital care and medical services to veterans under chapter 17 of this title.

“(2) The extent to which the owner of the patented invention has recovered or is expected to recover, through sales other than under this section, the research and development costs incurred by such owner.

“(3) Such other factors as the Secretary considers appropriate, including the impact of the patented invention on improving health outcomes for individuals.”

Questions & Comments

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