

April 2007

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Recommended Citation

Amanda Mitchell, *Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents*, 95 CALIF. L. REV. 535 (2007).

Link to publisher version (DOI)

<https://doi.org/10.15779/Z38KD95>

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Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents

Amanda Mitchell†

INTRODUCTION

As the United States and the world prepare to battle potential pandemics such as the avian flu,¹ new conflicts have arisen between governments and private owners of patents for medical vaccines and treatments. Such conflicts center in part around the growing concerns of domestic and international governments over the availability of Tamiflu, a privately held, patented medication used to treat the avian flu virus.² Governments fear that Roche, the holder of the exclusive worldwide rights of the Tamiflu patent,³ lacks the capacity to produce enough Tamiflu treatment to combat a large outbreak of the virus.

Property law provides the U.S. government with two options for gaining access to medical patents such as Tamiflu. First, the government may use compulsory licensing, which has traditionally been utilized to gain

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1. Avian flu is a form of influenza virus that occurs naturally among birds. Centers for Disease Control and Prevention, Avian Influenza (Bird Flu), <http://www.cdc.gov/flu/avian/gen-info/facts.htm>.

2. Tania Rodrigues, *Roche Compiles Short List of 12 Potential Partners to Enhance Production of Sought-After Antiviral Tamiflu*, WORLD MARKETS RESEARCH CENTRE, Dec. 12, 2005.

3. Roche acquired the worldwide rights to develop and market Tamiflu from Gilead Sciences in 1996. Gilead Sciences of Foster City, CA still officially owns the patent. Roche, Factsheet Tamiflu, Nov. 12, 2006, http://www.roche.com/med_mbtamiflu05e.pdf. Under the current licensing agreement between Roche and Gilead, a joint committee will oversee the coordination of Tamiflu manufacturing and consider third-party manufacturing licenses. Press Release, Roche, Roche and Gilead End Dispute on Influenza Drug Tamiflu (Nov. 16, 2005), available at <http://www.rochc.com/med-cor-2005-11-16>.

access to intellectual property rights.⁴ More specifically, the government has the power to use privately held intellectual property rights, such as patents, without the consent of the owner.⁵ This power, codified in 28 U.S.C. § 1498, permits the government to use patents even “without license of the owner thereof or the lawful right to use or manufacture the same.”⁶ As a remedy, the rightful owner of the patent may sue under § 1498 for “reasonable and entire compensation for such use and manufacture.”⁷ In short, this statute gives the government the ability to compel a license of any patent without the permission of the owner so long as the government compensates the owner. Through such licenses, the government can infringe on and manufacture a patent for as long as necessary. The government could thus force a license for a domestic medical patent and face an action for damages by the patent owner under 28 U.S.C. § 1498.

Second, and though traditionally applied to real property, eminent domain provides the government with another method to gain access to intellectual property rights. The Takings Clause, set forth in the Fifth Amendment of the U.S. Constitution, states that private property cannot be “taken for public use, without just compensation.”⁸

The government may take property through eminent domain either explicitly, through express condemnation, or implicitly, through a regulatory taking. If the government expressly condemns property through physical appropriation, it takes official title to the appropriated property.⁹ To properly condemn a piece of property under the Takings Clause, a public use must exist and just compensation must be paid. In contrast, a regulatory taking occurs when a government statute or regulation deprives a property owner of the economic value of the property.¹⁰ A regulatory taking may also occur when legislation results in a permanent physical

4. *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 757 (Fed. Cl. 1999) (describing the government as “a compulsory, nonexclusive licensee”); *see also* Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization’s Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 *AM. BUS. L.J.* 353, 369 (Winter/Spring 2004).

5. *See Leesona Corp. v. United States*, 599 F.2d 958, 966 (Ct. Cl. 1979); *William Cramp & Sons Ship & Engine Bldg. Co. v. Int’l Curtis Marine Turbine Co.*, 246 U.S. 28, 42 (1918); 28 U.S.C. § 1498 (2006).

6. 28 U.S.C. § 1498 (2006) (“Whenever an invention . . . covered by a patent of the United States is used or manufactured by or for the United States without license . . . 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.”).

7. *Id.*

8. U.S. CONST. amend. V.

9. *Best v. Humboldt Placer Mining Co.*, 371 U.S. 334, 340 (1963) (describing when title to the property passes to the government).

10. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1016 (1992) (summarizing previous courts’ determination that a statute effects a taking if it deprives the owner of his economically viable use of the land); *see also Palazzolo v. Rhode Island*, 533 U.S. 606 (2001).

occupation of private property¹¹ or when a court determines that a statute has so extensively impacted an owner that just compensation is due under the Takings Clause.¹²

This Comment will explore whether, in the face of a potential pandemic, the government should take ownership of a medical patent like Tamiflu or simply implement the compulsory licensing system currently in place. Part I gives a general overview of medical patents, current health threats and the potential issues that may arise if such patents remain in the hands of private property owners. In particular, this Part focuses on the emergence of the avian flu and the controversy surrounding its treatment, Tamiflu.

Part II discusses compulsory licensing and argues that, despite what some courts have said, § 1498 acts as a licensing statute that gives the government the authority to license patents. This Part also examines how compulsory licensing may be used to gain access to Tamiflu and what compensation might be required if the government issues such a license.

Part III discusses the history of eminent domain and examines the ability of the government to take medical patents through the Takings Clause. If the government shows a public use and compensates the owner, it becomes the legal titleholder.

Part IV examines how the Supreme Court has interpreted the government's power of eminent domain as it relates to intellectual property, and details the differences between the current licensing statute, 28 U.S.C. § 1498, and eminent domain. This Part then inspects both the advantages and disadvantages of licensing and eminent domain and explains why it is important for the government to have the option of using either a compulsory licensing system or eminent domain when responding to a medical threat or emergency. Depending on factors such as financial considerations and the potential threat of pandemic, it may be appropriate to simply license a patent for a limited period of time in some circumstances and take ownership of a patent in others. Thus, both licensing and eminent domain can play an important role in maintaining the health of the nation.

11. *Loretto v. Teleprompter Manhattan Catv Corp.*, 458 U.S. 419, 434-35 (1982) (“[W]hen the ‘character of the governmental action’ is a permanent physical occupation of property, our cases uniformly have found a taking to the extent of the occupation, without regard to whether the action achieves an important public benefit or has only minimal economic impact on the owner.”) (citation omitted).

12. *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 123-24 (1978).

