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# The Enforcement of Patent Rights in Government Funded Inventions

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In recent days, increased attention has been given to government funding on the national and state level, for example, through investment in our country's infrastructure. Some of those resources may be directed to research and development, spurring innovation in the private sector. The parties who accept government contracts or other federal grants should consider how such funds could lead to the development of patentable inventions and how patents obtained on those inventions may ultimately be enforced. This article is the second installment in a two-part series addressing the acquisition and litigation of patent rights directed to inventions developed with the support of government grants or contracts.

In the first article, we provided a brief overview of the Bayh–Dole Act, which controls the allocation of intellectual property rights in inventions developed using federal funding. In this second article, we explore the considerations and requirements when bringing or facing an enforcement action based on those patents.

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## I. Infringement Actions

### A. Enforcement

The Bayh–Dole Act provides a path whereby a recipient of government funding may “elect to retain title” to “any invention . . . conceived or first actually reduced to practice in the performance of work under a funding agreement.”<sup>2</sup> After retaining title to such a government-funded invention, the owner may pursue a U.S. patent, and if successful, obtain the right to exclude others from practicing the invention.<sup>3</sup> The federal government, however, is granted “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”<sup>4</sup> Further, if the owner fails to comply with the requirements of the Act, the funding agency has discretion to take title.<sup>5</sup>

Nonexclusive license holders generally have no standing to bring an infringement action. As the Federal Circuit has explained, “[w]here a patentee makes an assignment of all significant rights under the patent, such assignee may be deemed the effective ‘patentee’ under the statute and has standing to bring a suit in its own name for infringement,” but “[a]ny other party seeking enforcement of the patent can sue, if at all, only with the patentee or in the name of the patentee.”<sup>6</sup> With respect to nonexclusive license holders, such as the funding agency, “[i]t is well settled that a non-exclusive licensee of a patent has only a personal and not a property interest in the patent.”<sup>7</sup> For this reason, private patent owners under the Bayh–Dole Act are able to enforce their patents against other private party infringers in federal district court without the involvement of the federal government as a nonexclusive licensee.<sup>8</sup>

In the case where a federal government agency obtains title to an invention, it may “grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to [certain provisions] as determined appropriate in the public interest.”<sup>9</sup> In appropriate cases, the licensee is

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permitted to enforce the patent without the participation of the United States as the patent owner and licensor.<sup>10</sup>

## B. Inventor's Rights

Before asserting infringement of a patent subject to the Bayh–Dole Act, a patent owner should ensure that they effectively obtained rights in the invention from the inventors. In *Board of Trustees of The Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, the Supreme Court held that the Bayh–Dole Act alone does not “expressly deprive[] [inventors] of their interest in federally funded inventions.”<sup>11</sup>

That case involved an HIV diagnostic method developed by Stanford research fellow Dr. Mark Holodniy. Holodniy’s research was funded in part by the National Institutes of Health (NIH) through Stanford University but he developed the new diagnostic method while conducting research at facilities owned by Cetus, a small California research company collaborating with Stanford on HIV research.<sup>12</sup> As a condition for using Cetus’ facilities, Holodniy assigned to Cetus his “right, title and interest in each of the ideas, inventions and improvements” made there.<sup>13</sup> Despite Holodniy’s assignment to Cetus, Stanford disclosed his invention to NIH, notified the agency that Stanford had elected to retain title, and obtained a patent on Holodniy’s diagnostic method.<sup>14</sup> Meanwhile, Cetus’s assets, including its rights in Holodniy’s research, were acquired by Roche Molecular Systems, which successfully commercialized Holodniy’s method.<sup>15</sup> When Stanford filed a patent infringement action against Roche, Roche argued that it had rights to the invention via Holodniy’s assignment to Cetus. Stanford contended that Holodniy “had no rights to assign because the University’s HIV research was federally funded, giving the school superior rights in the invention under the Bayh–Dole Act.”<sup>16</sup>

The Supreme Court reasoned that because “[y]ou cannot retain something unless you already have it,”<sup>17</sup> the Bayh–Dole Act’s mechanism to allow a contractor to “elect to *retain* title’ . . . does not *vest* title.”<sup>18</sup> Therefore, to *retain* patent rights in a government-funded invention under the Bayh–Dole Act, an employer should first *obtain* those rights by assignment from the inventor. Because Stanford had not done so, the Court affirmed the decision of the Federal Circuit, remanding the case with instructions to dismiss the infringement claim.<sup>19</sup>

