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# COMPULSORY LICENSING OF GENE PATENTS IN THE PUBLIC INTEREST

*William G. Pagán*<sup>1</sup>

## I. Introduction

Recent decisions holding that gene patents are valid create a potential for placing research and development of genetic medical solutions at odds with public policy. The risk of populations being subject to a genetic epidemic is increasing. Nuclear proliferation, environmental degradation, and the pervasive adoption of new technologies are but a few examples of potential sources for wide-scale genetic damage to a population. Should such an epidemic occur, the exclusive right to practice certain gene patents could hold the lives of millions for ransom during a time of national crisis due to the importance of such patents in medical diagnostics and clinical treatment. Many governments, including the United States, have laws that allow their nations to grant a compulsory license to patents in such scenarios.<sup>2</sup> Relief against the United States is available when the federal government infringes a patent, but not to the same extent as would be available when a private party infringes a patent.<sup>3</sup> While other countries have wantonly exercised their power to grant compulsory licenses with little recompense back to patent holders who have made substantial investment in various medical advances,<sup>4</sup> the United

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2. Peter Maybarduk & Sarah Rimmington, *Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine?*, 35 AM. J. L. & MED. 323, 328 (2009).

3. B.E. Meyers & Co., Inc. v. United States, 47 Fed. Cl. 375, 380 (Fed. Cl. 2000) (“Because the government has the right to use patented inventions for the public good, infringement by the government is treated as an exercise of eminent domain, rather than tortious conduct, as would be the case with private litigants.”).

4. Aileen M. McGill, *Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public*

States offers a compromise between capricious government patent infringement and oppressive corporate exploitation of public crises.

This article discusses how compulsory licensing has been used internationally in response to public health issues of varying degrees and argues that the United States has a legal framework for patents that enables it to equitably balance between public health and private industry interests. This article also explores the patentability of isolated gene sequences in the United States and proposes that the breadth of exclusivity they could enjoy makes fair compulsory licensing solutions critical.

## II. The Threat of Genetic Damage to the Public

It wasn't long after the United States unveiled nuclear weapons in Hiroshima and Nagasaki during World War II that scientists were able to confirm a direct correlation between radiation and genetic damage.<sup>5</sup> Almost 70 years later, Japan would again suffer a major nuclear event after an earthquake and subsequent tsunami caused the release of radioactive materials from the Fukushima Nuclear Power Plant.<sup>6</sup> Such major nuclear disasters dramatically increase the incidence of various cancers and genetic inconsistencies in surrounding populations.<sup>7</sup> In the absence of a major nuclear event, there still remains a globally ubiquitous background level of radiation from naturally-occurring and man-made sources.<sup>8</sup> The effect of persistent low-dose background radiation on human health is not entirely known,<sup>9</sup> but the average annual exposure in the United States is increasing as a result of the adoption of new technologies.<sup>10</sup> A typical computed

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Health Crisis Under the Doha Declaration, 10 WAKE FOREST INTELL. PROP. L. J. 69, 89 (2009) (discussing Egypt's issuance of compulsory licenses to Viagra).

5. A. JAMIE CUTICCHIA, GENETICS: A HANDBOOK FOR LAWYERS 18 (2010).

6. Leonid Maksymov, *Environment Related Problems Caused by Tohoku Earthquake and Fukushima Nuclear Disaster*, JAPAN ENVIRONMENTAL EDUCATION FORUM, <http://www.jeef.or.jp/yelp/2012/02/environment-related-problems-caused-by-tohoku-earthquake-and-fukushima-nuclear-disaster/> (last visited Jan. 3, 2012).

7. *Id.*

8. Linnea E. Wahl, *Environmental Radiation*, HEALTH PHYSICS SOCIETY (Jan. 2010), [http://hps.org/documents/environmental\\_radiation\\_fact\\_sheet.pdf](http://hps.org/documents/environmental_radiation_fact_sheet.pdf).

