28 U.S.C. 1498 Is Not a Price Control Provision

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Why Section 1498 is of interest now

- > New York Times articles
- > Brennan et al., A Prescription for Excessive Drug Pricing ..., 18 Yale J. L. & Tech. 275 (2016)
- > Narrative: 1498 an "obscure" provision that gives fed govt compulsory license for patented goods and is currently underused
- > Appears to be a newer focus for weakening patents to control drug prices after attempts to use Bayh-Dole March-In Rights were unsuccessful

Roots of Section 1498: "Crown Rights" and Sovereign Immunity

- From beginning of U.S. patent system, Congress and courts rejected British "Crown Rights" approach to gov't use of patented inventions
 - U.S. govt stands as any other legal person with regard to unauthorized use of patented inventions
- However, rejection of Crown Rights did not eliminate sovereign immunity issue
 - Court of Claims rejected notion that "petty officer" of fed govt could authorize or commit govt to tortious act and no taking or property because act was mere use. *Pitcher v. U.S.*, 1 Ct. Cl. 7 (1863)

Roots of Section 1498: "Crown Rights" and Sovereign Immunity

- By end of nineteenth century, courts resorted to legal fictions such as implied or direct liability of govt agents to compensate patentees even as injunctive relief was introduced
- The confusion soon extended to gov't contractors and the legal fiction approaches were overturned in *Schillinger v. U.S.*, 155 U.S. 163 (1894)
- Patentees were once again left without remedy against gov't infringement

Predecessor Statutes

- "An Act to Provide Additional Protection for Owners of Patents of the United States, and for Other Purposes" Act of June 25, 1910:
 - Intended to benefit *patentees*, neither an eminent domain nor govt use statute;
 - meant to solve sovereign immunity and jurisdiction issues for patentees
 - Expands jurisdiction of Court of Claims
- > Amended by Naval Appropriations Act of 1918 to expressly cover contractors (upheld in *Richmond Screw Anchor v. U.S.*, 275 U.S. 331 (1928))

Predecessor Statutes

- Final amendments in 1942 Royalty Adjustment Act
- May be roots of the (incorrect) sense that Sec 1498 is a price control provision:
 - Secretary of War sought clarity that military not bound by higher royalty peacetime munitions contracts
 - Statute amended to clarify that it applied to true govt use and that contractors (and subcontractors) were covered under codified "authorization and consent" (from *Cramp v. Intl Curtis Marine Turbine*, 246 U.S. 28 (1918))
- > Act of June 25, 1948 transferred statute into Title 28, where it currently remains as 28 U.S.C. 1498

Use of Section 1498 in Twentieth Century

- Distinguish *gov't use* from *compulsory license*:
 - True gov't use is where gov't produces goods or services for its own use *or* for direct non-market distribution to public
 - Compulsory licenses gives rights to market players to supply market with patented goods or services
 - Section 1498 is the former

Use of Section 1498 in Twentieth Century

- Gov't use issues were intertwined with questions of ownership of gov't employee inventions and extramural research inventions
 - Gov't employees wind up with something similar to private employee ownership under shop rights system
 - Gov't contractors retain qualified right to own subject inventions under Bayh-Dole rules
 - Compare Sec 1498 to Bayh Dole gov't use license for federally funded inventions (35 U.S.C. 202(c)(4))
 - Contrast to Bayh Dole's March-in Rights compulsory license (35 U.S.C. 203)

Misinformation About Section 1498 Uses

NYT and Yale JOLT article claims about mid-century use of 1498 are misleading

- > During 1950s and 1960s, the Department of Defense did rely on 1498, but only to *procure* medicines for internal govt use
- > This practice underscores 1498 as part of the fed procurement system currently regulated under the FARS and DFARS
- > None of these cases involved the govt authorizing contractors to infringe patents to provide drugs to the public, either generally or through govt services
- > 1498 not "obscure": standard fed procurement tool used with contractors

Conclusion: Use of Section 1498 as price control is not supported by statutory history or text

- > The basis of 1498 was to overcome a technical sovereign immunity obstacle for patentees in cases of unauthorized govt use (Title 28 not 35)
- > Only gov't use is covered—1498 is not a compulsory license
- > Modern invocations, such as early 2000s Anthrax/Cipro incident, are premised on potential supply failures *not* price control (1498 not actually used in this situation)
- > Further, gov't use subject to "reasonable and entire compensation"; no "discount" authorized or implied
- > Finally: anyone familiar with fed procurement spending will not expect reduced prices, even if provided under gov't use