## C. Compliance Issues

While certain provisions of the Bayh–Dole Act may allow the federal government to receive title to a contractor’s invention,<sup>20</sup> title is not automatically forfeited.<sup>21</sup> For

example, the Act states that “the Federal Government may receive title to any subject invention not disclosed to it within” “a reasonable time after it becomes known to the contractor personnel responsible for the administration of patent matters.”<sup>22</sup> For the government to receive title, however, certain procedures are required. For example, according to a procedural regulation established by the Department of Commerce and followed by most agencies, transferring title to the funding federal agency (where a contractor has failed to disclose or elect title) requires a written request.<sup>23</sup> In the absence of such a request by the federal agency, title to the invention remains with the inventor or his employer, even if the Bayh–Dole Act has been violated. As the Federal Circuit explained in *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*,

When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish its title and invoke forfeiture.<sup>24</sup>

*Central Admixture* involved a patent claiming a chemical solution used during heart surgery, which was developed under a grant from NIH to the University of California.<sup>25</sup> In accordance with the Bayh–Dole Act, when the University elected to abandon its interest in the pending application, NIH granted a request from the inventor that he be allowed to pursue the application in his personal capacity on condition that the inventor send NIH an executed copy of a license granting the federal government “a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes.”<sup>26</sup> The inventor failed to execute the requested license to the federal government.<sup>27</sup> He successfully obtained a patent, however, and granted an exclusively licensed to Central Admixture Pharmacy Service (CAPS).<sup>28</sup> When CAPS brought an infringement suit (to which the inventor was later joined) against another private party, the defendants argued the claims should be dismissed because the inventor had failed to execute the license required by NIH under the Bayh–Dole Act and therefore neither he nor his licensee had rights to the patent.<sup>29</sup> The Federal Circuit disagreed, finding that “NIH [had] shown no interest in” “exercise[ing] its discretion to void [the inventor’s] title in the . . . patent” and, thus, “[t]he two plaintiffs together own all present rights in the . . . patent.”<sup>30</sup> “The defendants here have no basis,” the court explained, “to challenge the government’s discretion in not invoking forfeiture.”<sup>31</sup>

Thus, under *Central Admixture*, a patent owner's failure to comply with the requirements of the Bayh–Dole Act does not void his patent rights and does not create a defense to patent infringement.<sup>32</sup>

## D. Government License Defense

Where the government is sued for patent infringement in the Court of Federal Claims, the Bayh–Dole Act may provide a government license defense.<sup>33</sup> As the court in *Madey v. Duke University* concluded, however, “the Government License defense may not be asserted by a private party in a patent infringement suit.”<sup>34</sup> Nevertheless, the *Madey* court also determined that a similar defense can be raised by a private party based on 28 U.S.C. § 1498(a) “where a private party’s use of a patented invention is ‘for the United States,’ which includes any use ‘for the Government’ and with the ‘authorization or consent of the Government.’”<sup>35</sup>

## II. No Private Cause of Action for Failure to Comply with Bayh–Dole Act

Courts have held that the Bayh–Dole Act does not create a private right of action, either explicitly or implicitly. For example, the court in *Platzer v. Sloan-Kettering Institute for Cancer Research*, held that no

private cause of action exists under the Bayh–Dole Act granting a contractor an exclusive title to inventions developed through federal funding or requiring that the contractor share royalties with the inventor.<sup>36</sup> And Complaints brought by private parties to establish patent ownership under the Bayh–Dole Act have been dismissed.<sup>37</sup> The same principal applies to would-be counterclaims and affirmative defenses.<sup>38</sup> In some instances, courts have exercised jurisdiction over disputes involving patents subject to the Bayh–Dole Act, including as to patent ownership; however, in those cases the basis of the action was not the Bayh–Dole Act itself.<sup>39</sup> As the Southern District of California explained, “In short, no court has concluded that a private right of action exists under Section 202. In fact, every court that has considered the issue has reached the opposite conclusion.”<sup>40</sup>

## III. Conclusion

The Bayh–Dole Act allows private parties to retain ownership and enforcement rights over inventions developed using federal dollars, largely without the interference of the federal government. Strict compliance with the Act is the best way to ensure retention of rights. However, rights may still remain for non-compliant parties in appropriate circumstances. Parties dealing with patents implicated by the Bayh–Dole Act should carefully evaluate their positions.