9. *Id.*

10. Mark Fishetti, *Exposed: Medical Imaging Delivers Big Doses of Radiation*, SCIENTIFIC AMERICAN (May 2011), <http://www.scientificamerican.com/article.cfm?id=exposed-graphic-science>.

tomography scan (popularly known as a “CT scan”)<sup>11</sup> of the abdomen, for example, subjects the body to approximately 8 millisieverts of radiation.<sup>12</sup> By contrast, Japanese atomic bomb survivors have presented a small, but demonstrable, increase in cancer mortality risk after exposure to between 5 and 20 millisieverts.<sup>13</sup>

### III. Gene Patents

The United States Constitution empowers inventors to be granted “the exclusive Right to their respective Writings and Discoveries” for a limited time “to promote the Progress of Science and useful Arts.”<sup>14</sup> By obtaining a patent, an inventor is granted “the right to exclude others from making, using, offering for sale,” importing or selling anywhere in the United States either the invention, or products made therefrom.<sup>15</sup> This “right to exclude” typically lasts for twenty years, extending from the date the patent application is filed,<sup>16</sup> and creates a monopoly power that allows the patent holder “to set prices with relative impunity.”<sup>17</sup> This exclusive right often benefits the public since it incentivizes companies to bear the risk and expense of researching and developing new technologies.<sup>18</sup> Patents also protect innovators from those who would opportunistically copy scientific and technical breakthroughs without bearing any portion of the initial development costs.<sup>19</sup> To qualify for patent protection, however, a new discovery must qualify as a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>20</sup> The extent to which isolated genes can

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11. See U.S. Food and Drug Admin., *What is Computed Tomography?*, FDA.GOV (Jun. 6, 2012), <http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115318.htm> (A CT scan passes x-ray radiation through the body to generate an image of the body’s internals.).

12. U.S. Food and Drug Admin., *Radiation-Emitting Products*, FDA.GOV (Aug. 6, 2009), <http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115329.htm>.

13. *Id.*

14. U.S. CONST. art. I, § 8, cl. 8.

15. 35 U.S.C. § 154 (2012).

16. *Id.*

17. JOHN GLADSTONE MILLS III ET AL., PATENT LAW BASICS § 1:4 (2011).

18. Bratislav Stankovic & Mirjana Stankovic, *The Selfish Patent*, 3 CASE W. RESERVE J. L. TECH. & INTERNET 195, 208 (2012).

19. MILLS III, *supra* note 17, at § 1:3.

20. 35 U.S.C. § 101 (2012).

be considered patent-eligible subject matter within this definition has been the subject of much debate.<sup>21</sup>

The case *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad I)*, held that isolated genes are patentable, overturning the decision of the District Court.<sup>22</sup> This decision, however, was vacated and remanded for reconsideration<sup>23</sup> in view of the recent Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Prometheus)*.<sup>24</sup> Upon reconsideration, the Federal Circuit held that “Mayo does not control the question of patent-eligibility of” isolated DNA molecules.<sup>25</sup> The Federal Circuit’s second *Myriad* decision (*Myriad II*) provides the most current analysis on the patentability of isolated genes.<sup>26</sup>

In *Myriad I*, Plaintiffs challenged the validity of Defendants’ patents related to the isolation of the BRCA1 and BRCA2 genes as “patent-ineligible products of nature under [35 U.S.C.] § 101”<sup>27</sup> since such molecules “retain the same nucleotide sequence as native DNAs.”<sup>28</sup> The court disagreed with the Plaintiffs and the court below, holding that “the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material that embodies it.”<sup>29</sup> The Court held that what makes isolated DNA molecules patentable is neither “their informational content,” nor the “molecules in terms of their uses” but that “genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their

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21. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), reh'g denied (Sept. 13, 2011), reh'g denied (Sept. 16, 2011), cert. granted, judgment vacated sub nom. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) and opinion vacated, appeal reinstated, 467 F. App'x 890 (Fed. Cir. 2012). (This case is herein referred to as *Myriad I*).

22. *Id.*

23. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

24. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012). (This case is herein referred to as *Prometheus*).

25. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1325 (Fed. Cir. 2012), *petition for cert. filed*, 2012 WL 4502947 (U.S. Sept. 25, 2012) (No. 12-398). (This case is herein referred to as *Myriad II*).