I

PATENTS AND POTENTIAL PANDEMICS

A. *The Threat of an Avian Flu Pandemic*1. *Previous Pandemics and Epidemics*

Avian flu is not the first potential pandemic to threaten the international community. The world has previously faced health threats in the form of bio-terrorism and infectious diseases. For example, the threat of anthrax attacks in the aftermath of September 11, 2001, led to a concern over the availability of the prescription drug Cipro.¹³ In November 2002, over 8,000 people contracted Severe Acute Respiratory Syndrome (SARS).¹⁴ By 2003, "an estimated 1,039,000 to 1,185,000 persons in the United States were living with HIV/AIDS, with 24-27% undiagnosed and unaware of their HIV infection";¹⁵ and since 1981, 25 million people have died from AIDS worldwide.¹⁶ The emergence of the avian flu, also known as bird flu, is the latest health scare to threaten national and international populations. The increasing fear of a potential pandemic raises the issue of whether enough medication can be manufactured to combat an outbreak and to protect the domestic and international communities.¹⁷

2. *The Potential Danger of Avian Flu*

Avian flu is a strain of influenza, known as H5N1, that infects poultry and humans who come into contact with infected poultry.¹⁸ Thus far, human outbreaks have only occurred in Asia and Eastern Europe among individuals who have directly handled infected birds.¹⁹ Currently, the virus is only transmitted from bird to person, but the great concern is that it may mutate into a strain capable of person-to-person transmission.²⁰ The ability to spread easily from person to person could lead to a deadly pandemic because humans have little to no immunity to the H5N1 strain of the flu.²¹ Studies have projected that even a mild avian flu outbreak could result in

13. See Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM BUS. L.J. 125 (2002).

14. See David Bishop, *Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT'L LAW 1173, 1180 (2005).

15. CDC Website, Division of HIV/AIDS Prevention, <http://www.cdc.gov/hiv/stats.htm#hivest>.

16. World HIV & AIDS Statistics, <http://www.avert.org/worldstats.htm>.

17. *Drug Pricing*, FINANCIAL TIMES, Nov. 28, 2005, at 20.

18. CDC Website, Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus, <http://www.cdc.gov/flu/avian/gen-info/facts.htm>.

19. *Id.*

20. *Id.*

21. *Id.*

1.4 million deaths and cost approximately \$330 billion while a worst-case scenario could lead to deaths upward of 142 million.²²

This H5N1 strain of the virus does not respond to typical flu medications.²³ Though there is no approved vaccine for avian flu in its current or predicted mutated form,²⁴ Tamiflu serves as an antiviral treatment to combat the avian flu.²⁵ Swiss drug-maker Roche both produces and holds the patent rights to Tamiflu.

B. *A Brief Overview of Patent Rights*

Patent law protects new, unobvious, and useful inventions, such as machines, devices, chemical compositions, and manufacturing processes.²⁶ The U.S. Constitution grants Congress the power to regulate patents.²⁷ Congress enacted the first statute regarding patents in 1790, and the laws eventually developed to award the “first to invent” with the patent.²⁸

I. *Property Protection for Patents*

Tamiflu, like most medical products, is a patented drug. Patented products are “as much entitled to protection as any other property,”²⁹ and their owners possess exclusive rights to the patent for an initial period of twenty years, during which time they can recover damages for any infringement.³⁰ The patent enters the public domain at the expiration of this twenty-year period.³¹ Further, “the right to exclude exists even if the infringing party developed the infringing product independently and without knowledge of the patent.”³² Roche holds the exclusive rights to the

22. *Bird Flu 'Could Take 142m Lives'*, CNN, available at <http://www.cnn.com/2006/HEALTH/conditions/02/15/birdflu.cost/index.html> (citing study by WARWICK MCKIBBIN & ALEXANDRA SIDORENKO, GLOBAL MACROECONOMIC CONSEQUENCES OF PANDEMIC INFLUENZA, LOWY INSTITUTE FOR INTERNATIONAL POLICY, Feb. 2006); see also N. Pictet M. O'Leary, *Cock-a-Doodle-Do: Pandemic Avian Influenza and the Legal Preparation and Consequences of an H5N1 Influenza Outbreak*, 16 HEALTH MATRIX 511, 523 (2006) (describing potential ramifications of an avian flu pandemic).

23. CDC Website, *supra* note 15.

24. *Id.*

25. Rodrigues, *supra* note 2.

26. See 1-1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.01 (1978) [hereinafter CHISUM ON PATENTS]; 35 U.S.C. §§ 101-03 (2006).

27. U.S. Const. art. 1, § 8, cl. 8 (Congress shall have the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

28. 1-2 CHISUM ON PATENTS § 2.01, *supra* note 26; 1-4 CHISUM ON PATENTS § 4.01, *supra* note 26.

29. *Cammeyer v. Newton*, 94 U.S. 225, 226 (1877).

30. See 35 U.S.C. § 154(a)(1)-(2) (2006).

31. *Id.*

32. Cahoy, *supra* note 13, at 131.

Tamiflu patent, issued by the U.S. Patent and Trademark Office in 1996, until 2016.³³

2. Patent Protection from Infringement

If a private party infringes a patent by making, using, offering to sell, or selling the patent,³⁴ the patent owner shall be compensated for the infringement at an amount no “less than a reasonable royalty for the use made of the invention by the infringer.”³⁵ Damages may also take the form of lost profits or an established royalty if sufficient evidence exists.³⁶

Patent law not only protects the patent owner from infringement by private parties, but also from infringement by the U.S. government.³⁷ As early as 1870, the Supreme Court noted that the government could not use a patent “without license of the inventor or making compensation to him.”³⁸ However, the Court’s statement failed to wield much power because the constitutional doctrine of sovereign immunity deprived wronged patent owners of recourse against any federal or state government infringer.³⁹ In order to circumvent this problem of government sovereignty, Congress implemented the predecessor statute to § 1498, which granted patent owners a right to recover damages from the government for its unauthorized use of their patents.⁴⁰ Currently, under § 1498, if the government infringes a patent “without license right of the owner thereof or lawful right to use or manufacture the same,” it will be required to pay “reasonable and entire” compensation.⁴¹ In short, the government can force a license of a patent without the patent owner’s permission so long as compensation is paid.⁴² Courts generally interpret “reasonable and entire compensation” to mean a “reasonable royalty.”⁴³

33. Roche, Factsheet Tamiflu, http://www.roche.com/med_mbtamiflu05e.pdf.

34. See 35 U.S.C. § 271 (2006).

35. 35 U.S.C. § 284 (2006).

36. 7-20 CHISUM ON PATENTS § 20.03, *supra* note 26; see also *Hartness Int’l, Inc. v. Simplimatic Eng’g Co.*, 819 F.2d 1100, 1112 (Fed. Cir. 1987).

37. 28 U.S.C. § 1498 (2006).

38. *United States v. Burns*, 79 U.S. 246, 252 (1871); see also 5-16 CHISUM ON PATENTS § 16.06, *supra* note 26.

39. See Gregory C. Sisk, *A Primer on the Doctrine of Federal Sovereign Immunity*, 58 OKLA. L. REV. 439 (2005), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=722602; U.S. CONST. amend. XI (“The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by Citizens or Subjects of any Foreign State.”).

40. Act of June 25, 1910, No. 305, c. 423, 36 Stat. 851.

41. 28 U.S.C. § 1498 (2006).

42. See *United States v. Glaxo Group*, 410 U.S. 52, 60 (1973) (holding the government could demand mandatory sales and compulsory licensing and pay reasonable royalty rates for such use); *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 758 (Fed. Cl. 1999).

