

## VIRGINIA JOURNAL of LAW and TECHNOLOGY

UNIVERSITY OF VIRGINIA

SPRING 2003

8 VA. J.L. & TECH. 3

# Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole

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## I. Introduction

1. Over twenty years ago, Congress determined that in order to promote innovation and industry, small businesses and nonprofit organizations that develop inventions with the assistance of federal funds should be able to take title to patents for those inventions. This policy was codified by the enactment of the Bayh-Dole legislation (“Bayh-Dole”).<sup>1</sup> In the years since the enactment of Bayh-Dole, there

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<sup>1</sup> 35 U.S.C. § 200 *et seq.*; Public Law 96-517. Bayh-Dole has been amended a few times over the past two decades. Additionally, by Executive Order, federal agencies have been directed to assist in the acquisition

have been an overwhelming number of proclamations of its success.<sup>2</sup> The Bayh-Dole cheerleaders have been so effective at convincing agonistics of its success that little attention has been paid to the ambiguities and inconsistencies in the way that the law is written and implemented.

2. The current law provides that the recipient of federal funds may obtain title to a patent that issues based on research that was supported by those federal funds, if the recipient complies with certain requirements.<sup>3</sup> In an ideal world, there would be full compliance with these requirements by all recipients. However, as discussed below, there are strong indications that neither the federal agencies that have been providing funding nor the recipients that have been receiving funding are fulfilling their obligations. Further, under the current statutes, regulations, and case law, there is an open question as to the enforceability of these patents when there has been less than full compliance with Bayh-Dole.
3. There are a number of possibilities for the consequences of failing to comply with the requirements of Bayh-Dole. For example, a patent could be rendered unenforceable for failure to comply or a patent holder could suffer a smaller penalty (less than loss of title) for delayed compliance.<sup>4</sup> However, Congress has not expressed a clear intention as to what consequences should be imposed on noncompliant businesses and organizations. In order to highlight this problem and to offer a solution, Part II of this article provides a primer on Bayh-Dole and highlights the problems in its drafting and implementation, and Part III discusses possible outcomes for the failure by a recipient of federal funding to comply with Bayh-Dole. Finally, Part IV proposes legislation that would clarify the rights and obligations under Bayh-Dole.

## II. Primer on Bayh-Dole

### A. Policy

4. At the time of the enactment of Bayh-Dole, there was a grave concern that the United States was not maximizing its potential for innovation. Through the

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of title to patents by all contractors, regardless of their size. Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987). The application of the policies of Bayh-Dole to larger contractors is emphasized at 48 C.F.R. § 27.302(a) (2003).

<sup>2</sup> See, e.g., GAO/RCED-98-126, *Technology Transfer, Administration of the Bayh-Dole Act by Research Universities*, 2 (1998) (“Officials with agencies and universities ... said the act was having a positive impact and was working as the Congress intended.”); GAO/T-RCED-87-26, *Federal Patent Policy* (“we found that the patent policy changes have been viewed favorably by university and small business officials, who reported a significant positive impact on their research and innovation.”) (1987); Mark R. Wisner, *Proposed Changes to the Laws Governing Ownership of Inventions Made With Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193, 195 (1994) (“By all accounts, the Bayh-Dole Act has had a significant impact on the transfer of technology from academia to industry.”).

<sup>3</sup> 35 U.S.C. § 200, *et seq.*; 37 C.F.R. § 401 *et seq.*

<sup>4</sup> The phrase “delayed compliance” is an oxymoron; it is used herein to refer to substantive but untimely compliance.

enactment of Bayh-Dole, Congress sought to address this problem by allowing persons who receive federal funds to apply for patent rights, and by offering title to patents without overburdening the recipients of these funds with unnecessary requirements as preconditions to receiving title. The theory was that the incentive of patent rights would both drive more research and facilitate the dissemination of the benefits of research to the public. However, the advantages of Bayh-Dole do not come without costs; the public pays for its benefits both in taxes to the Government and in license fee payments to patent holders.

5. In enacting Bayh-Dole, Congress was clear as to the purpose of the legislation:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.<sup>5</sup>

6. In large part, these aforementioned goals could be met simply by providing federal funds to nonprofit organizations and small businesses and allowing the recipients of the funds to take title to patents without requiring any particular action. However, this is not the structure that Congress adopted. Instead, Congress was clear that although it would provide financial support, it would not give intellectual property rights away for free. Consequently, nonprofit organizations and small businesses may receive funding and the potential for patent rights, but these rights are accompanied by certain obligations designed to ensure that both the Federal agency that provides funding, as well as the public, benefit from the research.<sup>6</sup>

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<sup>5</sup> 35 U.S.C. § 200 (2000). This policy is reiterated at 48 C.F.R. § 27.302 (2002).