26. *Id.*

27. *Ass'n for Molecular Pathology*, 653 F.3d at 1334. (*Myriad I*).

28. *Id.* at 1353.

29. *Id.*

functions.”<sup>30</sup> Thus, “[b]ecause isolated DNAs . . . have a markedly different chemical structure compared to native DNAs[,]” the court found isolated DNAs to be patent-eligible.<sup>31</sup>

The Supreme Court vacated the *Myriad I* decision and asked the Federal Circuit to reconsider its holding in light of the *Prometheus* decision.<sup>32</sup> In *Prometheus*, Plaintiffs challenged the validity of Defendant’s patent claims that taught improvements to the way autoimmune diseases can be treated using thiopurine drugs.<sup>33</sup> The key claim at issue argued that a physician could improve treatment by taking the following steps: (1) administering a small amount of 6-thioguanine, (2) monitoring the extent to which a patient’s body metabolizes the drug, and (3) giving either more or less of the drug in a subsequent dose so as to keep the amount of drug in the patient’s blood stream below a toxicity level and above a minimum efficacy level.<sup>34</sup> The Supreme Court held that this claim simply tells a doctor to apply relevant, natural laws and take “conventional” and “routine” steps thereafter.<sup>35</sup> The court thus held that these steps, “when viewed as a whole, add nothing significant beyond the sum of their parts taken separately,” and held Defendant’s claim invalid.<sup>36</sup>

The Federal Court in *Myriad II*, however, held that *Prometheus*:  
does not control the question of patent-eligibility of [isolated DNA molecules because they are] expressly authorized as suitable patent-eligible subject matter in [35 U.S.C.] § 101. [Specifically, the court held that] [t]he isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity.<sup>37</sup>

Indeed, the decision in *Prometheus* was silent as to claims related to genes as compositions of matter, dealing instead with method claims in the application of drugs.<sup>38</sup> The consequence of holding that an isolated gene is patentable is that the holder of such a patent would

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30. *Id.*

31. *Id.*

32. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

33. *Mayo Collaborative Servs.*, 132 S. Ct. at 1294-95. (*Prometheus*).

34. *Id.* at 1295.

35. *Id.* at 1297-98.

36. *Id.* at 1298.

37. *Ass’n for Molecular Pathology*, 689 F.3d at 1325. (*Myriad II*).

38. *Mayo Collaborative Servs.*, 132 S. Ct. at 1295. (*Prometheus*).

have the right to exclude “anyone from working with” the claimed isolated gene.<sup>39</sup>

At issue in the *Myriad* cases were the isolated BRCA1 and BRCA2 genes, which are useful in determining whether a woman is at increased risk of breast and/or ovarian cancer.<sup>40</sup> Such broad patent claims, when exclusively licensed, have been blamed for delaying the emergence of relevant diagnostic tests and the development of markets therefrom.<sup>41</sup> A case study concluded in 2010 at the Duke Institute for Genome Sciences & Policy contrasted exclusively licensed gene test markets with non-exclusively licensed gene test markets.<sup>42</sup> The results suggested that the science for non-exclusively licensed tests was more advanced and enjoyed a healthier market.<sup>43</sup> If the purpose of patents is “[t]o promote the Progress of Science and useful Arts,”<sup>44</sup> then this case study suggests that a strict patent enforcement model is not-optimal.<sup>45</sup>

Other studies, however, have found such concerns to be overblown.<sup>46</sup> A study by the National Academy of Sciences in 2003 found that “asserting exclusivity could confer a benefit by increasing the incentives to do research to discover the target first.”<sup>47</sup> This might then motivate further investment in that research.<sup>48</sup> A second study conducted by the National Academy of Sciences in 2005 then found that patents caused only 3% of respondents to abandon a research project.<sup>49</sup>

Gene patenting proponents suggest that a deleterious effect to the science and market for biotechnology is nothing to be worried about and that such fear is “fueled by groups with a certain political agenda that is antithetical to patenting.”<sup>50</sup> However, the effects of an

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39. Ass’n for Molecular Pathology, 689 F.3d at 1326. (*Myriad II*).