43. See, e.g., *Tektronix, Inc. v. United States*, 552 F.2d 343, 347 (Ct. Cl. 1977) (“Where an established royalty rate for the patented inventions is shown to exist, that rate will usually be adopted as

II COMPULSORY LICENSING

A. Background

Licensing is one way in which the government or a private party may gain access to a patent. Permissible licensing occurs when a patent owner grants permission to a party to use his patent,⁴⁴ usually for a negotiated fee.⁴⁵ In contrast, a compulsory license is defined as “the imposition on a patent owner who would not have licensed his invention” to allow use of his patent by a wrongdoer.⁴⁶ Through either a compulsory or permissive license, the patent owner surrenders the right to exclude the licensee from “making, using, selling, offering to sell, or importing the patented subject matter.”⁴⁷ Though a license permits another to use the patent, the patent owner can simultaneously exercise his rights over the patent.⁴⁸

Section 1498 regulates the government’s licensing power over patents. The predecessor statutes to § 1498, the Act of 1910 and its amendments,⁴⁹ share many similarities to the current statute, which was passed in 1948. Both provide a damage remedy to a private patent owner when the government infringes the patent. However, the current statute gives the government the additional power to not only use, but also to manufacture a patent without permission, as long as it pays appropriate compensation.⁵⁰ Thus, should it infringe on a medical patent like Tamiflu, the government could manufacture the patented product independently or with the help of a third party.

Though some courts have equated the government’s infringement of a patent under § 1498 to an action in eminent domain,⁵¹ the statute is more

the best measure of reasonable and entire compensation.”); see also *Standard Mfg. Co.*, 42 Fed. Cl. 748 at 758-59.

44. 35 U.S.C. § 261 (2006) (“[Patents] shall be assignable in law by instrument in writing. The applicant, patentee or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.”).

45. See *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1383-84 (Fed. Cir. 2004) (“If the patent owner chooses not to totally exclude others, he or she may negotiate with a potential licensee to permit the licensee to make, use, sell, or import the patented subject matter under whatever terms the parties agree upon.”)

46. *Id.* at 1384 (quoting *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1328 (Fed. Cir. 1987)).

47. See 35 U.S.C. § 271 (2006).

48. See *id.*; see also Brook K. Baker, Health GAP, *Anxiety over Bird Flu Medicines Reveals Myopia in Patent and Public Health Policies*, CONSUMER PROJECT ON TECHNOLOGY, Oct. 18, 2005, <http://www.cptech.org/ip/hcalth/tamiflu/hgap10182005.html>.

49. Act of June 25, 1910, No. 305, c. 423, 36 Stat. 851, as amended July 1, 1918 (“That whenever an invention described in and covered by a patent of the United States shall hereafter be used by the United States without license of the owner thereof or lawful right to use the same, such owner may recover reasonable compensation for such use . . .”).

50. 28 U.S.C. § 1498 (2006).

51. See, e.g., *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 756 (Fed. Cl. 1999).

akin to compulsory licensing. In fact, in a recent letter to the Secretary of the Department of Health and Human Services, members of Congress explicitly stated that § 1498 grants the U.S. government the authority to issue compulsory licenses.⁵² When the government uses a domestic patent without permission, it effectively forces the private patent owner to license the use and manufacture of the product to the U.S. government.⁵³ However, as dictated by § 1498, the government must pay “reasonable and entire compensation” for the amount of time it uses the patent.⁵⁴

As the holder of the exclusive patent rights, Roche controls the use, manufacture and supply of Tamiflu. The government could issue a compulsory license for the Tamiflu patent and begin to manufacture a generic version of the drug after paying compensation.⁵⁵ Roche would continue to hold the patent rights for Tamiflu and could continue to manufacture their products for sale on the market. Therefore, patent owners who grant licenses, permissively or otherwise, gain an additional stream of revenue to their normal sales through licensing fees. However, as more licenses are granted, the cost of Tamiflu would likely go down due to increased competition in the market. While royalty payments might provide Roche with an additional stream of revenue, the company might actually experience a decrease in total consumer sales.

B. Determining Adequate Compensation for Compulsory Licensing

If the U.S. government issued a compulsory license for Tamiflu, it would have to pay “reasonable and entire compensation” to Roche for the amount of time that it produced the antiviral medication.⁵⁶ Courts have interpreted reasonable compensation to fall within two categories: lost profits and reasonable royalties.⁵⁷ Lost profits constitute those profits that the patent owner, with reasonable probability, would have made if the infringement had not occurred.⁵⁸ If the patent owner cannot prove lost profits, then “the floor for a damage award is no less than a reasonable royalty.”⁵⁹

Traditionally, when the government has issued a “compulsory compensable license,” courts have determined reasonable compensation to be the rate of reasonable royalty or, where that cannot be determined, the

52. Letter from Dennis J. Kucinich et al., Members of Congress, to Michael Leavitt, Secretary of Department of Health and Human Services (Oct. 26, 2005).

53. See 28 U.S.C. § 1498 (2006).

54. *Id.*

55. Baker, *supra* note 48.

56. 28 U.S.C. § 1498 (2006).

57. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc); see also Cahoy, *supra* note 13, at 152.

58. *State Indus. v. Mor-Flo Indus.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989).

59. *Id.* (citing *Seattle Box Co. v. Indus. Crating & Packaging Inc.*, 756 F.2d 1574 (Fed. Cir. 1985)).

estimated value of the loss.⁶⁰ Courts generally determine reasonable royalties to be the same amount that the patent owner has previously charged other licensees for the use of its patents.⁶¹ Though courts may choose to grant lost profits as an alternative measure of compensation, the award of lost profits has become less accepted in more recent case law,⁶² because the size of such lost profits is characterized as excessive.⁶³ Thus, if the government chooses to infringe on Roche's Tamiflu patent through the issuance of a compulsory license, a court must determine a reasonable royalty.

Section 1498 and its predecessors establish the power of the U.S. government to issue a compulsory license for Tamiflu or any other patented pharmaceutical. However, if the government issues a compulsory license, it must pay adequate compensation, likely in the form of a reasonable royalty.

C. *Establishing Reasonable Royalties: Private Negotiation of Tamiflu Licenses*

In order to address a potential pandemic, by the end of 2005 the United States government "expect[ed] to stockpile enough Tamiflu to treat 4.3 million people" or "enough antiviral medicine to treat nearly 90 million Americans."⁶⁴ Still, the United States and some Asian nations are considering issuing a compulsory license for a generic version of Tamiflu.⁶⁵ On November 25, 2005, the government of Taiwan issued a compulsory license for Tamiflu in order to begin local production of a generic version of the drug.⁶⁶ India is also "weighing whether there is enough risk of bird flu . . . to invoke a licensing clause to lift . . . Roche's patent of Tamiflu."⁶⁷

However, in an effort to maintain its exclusive patent rights over Tamiflu and avoid a compulsory license that would put a generic medication into the marketplace, Roche has attempted to increase the availability of Tamiflu to nations most susceptible to an avian flu outbreak. It has done so by identifying twelve potential partners that could produce

60. *Leesona Corp. v. United States*, 220 Ct. Cl. 234, 250 (Ct. Cl. 1979).

61. *Id.* at 259 (citing *Carley Life Float Co. v. United States*, 74 Ct. Cl. 682 (1932); *see also* *Decca Ltd. v. United States*, 640 F.2d 1156, 1172-73 (Ct. Cl. 1980).

62. *Leesona*, 220 Ct. Cl. at 259 ("The comparative royalty technique is the preferred method of determining just compensation.") (citation omitted).

63. *Tektronix, Inc. v. United States*, 552 F.2d 343, 349 (Ct. Cl. 1977).

64. Sabin Russell, *About-Face on Influenza Drug; Manufacturer Says it will Consider Licensing Tamiflu*, S.F. CHRON., Oct. 19, 2005, at A4.