<sup>6</sup> 48 C.F.R. § 27.305-1(a) (2003) summarizes the importance of compliance:

It is important that the Government and the contractor know and exercise their rights in inventions conceived or first actually reduced to practice in the course of or under Government contracts in order to ensure their expeditious availability to the public and to enable the Government, the contractor, and the public to avoid unnecessary

7. As discussed in more detail below, under the current statutory scheme, a Federal agency that provides funding may receive the right to acquire title to the subject invention under certain circumstances and does receive a non-exclusive license to the subject invention when it does not take title. The public, in addition to receiving the benefit of having its Government acquire a license to the technology, is supposed to receive certain guarantees that efforts will be made to commercialize the invention and to make it widely available in the United States.<sup>7</sup>

## **B. Framework and Implementation of Bayh-Dole**

8. Under the statutory framework of Bayh-Dole, a “nonprofit organization”<sup>8</sup> or “small business firm,”<sup>9</sup> (generically referred to as a “contractor,”<sup>10</sup>) that develops

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payment of royalties and to defend themselves against claims and suits for patent infringement. To attain these ends, contracts having a patent rights clause should be so administered that –

- (1) Inventions are identified, disclosed, and reported as required by the contract, and elections are made;
- (2) The rights of the Government in such inventions are established;
- (3) Where patent protection is appropriate, patent applications are timely filed and prosecuted by contractors or by the Government;
- (4) The rights of the Government in filed patent applications are documented by formal instruments such as licenses or assignments; and
- (5) Expeditious commercial utilization of such inventions is achieved.

<sup>7</sup> Professor Eisenberg correctly notes that the theory asserting that the public will benefit by allowing transfer of title to patents to private entities from the U.S. government is counterintuitive for a number of reasons:

First, by allowing private firms to hold exclusive rights to inventions that have been generated at public expense, it seems to require the public to pay twice for the same invention – once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market. Second, by calling for exclusive rights in inventions that have already been made through public funding (and thus, presumably, without the need for a profit incentive), it contravenes the conventional wisdom that patent rights on existing inventions result in a net social loss *ex post*, a loss that we endure only to preserve *ex ante* incentives to make future patentable inventions. Third, by promoting the private appropriation of federally sponsored research discoveries as a matter of routine, it calls into question the public goods rationale for public funding of research. And fourth, by providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic research, it threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors.

Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666-67 (1996). Whether Bayh-Dole actually met its goal or whether it is left in place due to a powerful lobby and inertia is beyond this article’s scope.

<sup>8</sup> 35 U.S.C. § 201(i).

<sup>9</sup> 35 U.S.C. § 201(h).

- an invention with the support of federal funding may elect to retain title to a “subject invention”<sup>11</sup> if the contractor complies with certain conditions.<sup>12</sup> These conditions are part of what is embodied in the funding agreement<sup>13</sup> between the contractor and the federal agency, which has been standardized by the Department of Commerce.<sup>14</sup> The conditions attach if an invention is either conceived or first actually reduced to practice when research is conducted with federal funding.<sup>15</sup>
9. It is important to note that there are certain conditions under which the federal government will acquire title even if the contractor complies with Bayh-Dole. For example, the federal government may take title when there is an issue of National Security or Public Health.<sup>16</sup> These provisions that describe these conditions are relatively straightforward, so they are not the source of ambiguities that are likely to be the subject of litigation between private parties. The more problematic provisions are found in the compliance requirements, which are codified in Title 35, section 202, subsection (c) and are discussed below.
  10. First, the contractor must, within a reasonable time, disclose the subject invention to the federal agency that provided funding.<sup>17</sup> According to regulations promulgated by the Secretary of Commerce, this time period is two months from the time that the inventor discloses the information to the person responsible for patent matters at the contractor.<sup>18</sup> With respect to this requirement, Congress has explicitly stated “the Federal Government may receive title to any subject invention not disclosed to it within such time.”<sup>19</sup>
  11. There are a number of ambiguities with respect to Title 35, section 202, subsection (c). For example, the federal government may, but is not obligated to, receive title if the disclosure is not made within a reasonable time. Further, there is no “electing” to take title, only “receiving” of it.
  12. Moreover, it appears that disclosures made after an unreasonable time may be forgiven. The Secretary of Commerce has provided that if the invention has not been disclosed within the two month time frame, the contractor may retain title if the invention is disclosed at a later date, provided that the federal agency has an additional sixty days in which to determine whether to take title.<sup>20</sup> But, there is no

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<sup>10</sup> 35 U.S.C. § 201(c).

<sup>11</sup> 35 U.S.C. §§ 201(d), (e).

<sup>12</sup> 35 U.S.C. § 202(a).

<sup>13</sup> 35 U.S.C. § 201(b).