40. *Id.* at 1309.

41. Kendall Morgan, *Patents Block Competition, Slow Innovation in Gene Testing*, DUKE INSTITUTE FOR GENOME SCIENCES & POLICY (Apr. 14, 2010), <http://www.genome.duke.edu/press/news/post.php?s=2010-04-14-patents-block-competition-slow-innovation-in-gene-testing>.

42. *Id.*

43. *Id.*

44. U.S. CONST. art. I, § 8, cl. 8.

45. Morgan, *supra* note 41.

46. Stankovic & Stankovic, *supra* note 18 at 206.

47. *Id.* at 207.

48. *Id.*

49. *Id.*

50. *Id.* at 208.

exclusive right to sell in the midst of a public health epidemic have already been observed in other countries.<sup>51</sup> In 2001, when almost four million South Africans were infected by HIV, necessary AIDS-fighting drug cocktails that could have been sold for as little as \$350 (U.S. dollars) per person, per year were instead sold for \$10,000 per person, per year due to patent-protected pricing.<sup>52</sup> The Coalition of South African Trade Unions accused drug company patents of “hold[ing] at ransom the health of [their] nation.”<sup>53</sup> After much international debate, South Africa’s solution was to enact legislation permitting compulsory licensing.<sup>54</sup> Compulsory licensing allows the state to license a patent without the patent holder’s permission.<sup>55</sup> To address the need for countries to protect against being held hostage by strict intellectual property protections, the practice of compulsory licensing would become officially endorsed by the World Trade Organization (“WTO”) under the Doha Declaration.<sup>56</sup>

#### IV. The TRIPS Agreement and Doha Declaration

Members of the WTO, such as the United States, are required to provide a minimum level of intellectual property protection to trading partners under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).<sup>57</sup> The initial goal of TRIPS was to guarantee patent protections among international trade partners and establish a means for enforcement.<sup>58</sup> However, the HIV/AIDS pandemic, combined with exorbitant patent-protected drug prices, forced

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51. Jonathan King, *Life Patents and AIDS Drug Access*, GENEWATCH (November 2001), <http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pageId=164>.

52. *Id.*

53. *Id.*

54. James Thuo Gathii, *The Legal Status of the Doha Declaration on Trips and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. & TECH. 291, 312 (2002).

55. Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS MED. (Jan. 2012), <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154>.

56. Michael A. Santoro, *Human Rights and Human Needs: Diverse Moral Principles Justifying Third World Access to Affordable HIV/AIDS Drugs*, 31 N. C. J. INT’L L. & COM. REG. 923, 930 (2006).

57. Gathii, *supra* note 54, at 294.

58. *Id.*

nations to revisit TRIPS in 2001.<sup>59</sup> The result of this special session of the WTO was the Doha Declaration.<sup>60</sup>

The Doha Declaration emphasizes that under TRIPS, countries have “the right to grant compulsory licenses” in times of national emergency.<sup>61</sup> What constitutes a national emergency is left to members of the WTO to decide, but “public health crises,” such as the HIV/AIDS pandemic, can qualify.<sup>62</sup> Since 2001, compulsory licenses have been issued on at least twelve separate occasions worldwide.<sup>63</sup> Even the United States, who was initially opposed to a separate WTO declaration supporting compulsory licensing,<sup>64</sup> used the threat of compulsory licensing to force German pharmaceutical company Bayer into selling the Ciproflaxin antibiotic at a deep discount in the wake of the September 11, 2001 terrorist attacks and the subsequent Anthrax scare.<sup>65</sup> The potential for abuse of this mechanism is perhaps best illustrated by Egypt’s authorization of a compulsory license to any company seeking to manufacture Viagra, a drug patented by Pfizer that is used to treat erectile dysfunction.<sup>66</sup> As a consequence of Egypt’s use of compulsory licensing for Viagra, Pfizer abandoned its plans to build a manufacturing facility in Egypt, and overall Foreign Direct Investment (FDI) in Egypt plummeted.<sup>67</sup> Thus, an overly-liberal patent-breaking scheme enables the state to deprive patent holders of the fair value of their patents<sup>68</sup> and can strongly deter foreign investment.<sup>69</sup>

## V. Remedies Available for Government Infringement

When the United States infringes or authorizes infringement upon a patent, relief is available under 28 U.S.C. § 1498.<sup>70</sup> An action

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59. *Id.* at 296.