65. Baker, *supra* note 48.

66. *Avian Influenza; Roche Allows Tamiflu Licensing; Other Developments*, FACTS ON FILE WORLD NEWS DIG., Dec. 8, 2005.

67. *World Officials Debate Breaking Tamiflu Patent*, USA TODAY, Oct. 25, 2005, available at http://www.usatoday.com/news/health/2005-10-25-bird-flu_x.htm.

the drug alongside the patent holder⁶⁸ and has already granted a sublicense to Shanghai Pharmaceutical Group.⁶⁹ By handpicking its partners in Tamiflu production, Roche can negotiate a private contract with these partners and determine the royalty amount to be paid for the use of the patent. Under any licensing scheme, Roche could also continue to produce Tamiflu along with the licensees.⁷⁰

There are distinct economic advantages to Roche negotiating private licensing agreements, which would give the company extensive market power. More specifically, a reasonable royalty “is the amount that a person desiring to manufacture [or use] a patented article . . . would be willing to pay as a royalty and yet be able to make [or use] the patented article, in the market at a reasonable profit.”⁷¹ Thus, as the avian flu becomes an ever-growing threat to populations and drug companies want access to Tamiflu, competing drug companies would likely pay a considerable royalty amount to Roche for use of the patent, thereby allowing Roche to control the market. With such use of the patent, a drug company could then manufacture a generic version of Tamiflu and, due to its high demand, sell it on the open market at a relatively high price. Given this ability to license Tamiflu at potentially high royalty rates, Roche emerges as the dominant market force in the fight against the avian flu.

Another advantage of Roche privately negotiating licensing rates is that once a royalty rate has been established, the government may have to pay that same amount as reasonable and entire compensation for infringement.⁷² Conversely, “[w]hen an established royalty does not exist, a court may determine a reasonable royalty based on ‘hypothetical negotiations between willing licensor and licensee,’”⁷³ which may be lower than the amount that actual private negotiations would yield. If Roche had previously negotiated a high royalty rate with private licensees, the government would likely have to pay that amount for the period of time in which it used, manufactured or sold Tamiflu or its generic equivalent. Thus, Roche would not have to look to the court to assess a reasonable royalty rate for a government infringement. Given these market benefits, it might be in Roche’s best interest to negotiate royalty rates with private parties.

68. Rodrigues, *supra* note 2.

69. Roche, Roche Update on Tamiflu Global Supply to Meet Future World Demands—From Partnerships to Regional Sub-licenses, <http://www.roche.com/med-cor-2005-12-12>.

70. Baker, *supra* note 48 (“Roche, in turn, would receive royalty payments on the medicines produced by the generic companies and would still be permitted to sell its own Tamiflu in a now more competitive market.”).

71. *Wright v. United States*, 53 Fed. Cl. 466, 469 (Ct. Cl. 2002).

72. *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995) (en banc).

73. *Wright*, 53 Fed. Cl. at 469 (quoting *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed. Cir. 1993)).

While the government has the power to license Tamiflu, eminent domain may be an alternative method by which to gain access to Tamiflu.

III EMINENT DOMAIN

A. *Background*

The government's eminent domain power to take official title to property comes from the Takings Clause of the Fifth Amendment. This power stems from the general principle that a sovereign nation has the right of absolute ownership and can resume ownership at any time.⁷⁴ State legislatures can also constitutionally take land if the taking satisfies the public use and just compensation requirements of eminent domain.⁷⁵

1. *Jurisdictional Authority to Take a Medical Patent*

The government can take any property that has been expressly or impliedly delegated by the Constitution to be within its jurisdiction.⁷⁶ Therefore, constitutional authority allows the federal government to condemn property in the exercise of its Commerce power,⁷⁷ its Property power,⁷⁸ its General Welfare power,⁷⁹ and other powers that lie within the purview of Congress, such as those laid out in Article I, Section 8 of the Constitution.

The government may legally and constitutionally exercise its eminent domain power over a medical patent. The Constitution grants Congress the power both to promote the progress of science and useful arts⁸⁰ as well as to provide for the general welfare.⁸¹ Therefore, the government could condemn Tamiflu under either one of these constitutional grants of power. Under the constitutional clause empowering the promotion of science, the federal government could assert jurisdiction over Tamiflu through eminent domain by stating that its ownership and production of the patent promoted

74. *United States v. Jones*, 109 U.S. 513, 518 (1883); *see also* 1-1 NICHOLS ON EMINENT DOMAIN § 1.13 (2006).

75. *See Kelo v. City of New London, Conn.*, 125 S. Ct. 2655, 2658 (2005) (“[T]he city . . . approved a development plan that . . . was “projected to create in excess of 1,000 jobs, to increase tax and other revenues, and to revitalize an economically distressed city. . . . The city’s development agent . . . proposes to use the power of eminent domain to acquire the remainder of the property from unwilling owners in exchange for just compensation.”).

76. 1A-3 NICHOLS ON EMINENT DOMAIN § 3.02 (1964).

77. *Fed. Power Comm’n v. Tuscarora Indian Nation*, 362 U.S. 99, 117 (1960) (holding that the Federal Power Act, passed pursuant to Congress’ Commerce power (Art. I, § 8, Cl. 3) and Property power (Article IV, § 3, Cl. 2) established a valid exercise of eminent domain even as applied to Native American tribal land).

78. *Id.*

79. U.S. CONST., art. I, § 8, Cl. 1 (“Congress shall have the power to . . . provide for . . . the general welfare of the United States”).

80. U.S. CONST., art. I, § 8, Cl. 8.

81. U.S. CONST., art. I, § 8, Cl. 1.

science. Congress could alternatively condemn Tamiflu by establishing that the General Welfare Clause warranted such condemnation, based on the government's duty to protect the general public and to ensure availability of medications like Tamiflu.⁸²

2. *Two Types of Takings: Express Condemnation and Regulatory Takings*

Two types of takings exist: (1) an express condemnation of land in which the government physically appropriates the land to be taken and (2) a regulatory taking, also known as inverse condemnation, in which the government does not expressly take the land, but otherwise diminishes its value. In a regulatory taking, "if a regulation goes too far it will be recognized as a taking."⁸³ Unlike express condemnation, physical appropriation of land does not need to occur for the government to effectuate a regulatory taking.⁸⁴

Three categorical rules exist in regulatory takings jurisprudence. First, a "total taking" occurs when the state or federal government places restrictions on land or regulates a property owner's land use in such a way as to eliminate all economic, productive value of the land.⁸⁵ The ability of a government body to pass these types of regulations stems from the government's police power to protect the health, safety and public welfare.⁸⁶ Second, any permanent physical occupation on private property resulting from government regulation will be considered a regulatory taking.⁸⁷ Finally, if a government regulation regulates a land use that would have constituted a nuisance at common law, then a regulatory taking will not exist.⁸⁸

If none of these three categorical rules apply, the court will engage in an ad hoc, factual inquiry to determine whether a regulatory taking has occurred.⁸⁹ In this factual inquiry, courts balance the regulation's economic

82. *Ivanhoe Irrigation Dist. v. McCracken*, 357 U.S. 275, 294 (1958) (noting that reclamation projects to promote agriculture fell within the federal government's general welfare power).

83. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922) (explaining the general rule that property may only be regulated to a certain extent before being deemed a taking).

84. *Tahoe-Sierra Pres. Council v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 326 (2002).

85. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992). "When, however, a regulation that declares 'off-limits' all economically productive or beneficial uses of land goes beyond what the relevant background principles would dictate, compensation must be paid to sustain it." *Id.* at 1030.

86. *See id.* at 1027 ("[T]he property owner necessarily expects the uses of his property to be restricted . . . by various measures newly enacted by the State in legitimate exercise of its police powers."); *See also Pennsylvania Coal*, 260 U.S. at 413.

87. *Loretto v. Teleprompter Manhattan Catv Corp.*, 458 U.S. 419, 427 (1982) ("[W]hen faced with a constitutional challenge to a permanent physical occupation of real property, this Court has invariably found a taking.") (citation omitted).

88. *Lucas*, 505 U.S. at 1030 ("Such regulatory action may well have the effect of eliminating the land's only economically productive use, but it does not proscribe a productive use that was previously permissible under relevant property and nuisance principles.")

89. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

effect on the landowner, the extent to which the regulation interferes with the owner's reasonable, investment-backed expectations, and the character of the government action in order to determine whether a taking has occurred and compensation is due.⁹⁰

If the government expressly condemns certain property, then it will take title to the property in question.⁹¹ However, if the court finds only a regulatory taking, in which the interests of the property owner have been significantly affected by a governmental regulation, then the government does not actually take title to the property in question, but rather only pays just compensation for the affected land.⁹² Should the government exercise its eminent domain power over Tamiflu, it should do so through express condemnation so as to avoid the more fact-based, subjective balancing that occurs when determining whether a regulatory taking has occurred.⁹³

B. *The Two Prongs of Eminent Domain*

In order for the government to effectuate a legal eminent domain action, it must satisfy two requirements: (1) the property taken must serve a "public use" and (2) just compensation must be paid. For an express condemnation, once these two prongs are met, "title and right to possession vest in the United States."⁹⁴ Further, when the government condemns land, its "entry into possession marks the taking . . . and fixes the date as of which the property is to be valued."⁹⁵

I. *Public Use*

In order to meet the public use prong of the Fifth Amendment, the government must simply demonstrate "a legitimate public purpose" and a rational relationship between the taking and the stated public purpose.⁹⁶ Under this broad "public purpose" test adopted by most courts,⁹⁷ the public does not have to be able to actually use the property in question in order to satisfy the public use prong.⁹⁸ Rather, the public only needs to be able to

90. *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

91. *Yee v. City of Escondido*, 503 U.S. 519, 522-23 (1992) ("Where the government authorizes a physical occupation of property (or actually takes title), the Takings Clause generally requires compensation.").

92. *See Lucas*, 505 U.S. at 1003; *see also Tahoe-Sierra Pres. Council v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 322 (2002) ("Thus, compensation is mandated when a leasehold is taken and the government occupies the property for its own purposes.").

93. *See Penn Central*, 438 U.S. at 124.

94. *Kirby Forest Indus. v. United States*, 467 U.S. 1, 4 (1984).

95. *Best v. Humboldt*, 371 U.S. 334, 340 (1963).

96. *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 244 (1984) (describing the power of the Hawaii state legislature to take property from consolidated property owners and sell it to tenants leasing the land from the current owners).

97. *See* 2A-7 NICHOLS ON EMINENT DOMAIN § 7.02 (2006).

98. *Kelo v. City of New London, Conn.*, 125 S. Ct 2655, 2662 (2005) (holding that a city's plan for economic rejuvenation qualified as a "public purpose" for eminent domain).

derive a benefit from the property.⁹⁹ In modern jurisprudence, courts generally give deference to state and federal legislatures and find the public use element met if the condemnation is at least minimally related to a public purpose.¹⁰⁰ For example, the Supreme Court has upheld both the breaking up of a “land oligopoly” in order to “correct deficiencies in the market”¹⁰¹ and plans for economic redevelopment of land as constitutional public uses.¹⁰² Interestingly, the Supreme Court has stated that the public use prong is not a requirement for regulatory takings.¹⁰³

2. *Just Compensation*

Just compensation comprises the second prong of the Takings Clause and must be paid whether the taking occurs through express condemnation or regulatory action. Generally, the fair market value of the condemned property, or “what a willing buyer would pay in cash to a willing seller,” is the measure of compensation without regard for any sentimental value that the owner may have for the property.¹⁰⁴ Thus, the fair market value for each taking will differ based on the unique characteristics of the condemned property.¹⁰⁵ It is up to the courts to determine the appropriate compensation amount. For example, in land takings, the selling price of adjacent land might serve as a guide for determining fair market value.¹⁰⁶

C. *Taking a Medical Patent through Eminent Domain*

1. *Taking a Medical Patent through Express Condemnation*

Though the government has never taken a medical patent through eminent domain, it has just as much authority as it does with real property to expressly condemn Tamiflu by showing public use and paying just compensation.¹⁰⁷ If the government chose to condemn the Tamiflu patent, then the patent title would pass to the government.¹⁰⁸ The original patent holder would lose all property interest in the patent and could no longer exercise his or her rights to sell, use or manufacture it.

99. *Hawaii Hous. Auth.*, 467 U.S. at 243.

100. *Kelo*, 125 S. Ct. at 2663; Thomas W. Merrill, *The Economics of Public Use*, 72 CORNELL L. REV. 61, 63 (1986).

101. *Hawaii Hous. Auth.*, 467 U.S. at 229.

102. *Kelo*, 125 S. Ct. at 2655.

103. *Tahoe-Sierra Pres. Council v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 326 (2002).

104. *United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 (1979) (quoting *United States v. Miller*, 317 U.S. 369, 374 (1943)).

105. *Miller*, 317 U.S. at 374 (1943).

106. *Id.* at 374-75.

107. *See* Section III.A.1.

108. *See Yee v. City of Escondido*, 503 U.S. 519, 522-23 (1992).

2. *Regulatory Taking of a Medical Patent*

Though it would be more efficient for the government to take a patent through express condemnation, the government might also take a medical patent through a regulatory taking. As with regulatory takings concerning real property, the patent owner would have to file an inverse condemnation suit and ask a court to determine whether a regulatory taking occurred. In this legal action, the patent holder would have to prove that the government's use of the patent effectuated a "total taking" by depriving him of all economic use of the patent.¹⁰⁹ If the patent owner could not prove a total taking, then the adjudicating court would engage in an ad hoc factual inquiry in which it would balance the "economic impact of the regulation on the claimant[,] . . . the extent to which the regulation has interfered with distinct investment-backed expectations . . . [and] the character of the government action" to determine if a compensable taking had in fact occurred.¹¹⁰ Only if the balancing of these interests favored the patent owner would the government be obligated to pay just compensation for the taking.

A total taking through regulation would be difficult for a patent owner to demonstrate. Even if the government affected the patent owner's economic interests through a compulsory license, a regulatory taking would likely not be found because the patent owner could continue to sell the patent on the open market and thus derive economic benefits from the sales. Also, a court would likely be unwilling to find a total taking since the owner can avail himself of the remedy of compensation under § 1498. However, it is the court's role to conduct the balancing test discussed above to evaluate whether a regulatory taking has occurred.

D. Meeting the Prongs of Eminent Domain for Express Condemnation of Tamiflu

While the federal government would have jurisdiction under the Constitution to exercise its eminent domain power for Tamiflu through express condemnation, it would still have to meet the Takings Clause's two prongs—public use and just compensation—in order to condemn a patent such as Tamiflu. Once met, the government would take official title to the patent.¹¹¹

109. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992).

