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About Government Use of Patented Inventions through § 1498

Existing law, 28 U.S.C. § 1498(a)¹, gives the U.S. government the authority to make or purchase a patented invention without the permission of the patent holder in exchange for reasonable compensation.

In the pharmaceutical context, through § 1498, the government could either produce a patented medicine or contract with generic producers to manufacture the medicine.

Generic competition is a proven and reliable method to realize lower prescription drug prices. A recent study² in the *New England Journal of Medicine* found that, on average, drugs with three generic manufacturers are priced at 60% of the brand name level. Drugs with five manufacturers are priced at less than half the brand price, and that prices of drugs with 10 or more manufacturers are only about one-fifth of brand prices.

The government exercising its § 1498 authority would remove the barrier that prevents such competition, helping to lower prices and expand access to affordable medicines.

In exchange for making use of a patented pharmaceutical product, the government would provide the patent holder with compensation. If the patent holder does not believe it has been adequately compensated, it can sue the government over the level of compensation, but it may not prevent the government or a

government contactor from making use of the patent.

When the government exercises its authority under § 1498, the patent holder may not seek injunctive relief, nor can a government contractor or subcontractor be held liable for infringement by the patent holder.

Under § 1498, in exchange for use of the patented invention, the government must provide the patent holder with “reasonable and entire” compensation. In modern § 1498 cases, this has been a reasonable royalty that is set taking into account case-specific analysis and numerous mixed considerations, including logic, common sense, justice, policy and precedent.

The government routinely relies on § 1498 to use or acquire a wide array of patented inventions without permission of the patent holder, ranging from fraud detection banking software and electronic passports to methods of removing hazardous waste and genetically mutated mice.

The most recent use of § 1498 in the pharmaceutical context was in 2001, when then-Secretary of Health and Human Services, Tommy Thompson, publicly considered using the authority to procure generic ciprofloxacin during the post-September 11th anthrax scare. The ciprofloxacin patent holder, Bayer, quickly cut its prices in half.

¹ For a more thorough exploration of 28 U.S.C. § 1498(a), see Brennan, Hannah; Kapczynski, Amy; Monahan, Christine H.; and Rizvi, Zain. "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," *Yale Journal of Law and Technology*: Vol. 18 : Iss. 1 , Article 7. Available at: <http://digitalcommons.law.yale.edu/yjolt/vol18/iss1/7>. This fact sheet relies heavily on the article.

² Dave, C. V., Hartzema, A., & Kesselheim, A. S. (2017). Prices of Generic Drugs Associated with Numbers of Manufacturers. *New England Journal of Medicine*, 377(26), 2597-2598. doi:10.1056/nejmc1711899