60. *Id.* at 292.

61. Santoro, *supra* note 56, at 930.

62. *Id.*

63. Beall & Kuhn, *supra* note 55 (Table 1 of this reference shows the incidents and countries that have issued compulsory licenses to address diseases from 2001 to 2010.).

64. Gathii, *supra* note 54, at 296-97.

65. McGill, *supra* note 4, at 87.

66. *Id.* at 90.

67. *Id.*

68. *Id.* at 87.

69. *Id.* at 90.

70. 28 U.S.C. § 1498 (2012).

against the United States for patent infringement must be brought in the Court of Federal Claims, and any third parties who are infringing under the Government's consent are immune from suit.<sup>71</sup>

In a typical suit for patent infringement filed against a private party, tort principles, such as the willfulness or reasonableness of the act, can enhance the damages award by up to three times.<sup>72</sup> This is not the case in an infringement action against the United States.<sup>73</sup> Federal case law has established that “the government has the right to use patented inventions for the public good,” and as such, infringement actions brought against the United States are “treated as an exercise of eminent domain, rather than tortious conduct.”<sup>74</sup> Thus, the Government “is not an ordinary infringer, but rather a compulsory, nonexclusive licensee.”<sup>75</sup> As an act of eminent domain, the Government's infringement cannot be enjoined by injunctive relief.<sup>76</sup> Attorney fees and costs are also not available if the Government's actions are considered by the Court to be “substantially justified” or if such an award would be unjust.<sup>77</sup> Essentially, if the United States wants to use an isolated gene that it knows is patented without a license from the patent holder, it could do so willfully and continually without incurring an equitable or punitive penalty.<sup>78</sup>

## VI. Reasonable Recovery Due to Government Infringement

When the Government takes a compulsory license, the patent holder is entitled to “recovery of his reasonable and entire compensation for such use and manufacture.”<sup>79</sup> The preferred method for calculating this recovery is to determine a “reasonable royalty for the license” and apply an interest rate that accrues from the date of the

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71. David R. Lipson, *We're Not Under Title 35 Anymore: Patent Litigation Against the United States Under 28 U.S.C. § 1498(a)*, 33 PUB. CONT. L. J. 243, 244 (2003).

72. *Id.* at 257.

73. *B.E. Meyers & Co., Inc. v. United States*, 47 Fed. Cl. 375, 380 (Fed. Cl. 2000).

74. *Id.*

75. *Standard Mfg. Co., Inc. v. United States*, 42 Fed. Cl. 748, 757 (Fed. Cl. 1999).

76. *Martin v. United States*, 99 Fed. Cl. 627, 632 (Fed. Cl. 2011).

77. 28 U.S.C. § 1498 (2012).

78. *B.E. Meyers & Co.*, 47 Fed. Cl. at 380.

79. 28 U.S.C. § 1498 (2012).

taking to the date of payment in order to offset any payment delay.<sup>80</sup> If the infringed patent has already been licensed to others for a royalty, then the rate others enjoy is typically what will be adopted as reasonable.<sup>81</sup> However, given that gene patents are commonly used to exclude all competitors, or are exclusively licensed to a single practitioner,<sup>82</sup> computation of a reasonable royalty in such cases may need to be made on a case-by-case basis.<sup>83</sup>