110. *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

111. *Kirby Forest Indus. v. United States*, 467 U.S. 1, 4 (1984) ("If the Government wishes to exercise [the option of paying just compensation], it tenders payment to the private owner, whereupon title and right to possession vest in the United States."); *see also Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 233 (1984) ("[The Hawaii Housing Authority] then acquires, at prices set either by condemnation trial or by negotiation between lessors and lessees, the former fee owners' full 'right, title, and interest' in the land.").

1. *Public Use for Tamiflu*

To meet the public use prong, the government would need to demonstrate a public purpose rationally related to the condemnation of the patent.¹¹² This minimal requirement is generally easy to meet because the public use component is rarely grounds for invalidating a taking.¹¹³ In condemning Tamiflu, the government would meet the public use prong by demonstrating that such a condemnation promoted the protection and the health of the population from a pandemic.

2. *Just Compensation for Tamiflu*

The government would also have to pay just compensation for a taking, as directed by the Fifth Amendment. Some courts have analogized just compensation to “reasonable and entire compensation” under § 1498.¹¹⁴ However, reasonable and entire compensation under § 1498 has generally been held to mean a reasonable royalty, which may not be the same as just compensation for eminent domain.¹¹⁵ Payment of a reasonable royalty for an ongoing period of time might not adequately compensate a patent owner because, if the government exercised its eminent domain power, the patent owner would no longer hold any interest in the patent. Thus, just compensation for eminent domain would have to reflect the private property owner’s total loss in his property rights rather than just the loss of his exclusive property rights, as is the case when the government simply licenses a patent.

In land takings, the general measure of compensation has generally been the fair market value of the property,¹¹⁶ or what a willing buyer would pay in cash.¹¹⁷ Thus, the fair market value of Tamiflu would likely be the measure of compensation for the official taking of that patent. The question, then, is how to measure the fair market value of a medical patent like Tamiflu. The courts would have to determine this value by taking into account a totality of the circumstances.¹¹⁸ More specifically, a court would have to consider Roche’s loss of all property rights to Tamiflu, Roche’s extreme market power and the high demand for Tamiflu in the face of a pandemic. Given these factors, the fair market value of Tamiflu is likely

112. *Hawaii Hous. Auth.*, 467 U.S. at 233.

113. *Wisconsin Cent. v. PSC*, 95 F.3d 1359, 1368 (7th Cir. 1996) (holding that plaintiffs failed to make a claim under the Due Process Clause of the 14th Amendment because the harm was redressable through monetary compensation).

114. *Leesona Corp. v. United States*, 220 Ct. Cl. 234, 251 (Ct. Cl. 1979) (noting that a reasonable royalty served as just compensation for taking a patent under 28 U.S.C. § 1498).

115. *Id.*

116. *See* Section III.B.2.

117. *United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 (1979) (quoting *United States v. Miller*, 317 U.S. 369, 374 (1943)).

118. *See Miller*, 317 U.S. at 374-75 (noting that determination of market value involves the “use of assumptions”).

quite high. Depending on its value, a taking of Tamiflu could potentially become costlier than simply paying licensing fees for its use.

IV

COMPULSORY LICENSING VERSUS EMINENT DOMAIN

A. *The Supreme Court's Interpretation of Licensing under 28 U.S.C. § 1498 and Eminent Domain*

Recent Supreme Court decisions have generally not compared § 1498 to eminent domain. However, some lower federal courts have considered § 1498 to be an eminent domain statute by classifying government infringement of a patent as a taking.¹¹⁹

These lower courts likely have made this comparison between § 1498 and eminent domain based on the statute's requirement of compensation, which is also a constitutional requirement for takings. Further, very early Supreme Court decisions analogized the Act of 1910, the predecessor to § 1498, to an action in eminent domain.¹²⁰ Such comparisons between earlier incarnations of § 1498 and eminent domain began with the Supreme Court's interpretation of the statute in the early part of the twentieth century.¹²¹ In 1918, the Supreme Court stated in *William Cramp & Sons Ship & Engine Building v. International Curtis Marine Turbine Co.* that the Act of 1910 gave the United States the authority "to take patent rights under eminent domain in reliance upon the provision to recover the adequate compensation which the Act of 1910 affords."¹²² Later, in 1933, the Court stated that the Act of 1910 was "in effect an eminent domain statute by which just compensation was secured."¹²³

Despite these early Supreme Court comparisons between the § 1498 predecessor statutes and eminent domain, more recent decisions have made no such comparison. In fact, modern courts have noted that "[s]ection 1498(a) does not anywhere state that an action thereunder constitutes an 'eminent domain proceeding.'"¹²⁴ Thus, the Supreme Court's silence on the current statute renders it, at most, a statute with similarities to eminent domain, but not an eminent domain statute per se. Section 1498 simply

119. See, e.g., *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 697 n.12 (Ct. Cl. 2003); *Irving Air Chute Co. v. United States*, 117 Ct. Cl. 799, 802 (Ct. Cl. 1950); *Leesona*, 220 Ct. Cl. at 246-47.

120. Thomas F. Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 50 FLA. L. REV. 529, 541 (1998) (citing as exemplary of such cases *James v. Campbell*, 104 U.S. 356 (1881)).

121. *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290, 308 (1912) (describing how the United States acquires patented inventions "under the right of eminent domain, as a result of the statute of 1910").

122. 246 U.S. 28, 42 (1918).

123. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 219 (1933); *but cf. Crozier*, 224 U.S. at 305.

124. *De Graffenried v. United States*, 29 Fed. Cl. 384, 386-87 (Ct. Cl. 1993); see also Cotter, *supra* note 120.

allows for payment to a private owner for the government's issuance of a compulsory license. Additionally, many differences exist between § 1498 and eminent domain that help explain the Supreme Court's lack of recent comparison between the two.

B. Differences between 28 U.S.C. § 1498 and Eminent Domain

Given its characterization as property,¹²⁵ it is easy to understand why some courts have analogized intellectual property licensed without consent to an action in eminent domain. However, in addition to the silence of the Supreme Court as to § 1498, the statute differs from an action in eminent domain for five distinct reasons.

First, § 1498 and eminent domain are two very different types of legal actions implemented by different actors. Eminent domain, on the one hand, gives the government the affirmative power to take property from a private property owner. On the other hand, § 1498 simply provides a private property owner a remedial right against the government. Because of the structural differences between the two, compulsory licensing and eminent domain are not interchangeable.

Second, unlike an action in eminent domain, neither § 1498 nor its predecessor statutes require the government to have a public use or public purpose when it uses a patent without a license.¹²⁶ More specifically, the early Supreme Court comparison of the § 1498 predecessor statute to eminent domain¹²⁷ seems inappropriate because the statute does not refer to a public use, which is a requirement under traditional eminent domain. Rather, § 1498 merely offers a remedy for any unlawful government infringement, regardless of the purpose of the infringement.

Third, when the government uses a patent, it acts as a "compulsory, non-exclusive licensee"¹²⁸ and does not take title to the patent as it does with real property. Taking official title through express condemnation is a key element of eminent domain which further distinguishes it from § 1498. Thus, despite what some courts have stated, the statute does not constitute an exercise of the government's power of eminent domain.