1. The authors are attorneys at the intellectual property firm of Finnegan, Henderson, Farabow, Garrett & Dunner LLP. This article is for informational purposes, is not intended to constitute legal advice, and may be considered advertising under applicable state laws. This article is only the opinion of the authors and is not attributable to Finnegan, Henderson, Farabow, Garrett & Dunner LLP, or the firm’s clients.
2. 35 U.S.C. § 202(a); § 201(e).
3. § 202(c)(3); §§ 271, 281 (“A patentee shall have remedy by civil action for infringement of his patent.”); 100 (“patentee” includes successors in title to the patentee).
4. § 202(c)(4).
5. § 203.
6. *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1030 (Fed. Cir. 1995).
7. *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1147 (Fed. Cir. 2003) (quoting *In re CFLC, Inc.*, 89 F.3d 673, 679 (9th Cir. 1996)).
8. *See, e.g., Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614, (D.N.J. 1992) (holding that the exclusive licensee of a patent under the Bayh–Dole Act (35 U.S.C. §§ 200 to 204), had standing to maintain an action for infringement in its own name without joining as a necessary party the contractor/patent owner which granted the license, where the license agreement expressly provided the licensee substantial rights of exclusivity, to transfer rights, and to institute a lawsuit under the patent).
9. 35 U.S.C. § 207(a)(2).
10. *Nutrition 21 v. United States*, 930 F.2d 862, 867 (Fed. Cir. 1991) (“In sum, we hold that pursuant to 35 U.S.C. § 207(a)(2) and the patent license and enforcement agreement involved here, Nutrition 21 can maintain this action against Thorne without the U.S. as a party.”); *Cent. Inst. for Experimental Animals v. Jackson Lab’y*, No. C-08-05568 RMW, 2010 WL 147935, at \*2 (N.D. Cal. Jan. 12, 2010) (“35 U.S.C. § 207 authorizes the grant of enforcement rights to nonexclusive, exclusive, or partially exclusive licensees.” (citing *Nutrition 21*, 930 F.2d at 865 n.7)).
11. *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 787 (2011) (“Nowhere in the Act is title expressly vested

- in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions.”).
12. *Id.* at 780–81.
13. *Id.* at 781.
14. *Id.* at 783.
15. *Id.* at 781–82.
16. *Id.* at 783.
17. *Id.* at 789.
18. *Id.* (quoting 35 U.S.C. § 202(a)).
19. *Id.* at 793, 784.
20. 35 U.S.C. § 202(c).
21. *Cent. Admixture Pharmacy Servs.*, 482 F.3d at 1353.
22. 35 U.S.C. § 202(c)(1).
23. 37 C.F.R. § 401.14(d).
24. *Cent. Admixture Pharmacy Servs.*, 482 F.3d at 1352–53.
25. *Id.* at 1349–51.
26. *Id.* at 1351.
27. *Id.*
28. *Id.* at 1351, 1349.
29. *Id.* at 1352.
30. *Id.* at 1353.
31. *Id.*
32. *Id.* (“Absent any action by NIH, Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid.”).
33. *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 611 (M.D.N.C. 2006) (“Although the terms of the Bayh–Dole Act and the provisions incorporated into federal funding agreements do not specify how the Government License may be raised, courts have recognized that the license may be raised by the Government as an affirmative defense when the Government is sued for patent infringement in the Court of Federal Claims.” (citing *Tech. Dev. Corp. v. United States*, 597 F.2d 733, 745–46 (Ct. Cl. 1979); *Technitrol, Inc. v. United States*, 440 F.2d 1362 (Ct. Cl. 1971))).
34. *Id.* at 615.

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35. *Id.* at 614.
36. *Platzer v. Sloan-Kettering Institute for Cancer Research*, 787 F. Supp. 360, 22 U.S.P.Q.2d 1845 (S.D.N.Y. 1992), *aff'd without opinion*, 983 F.2d 1086 (Fed. Cir. 1992).
37. *Vartanian v. Gen. Elec. Co.*, 232 F.3d 911 (Fed. Cir. 2000).
38. See *Network Signatures, Inc. v. Citibank, N.A.*, 2008 WL 5216032, at \*4 (C.D. Cal. 2008) (holding that counterclaims are barred under the Act as private rights of action no less than primary claims).
39. *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 138 (D. Conn. 2004), *aff'd*, 184 F. App'x 21 (2d Cir. 2006) (“The fact that individuals may not bring suit

- directly under the Bayh–Dole Act does not mean, however, that federal agencies assume exclusive jurisdiction over all disputes relating to subject inventions. In *Platzer*, the district court denied that a private right of action existed under the Bayh–Dole Act, yet still held that the plaintiff’s related third-party beneficiary and breach of contract claims raised federal issues ‘sufficiently substantial to confer “arising under” jurisdiction [pursuant to 28 U.S.C. §§ 1331, 1338(a)].’” (citing *Platzer v. Sloan-Kettering Inst. for Cancer Rsch.*, 787 F. Supp. 360, 367 (S.D.N.Y. 1992), *aff'd*, 983 F.2d 1086 (Fed. Cir. 1992))).
40. *Gen-Probe Inc. v. Ctr. for Neurologic Study*, 853 F. Supp. 1215, 1218 (S.D. Cal. 1993).

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