In the absence of an existing royalty upon which to base recovery, the Court imagines a hypothetical encounter between a willing buyer and willing seller to determine what a negotiated licensing agreement would have been between the parties.<sup>84</sup> The actual willingness of the parties to negotiate is irrelevant in this determination.<sup>85</sup> The ability of the patent holder to exact an exorbitant sum from private users under normal market conditions is also irrelevant since the goal of a reasonable royalty is not to determine the sum that the market would have yielded among private users.<sup>86</sup> Rather, the goal of a reasonable royalty is to fulfill the “just compensation clause of the Fifth Amendment” pertaining to eminent domain takings by the Government.<sup>87</sup> Therefore, the patent holder’s recovery will be based on “what the owner has lost, not what the taker has gained.”<sup>88</sup>

Determining a royalty depends on determining a royalty base, which represents the entire market value of the infringing product,<sup>89</sup> and a royalty rate, which represents a percentage of the royalty base to which the patent holder is entitled.<sup>90</sup> The royalty base is not intended to “include items that merely constitute spare or additional parts or supplies.”<sup>91</sup> However, the royalty base shall include items that have a “financial and marketing dependence on the patented

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80. *Decca Ltd. v. United States*, 640 F.2d 1156, 1167-68 (Ct. Cl. 1980).

81. *Tektronix, Inc. v. United States*, 552 F.2d 343, 347 (Ct. Cl. 1977) opinion modified on denial of reh’g, 557 F.2d 265 (Ct. Cl. 1977).

82. *Morgan*, *supra* note 41.

83. *Tektronix*, 552 F.2d at 347.

84. *Id.* at 349.

85. *Id.*

86. *Id.* at 351.

87. *Id.*

88. *Leesona Corp. v. United States*, 599 F.2d 958, 969 (Ct. Cl. 1979) (citing *United States v. Chandler-Dunbar Co.*, 229 U.S. 53, 76 (1913)).

89. *Decca Ltd.*, 640 F.2d at 1175.

90. *Id.*

91. *Brunswick Corp. v. United States*, 36 Fed. Cl. 204, 210-11 (Fed. Cl. 1996) *aff’d*, 152 F.3d 946 (Fed. Cir. 1998).

item.”<sup>92</sup> Since a gene patent can cover the gene itself, the manner in which it is produced, the apparatus that administers the genetic test, and the diagnostic process itself, there might not be anything of significant value that is excluded from the royalty base.<sup>93</sup> When the infringed patent contributes such a dramatic amount of the total product’s value, the royalty base could very well be all sales revenue of the infringing product.<sup>94</sup>

The computation of a royalty rate is far more complex and heavily leverages the fifteen factors laid out in the case *Georgia-Pacific Corp. v. U.S. Plywood Corp.*<sup>95</sup> Given the multivariate and fact-specific nature of a royalty rate analysis, perhaps the best view into what rates Courts have held to be reasonable can be found by examining what Courts have awarded in the past.<sup>96</sup> In a study of all cases awarding reasonable royalties in trial verdicts between 1982 and mid-2005, biotechnology cases averaged 9.6%.<sup>97</sup> This rate tends to be substantially higher than what would actually be negotiated.<sup>98</sup> The nature of this study tended to reflect amounts awarded in court opinions rather than by jury verdicts,<sup>99</sup> which is helpful in this analysis since actions against the Government in the Court of Federal Claims are exclusively bench trials.<sup>100</sup> It should be noted, however, that this study is not exclusive to claims against the government,<sup>101</sup> so these rates may be higher than what should be expected in an action under 28 U.S.C. § 1498.<sup>102</sup>

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92. *Leesona Corp.*, 599 F.2d at 974.

93. U.S. Patent No. 5,747,282 (filed June 7, 1995).

94. *The Boeing Co. v. United States*, 86 Fed. Cl. 303, 316. (Fed. Cl. 2009).

95. JEFFREY A. FINN, *PATENT LITIGATION* § 14:2.6 (Laurence H. Pretty ed., 2d ed. 2012) (citing *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) *modified sub nom.* *Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971)).

96. Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 *TEX. L. REV.* 1991, 2030-32 (2007).

97. *Id.*

98. *Id.* at 2032-33 n.134 (explaining that negotiated rates tend to be substantially lower than litigated rates).

99. *Id.* at 2031.

100. R.C.F.C. Rule 38 (2012).

101. Lemley & Shapiro, *supra* note 96, at 2049.

102. *Tektronix*, 552 F.2d at 351.