Fourth, the compensation due to the patent holder in an action under § 1498 and eminent domain differs. Generally, eminent domain

125. See *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 696 (Ct. Cl. 2003) ("The Federal Circuit, its predecessor court, the Court of Claims, and the U.S. Supreme Court have repeatedly recognized that patent rights are property rights.").

126. 28 U.S.C. § 1498 (2006).

127. See, e.g., *Dubilier Condenser Corp.*, 289 U.S. at 219.

128. *Motorola, Inc. v. United States*, 729 F.2d 765, 768 (Fed. Cir. 1984); see also *Leesona Corp. v. United States*, 220 Ct. Cl. 234, 250 (Ct. Cl. 1979). Though the court equated 28 U.S.C. § 1498 to eminent domain, it acknowledged that "[t]he nature of the property taken by the government in a patent infringement suit has traditionally been a compulsory compensable license in the patent."

compensation is measured through an assessment of fair market value.¹²⁹ However, under 28 U.S.C. § 1498, a reasonable royalty, or lost profits in certain circumstances, provides the measure of compensation¹³⁰ rather than the total fair market value of the patent. The fair market value indicates what a willing buyer would pay for ownership, while a reasonable royalty is simply what a licensee would pay for ongoing use of the patent as a licensee.

Fifth, 28 U.S.C. § 1498 shares many similarities with 35 U.S.C. § 284, the statute governing the remedy for private patent infringement, further demonstrating that § 1498 is a remedy for an infringement by which a patent owner can be made whole, not an action in eminent domain. Had Congress intended for § 1498 to be a Takings statute, such similarities between the two statutes would likely not exist. In fact, courts have noted the commonalities between the two.¹³¹ Under the private infringement statute, if a private party infringes a patent, the infringer must compensate the owner for the infringement at an amount “in no event less than a reasonable royalty for the use made of the invention by the infringer.”¹³² This use of a reasonable royalty as a floor for damages is similar to the amount that the government generally would pay for the unlawful use of a patent under 28 U.S.C. § 1498.¹³³ Moreover, the government has the same defenses available to it under 28 U.S.C. § 1498 as a private infringer has under 35 U.S.C. § 284; this demonstrates that Congress likely intended both statutes simply to provide remedies to patent owners, not to grant the government the power of eminent domain.

C. Advantages and Disadvantages of Compulsory Licensing for the U.S. Government

1. Advantages

One benefit of compulsory licensing is that the government would only need to pay “reasonable and entire compensation” under 28 U.S.C. § 1498 for the period of time during which it used the patent. As discussed above, compensation for use of the patent would likely be a reasonable royalty comparable to what other Roche licensees were paying for use of the Tamiflu patent.¹³⁴ Thus, were the government were to license Tamiflu, it would have to pay Roche a royalty rate only for the time necessary to get

129. See Section III.B.2.

130. *Leesona*, 220 Ct. Cl. at 250.

131. See, e.g., *Lemelson v. United States*, 752 F.2d 1538, 1548 (Fed. Cir. 1984) *on remand* 8 Cl. Ct. 789 (Cl. Ct. 1985) (“Although this court has noted that a section 1498 action and a title 35 action are only parallel and not identical, . . . the principles of claim construction and reading claims on accused devices are the same for either type of action.”).

132. 35 U.S.C. § 284 (2006).

133. See Section II.B.

134. *Id.*

the population over the potential health crisis of an avian flu pandemic. Once the health emergency passed, the government would no longer need to pay for the use of the patent.

Further, unlike eminent domain, the government would not need to prove a public purpose each time it licensed a patent like Tamiflu. Section 1498 gives the government a relatively easy method for using and manufacturing a patent. In fact, § 1498 does not require the government to give an explanation as to why it has used or manufactured a certain patent.¹³⁵ Rather, it may use any patent and pay the appropriate compensation. In the absence of a public purpose requirement, the use of compulsory licensing is a fairly uncomplicated way of taking advantage of a privately held patent for a finite period of time.

Another potential advantage of a compulsory licensing system is that it may encourage private patent owners to negotiate with private licensees in order to establish a reasonable royalty rate. Once determined, the government would likely have to pay the same reasonable royalty if it issued a compulsory license. The issuance of licenses to produce Tamiflu would lead to an increase in the production of the drug or its generic equivalent. With more Tamiflu in the marketplace, the risk of a shortage during a pandemic would decrease.

Also, the threat of the government's issuing a compulsory license may also encourage the private patent holder to grant the government permissive use of the patent at a reasonable royalty¹³⁶ in order to avoid costly litigation under § 1498. If such negotiations occurred, both the government and the private patent owner would save the cost and burden of litigation. Potentially, in these negotiations, Roche could take advantage of its market power and charge the government or any other licensee extreme royalty rates, particularly if avian flu became a widespread pandemic. However, powerful governmental agencies may be more likely to negotiate fair royalty rates with influential patent owners like Roche because these agencies possess more compelling "capabilities for securing compliance" from private entities.¹³⁷

135. 28 U.S.C. § 1498 (2006); *see also* Cahoy, *supra* note 13, at 140 ("The courts have recognized that § 1498 is the sole means by which patent and copyright owners who have suffered an appropriation . . . can recoup compensation.").

136. 35 U.S.C. § 261 (2006); *see also* Hartford-Empire Co. v. United States, 323 U.S. 386 (1945) ("A patent owner may lawfully set the price for the use of the patented invention by others and may elect to use it himself and refuse to license it or, or to retain it and neither use nor license it.").

137. Such power of strong government agencies is known as the "benign big gun" theory developed by Ian Ayres, John Braithwaite and Peter Grabosky. John Braithwaite, *A Future Where Punishment Is Marginalized: Realistic or Utopian?*, 46 UCLA L. REV. 1727, 1729 (1999) ("Benign Big Guns have capabilities for securing compliance that are superior to those of weak prosecutorial regulatory agencies that consistently pursue administration of punishment. One reason is that Benign Big Guns have the authority to encourage compliance that would otherwise be coerced, and their authority is accepted as more legitimate when it is not exercised coercively.").

2. *Disadvantages*

Compulsory licenses also have disadvantages. For example, even if the government issued a compulsory license for Tamiflu, it would still need to find an entity to produce the patent, thus adding another cost to the payment of reasonable and entire compensation. Also, the government would have to reissue a compulsory license and again pay compensation under § 1498 each time it used a patent if the patent owner did not grant the government permissible use. Such continued payments for use could be costly. Further, the government may face expensive litigation from the private patent owner each time it issued a compulsory license for a patent like Tamiflu, due to possible changes in the estimation of “reasonable and entire compensation.”

D. Advantages and Disadvantages of Eminent Domain for the U.S. Government

As there are advantages and disadvantages in implementing a compulsory licensing scheme, there are also unique advantages and disadvantages to taking a medical patent such as Tamiflu through express condemnation.

