

With no end in sight to the ongoing, and widening, opioid epidemic in the United States, politicians, public health officials, and healthcare providers are scrambling for effective solutions to deal with the wave of opioid overdoses that is occurring. A commonly employed, and effective, solution is the administration of naloxone hydrochloride (sold under the mark NARCAN®) to a person who has overdosed on an opioid. For a variety of reasons however, agencies and healthcare providers have struggled, and often failed, to obtain adequate supplies of naloxone hydrochloride.

For example, while naloxone hydrochloride has been off-patent for over 50 years, pharmaceutical companies have been successful in obtaining patents (see, e.g., US 9,474,869) covering delivery systems, methods for delivery, and formulas for naloxone hydrochloride. These patents serve to limit the number of participants in the market. Another problem is that while demand for naloxone hydrochloride has greatly increased, the number of manufacturers has decreased.^[1] The confluence of these factors has resulted in significantly price increases^[2] for items such as naloxone hydrochloride delivery systems. These price increases present a challenge to agencies and healthcare providers who have limited budgets.

In light of the problems noted, one possible solution is for the government to step in, pursuant to 28 USC 1498(a)^[3], and contract for the sale and manufacture of patented naloxone hydrochloride formulas and delivery systems. Under this statute, the purpose of which has been described as to enable *'the Government to purchase goods for the performance of its functions without the threat of having the supplier enjoined from selling patented goods to the Government,' the liability of the government to the patent owner for infringement of the patent is limited to 'reasonable and entire compensation for such use and manufacture.'*^[4] The patent owner is not entitled to injunctive relief, nor to enhanced damages for willful infringement of the patent. As well, the government need only show that infringement of the patent is necessary for the *'performance of its [government's] functions,'* and may contest both infringement, and validity of the patent in question, should the patentee choose to pursue the remedy provided by the statute. The statute would thus seem

to strongly favor the position of the government over the rights of the patent owner.

Although it has not often been the case that the government has relied on the statute, such reliance, or the threat of it, presents some potential problems. In fact, one commentator has suggested that the statute provides for an unconstitutional taking of patent rights.^[5] Regardless of its constitutionality however, the statute is problematic insofar as: the statute can be arbitrarily applied by government bureaucrats with little or no justification; there is little in the way of guidelines to establish under what circumstances the statute should be applied, and who should decide when it should be applied; its use may provide a disincentive for manufacturers to invest in drug development and trials; it may be unfair to drug manufacturers who have made significant investments to patent products and bring them to market; and, the statute may provide a windfall for the competitors of the patent owner since the competitor may manufacture for the government under protection of the statute, without incurring development costs.

In sum, the opioid epidemic is a serious health crisis to which there are no easy solutions. But before infringing on patent rights in pursuit of a solution to the problem, the government should carefully consider whether or not it is a good idea and good policy to take action under 28 USC 1498.

[1] <https://www.businessinsider.com/price-of-naloxone-narcan-skyrocketing-2016-7>

[2]

<https://www.washingtontimes.com/news/2018/may/1/naloxones-steep-price-hinders-battle-against-opioid/>

[3] <https://www.law.cornell.edu/uscode/text/28/1498>

[4] *Coakwell v. United States*, 372 F.2d 508, 511 (Ct. Cls. 1967)

[5] (Miller, Joshua I. (2011) '28 USC 1498(A) And the Unconstitutional Taking of Patents,' Yale

Overriding Patents – The Naloxone Dilemma
by Peter Malen

Journal of Law and Technology: Vol. 13: Iss. 1, Article I.)