Even so, a 10% royalty rate against the Government is not unprecedented.<sup>103</sup> In *Gargoyles, Inc. v. United States*, the Court awarded a 10% royalty rate based on “the unwillingness of Gargoyles to license their patent, the obvious value the patent holds in sustaining Gargoyles as a viable, profitable company, and the fact that the government’s actions placed [the infringing government contractor] in a very favorable position from which to compete more effectively with Gargoyles in the future.”<sup>104</sup> Since these conditions are also widespread for institutions that develop gene patents, a 10% royalty rate for government infringed gene patents might be reasonable to expect.<sup>105</sup>

By contrast, in the case *The Boeing Co., Inc. v. United States*, a royalty rate of 1.25% was deemed reasonable since there was evidence that Boeing had offered this royalty rate to various manufacturers for the patent at issue.<sup>106</sup> This reinforces the Court’s preference toward using existing deals to determine a reasonable rate, rather than formulating their own rate.<sup>107</sup> This 1.25% royalty rate, however, was proposed with the entire infringing \$1.24 billion contract acting as the royalty base.<sup>108</sup> The award to Boeing of \$16.9 million is thus viewed as a shift toward enforcing greater Government liability despite the seemingly small royalty rate determination.<sup>109</sup> A trend toward greater Government liability, in combination with the Court’s willingness to compute high royalty rates as in *Gargoyles* decision, implies that a gene patent subjected to a compulsory license could be deserving of a substantial award.<sup>110</sup>

## VII. Conclusion

Pursuing relief under 28 U.S.C. § 1498 might be the most universally just method for patent holders to be compensated when the United States infringes a patent. A patent system that bars any form

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103. *Gargoyles, Inc. v. United States*, 37 Fed. Cl. 95, 108 (Fed. Cl. 1997), *aff’d*, 113 F.3d 1572 (Fed. Cir. 1997).

104. *Id.*

105. Morgan, *supra* note 41.

106. *The Boeing Co.*, 86 Fed. Cl. at 312-13.

107. *Decca Ltd.*, 640 F.2d at 1167-68.

108. Timothy R. Wyatt, *In Search of “Reasonable Compensation”: Patent Infringement by Defense Contractors with the Authorization and Consent of the U.S. Government*, 20 FED. CIR. B. J. 79, 98 (2010).

109. *Id.* at 97-98.

110. *Gargoyles, Inc.*, 37 FED. Cl. at 108.

of compulsory licensing would give private companies the authority to completely withhold medical treatment from the public or set outrageous prices that make treatment available only to the very rich. In such a system, a sufficiently serious epidemic could kill millions of Americans and create widespread civil unrest as the desperate poor protest, riot, or worse. On the other hand, a patent system that liberally breaks patents to make cheap generic treatments available to the public would demotivate biotechnology companies from researching and developing these necessary treatments in the first place. Consequently, the United States would lose the ability to export valuable products and services, the American economy would suffer, and American scientists would find themselves increasingly unemployed as biotechnology companies move their research to foreign countries.

28 U.S.C. § 1498 allows patent holders to bring a patent infringement action against the Government so that the Court of Federal Claims can provide a check against the tyranny of these two extremes. There is ample case law demonstrating that the United States is willing and legally-enabled to take compulsory licenses for patents in the public interest. The international community also supports taking compulsory licenses in times of a true national health crisis because it is necessary to protect the public from companies that would jeopardize public health to maximize profits. Given the breadth of patent claims for isolated genes as compositions of matter, it may be just a matter of time before the taking of a compulsory patent becomes necessary. The application of 28 U.S.C. § 1498 by the Court, however, has also protected the interests of private industry in the past. While damages against the United States are strictly monetary and are limited to just compensation under an eminent domain takings theory of recovery, recent royalty determinations seem to be increasingly favoring the patent holder. As such, patent holders should feel secure in their decision to research and develop patents in the United States, because on the off chance that the Government decides a compulsory license is necessary, the Court has historically ordered monetary recovery that is reasonable to protect their investment.