1. *Advantages*

If the government actually condemned Tamiflu, it would become the official titleholder and no longer would be required to pay the patent owner or face litigation under § 1498 each time it used the patent under a compulsory license scheme.¹³⁸ Therefore, as the owner of a medical patent, the government might be able to navigate health emergencies more effectively because the patent would be readily available for use and production. Further, as owner of the patent, the government would no longer risk litigation alleging infringement. Also, through eminent domain, the government could create an effective stockpile of vaccines and medical patents that might aid in responding quickly to future pandemics or health emergencies.¹³⁹

However, the issue of just compensation, the second prong of the Takings Clause, may pose either an advantage or a disadvantage to the government depending on the circumstance. Specifically, if the government took the patent through eminent domain, just compensation could be higher or lower than the reasonable royalty rate for licensing the patent depending on the circumstances. Because a patent has yet to be taken through eminent domain, no legal standard exists as to what would

138. Kirby Forest Indus. v. United States, 467 U.S. 1, 4 (1984); see also Hawaii Hous. Auth. v. Midkiff, 467 U.S. 229, 233 (1984).

139. Russell, *supra* note 64.

constitute “just compensation” under these circumstances. Though lower federal courts have equated just compensation to a reasonable royalty rate, the Supreme Court has yet to determine what would, in fact, constitute just compensation should the government effectuate the taking of a patent. In jurisprudence related to real property, just compensation has been determined to be fair market value.¹⁴⁰ For patents, the fair market value would have to equal the total worth of the patent over its life, as well as take into account the fact that the taking would forever preclude the patent owner from earning profits from the patent. Thus, paying just compensation rather than licensing fees would be beneficial to the government if the court’s projected assessment of need and demand in determining just compensation underestimated the actual need for the patent therefore undervaluing the patent. Conversely, the government might overpay for the taking of a patent if the court overestimated the actual need for the patent. However, it is difficult to predict whether a patent will gain or lose value in the future, thus making it difficult for the government to determine whether to take it.

2. *Disadvantages*

Eminent domain also poses disadvantages to a government in urgent need of a patent. Primarily, as under a compulsory licensing scheme, once the government took the patent, it would still need to find a manufacturer to produce the patent for public consumption. This would add yet another cost to the acquisition of the patent. Also, in taking the patent from the private owner, the government would eliminate the power of the original owner to manufacture the patented product in conjunction with the government.¹⁴¹ Thus, potential production difficulties might make licensing more appealing than eminent domain in order to keep the original patent owner producing the patent.

Further, the threat of the government’s taking a patent like Tamiflu through eminent domain might create a disincentive for pharmaceutical companies to engage in research and development of medical patents. If a pharmaceutical company believes that it will lose a lucrative patent to the government, it might potentially focus its resources elsewhere.

Finally, the government would not be able to utilize eminent domain for a patent issued by a foreign country because the Takings Clause only applies to property within the United States.¹⁴² However, this is not a

140. *United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 (1979); *see also* Section III.B.2.

141. *Best v. Humboldt Placer Mining Co.*, 371 U.S. 334, 340 (1963).

142. *See* U.S. CONST., amend. V.

concern for Tamiflu because the United States Patent and Trademark Office issued the Tamiflu patent in 1996.¹⁴³

*E. Eminent Domain or Compulsory License:
Which is the Better Option?*

It may be most effective for the government to license certain types of patents through compulsory licensing and to take other types of patents under a theory of eminent domain. It is important to note that, no matter which option the government chooses to pursue, it must also find an entity to produce the medical patent once the government licenses or takes it.¹⁴⁴

Sometimes, the government might have no alternative but to issue a compulsory license for a medical patent. For example, a foreign government might hold, or have issued, a necessary patent. Because the Takings Clause applies solely to people and property within the United States, the government would not have the authority to take a foreign patent through eminent domain. In this situation, the government would likely license the patent through the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in which member nations can license a patent without permission from the patent owner if the infringing nation compensates the owner and receives consent from the nation that issued the patent.¹⁴⁵

However, assuming that the government has a choice between compulsory licensing and eminent domain, it must consider the unique circumstances surrounding its needs for the patent. If the government anticipated licensing the patent on a regular basis, it could become expensive to pay a royalty rate to the patent owner each and every time that it used the patent; this is particularly true in the case of Roche, which could leverage its market power over Tamiflu and charge high royalty rates. Thus, if the government anticipated an avian flu pandemic every few years and needed Tamiflu on a relatively regular basis, it should probably expressly condemn the patent and become the titleholder to Tamiflu. If it did so, then it would only have to pay just compensation at the fair market value once and could avoid paying a royalty rate that may increase unexpectedly over time whenever it used the patent. However, such a taking would only be beneficial if the amount of just compensation was lower than the royalty rates that the government would pay to the patent owner for a license over the life of the patent.

143. See U.S. Patent No. 5,763,483 (issued Dec. 27, 1996). Roche acquired the worldwide rights to develop and market Tamiflu from Gilead Sciences in 1996. Gilead Sciences of Foster City, CA still officially owns the patent. Roche, Factsheet Tamiflu, Nov. 17, 2006, http://www.roche.com/med_mbtamiflu05e.pdf.

144. See also Baker, *supra* note 48.

145. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Jan. 1, 1995, Article 31 (a), (h), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

Further, the government would also have to account for the cost of manufacturing the patented product without the aid of the patent owner's production. It would need to manufacture more of the medical patent than it would have had it licensed the patent because the patent owner's product would no longer be in the marketplace.

If the government truly believed that it would only need a patented product for a limited number of times or if the patent will shortly enter the public domain, then the government would be well served simply to license the patent and pay "reasonable and entire compensation" under § 1498. However, given the capacity of pandemics to strike quickly and without warning, the government might struggle to predict when and in what quantity it will need a patented medical treatment.

Depending on the circumstances surrounding the need for the government's use of a patent, it should at times issue a compulsory license and at other times exercise its power of eminent domain for medical patents such as Tamiflu. Therefore, the government will need to make a detailed financial assessment when deciding which option to pursue. However, such an assessment may be difficult since it may be complicated to determine *ex ante* what the courts will deem just compensation or reasonable and entire compensation.

CONCLUSION

Avian flu has the potential to become an international pandemic – and Roche's Tamiflu offers an antiviral treatment to combat it. Given the potential health impact, governments, both foreign and domestic, are analyzing their options for ensuring the safety of their populations should Roche choose not to issue permissive licenses to governments to produce generic versions of Tamiflu. The U.S. government has two key options by which it can use the Tamiflu patent in the event of a health crisis posed by avian flu.

Compulsory licensing is one such option for making sure that the government maintains an adequate supply of Tamiflu in the event of a pandemic. Further, 28 U.S.C. § 1498 gives domestic patent owners a remedy in the form of reasonable and entire compensation for the government's unauthorized appropriation of a patent.¹⁴⁶

The government has never taken a medical patent through eminent domain. However, despite the licensing schemes in place, the government, based on prior eminent domain jurisprudence, also has the ability to take a patent under the Fifth Amendment's Takings Clause, which states that private property shall only be taken for public use and with just compensation. Once the government has proven its public use or purpose

146. See also Cahoy, *supra* note 13, at 139.

and paid appropriate compensation, it takes title to the patent thus stripping the original patent owner of his rights to it.

Advantages and disadvantages exist in exercising either the power of eminent domain or issuing a compulsory license for a patent. More specifically, the financial repercussions of using a patent along with the foreseeability of potential pandemics will likely dictate which scheme the government will employ in order to gain use of the patent. Both offer the government the ability to use a patent and to protect the domestic population in the face of pandemic or another national emergency. While it remains to be seen how the world will respond to the potential threat of avian flu, the government should assess its potential assertion of eminent domain and use of compulsory licensing as these powerful tools could potentially help the government respond to a pandemic.