<sup>14</sup> 37 C.F.R. § 401.14 (2003).

<sup>15</sup> 37 C.F.R. § 401.1 (2003). The term “conception” and the phrase “reduction to practice” have specialized meaning in patent law; readers who are unfamiliar with the phrases may consult any of a number of cases and scholarly articles. *See, e.g.,* William L. Geary, *Protecting the Patent Rights of Small Businesses – Does the Bayh-Dole Act Live Up to Its Promise?* 20 AIPLA Q.J. 10, 19-21 (1992).

<sup>16</sup> 35 U.S.C. § 202(a).

<sup>17</sup> 35 U.S.C. § 202(c)(1).

<sup>18</sup> 37 C.F.R. § 401.14(a), subsection d (2003).

<sup>19</sup> 35 U.S.C. § 202(c)(1).

<sup>20</sup> 37 C.F.R. § 401.14(a), subsection d (2003).

indication in the regulations as to what the Secretary of Commerce would deem unreasonable, or how the degree of unreasonableness should factor into the federal agency's decision to take title. Is one year, three years, ten years after a patent issues ever "reasonable"? It would seem that at some point in time, the delayed compliance becomes unreasonable. Still, a granting agency might not rule on an issue of reasonableness independent of whether it wants either to take title based on the subject matter of the invention or to ensure that the invention is commercialized and/or licensed. If it does not want the invention, a punitive action based on delayed compliance would only harm the agency's goodwill. Thus, there is little incentive for the agency to demand, or for the contractor to provide, timely compliance.

13. The importance of this issue becomes apparent in a situation where, for example, a patentee makes the disclosure of the invention ten years after the patent issues. The funding federal agency might determine that it has no interest in taking title and does not want to become involved in the thorny issue of reasonableness. Imagine next that the patentee sues on the patent and the defendant argues that because the disclosure was made after an unreasonable time, the patentee violated Bayh-Dole, thus divesting itself of title. The patentee may respond that if the federal agency that provided funding chose not to take title, it implicitly sanctioned title remaining in the patentee's hands. This may be correct under the literal language of the statute. But it hardly seems consistent with the goal of ensuring compliance. Further, at least arguably implicit in the statute is the notion that some delays in compliance are sufficiently long that they are too unreasonable to be forgiven. This issue begs the unanswered question with respect to all of the compliance provisions: *When a patentee fails to comply with Bayh-Dole, but the federal agency that supplied funding does not take title, should the patentee be entitled to enforce the patent?* There is no explicit direction from Congress as to how a court should address this issue.<sup>21</sup>
14. Second, within two years after disclosure to the federal agency that provided funding, or within any additional time that the federal agency deems appropriate, the contractor must make a written election indicating whether it will retain title.<sup>22</sup> If the contractor fails to elect to retain rights during that time period, the federal Government may receive title.<sup>23</sup> Here, unlike the previous provision, Congress has provided an explicit timeframe, albeit a flexible one.<sup>24</sup>
15. Although Congress explicitly vests the federal agency providing the funds in this situation with discretion to extend the timeframe, as with the previous section, it is questionable whether such a limitless timeframe is prudent and furthers compliance with the goals of the statute. If the purpose is to provide the federal

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<sup>21</sup> As discussed *infra* ¶¶ 31-32, one court has touched on this issue, but it addressed the situation in which there was complete failure to comply with Bayh-Dole as opposed to delayed compliance. *See* TM Patents v. IBM, 121 F. Supp. 2d 349 (S.D.N.Y. 2000).

<sup>22</sup> 35 U.S.C. § 202(c)(2).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

- agency with the opportunity to determine whether to take title for reasons of public policy, then strict and clear consequences for failure to comply may be more prudent. As with the previous requirement, a federal agency may not have the incentive to take title based on delayed compliance, and contractors are probably aware of this.
16. Third, a contractor that elects rights must file a patent application prior to any statutory bar dates.<sup>25</sup> The contractor is also required to file any corresponding foreign applications within a reasonable time.<sup>26</sup> According to the regulations promulgated by the Secretary of Commerce, the contractor must file the patent application within one year after it elects to take title and file foreign applications within ten months of filing the initial application or within six months of receiving permission from the Commissioner of Patents to file foreign applications.<sup>27</sup> Failure to comply permits the federal government to receive title in any country in which a patent application has not been filed.<sup>28</sup> Because failure to comply with statutory bar dates will preclude an applicant from obtaining rights,<sup>29</sup> failure to comply with this subsection of Bayh-Dole, in most situations, will automatically divest the contractor of its potential rights.<sup>30</sup>
  17. Fourth, with respect to any invention in which the contractor elects rights, the funding federal agency shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice the invention throughout the world.<sup>31</sup> This provision is intended to permit the federal agency that provided funding to use the invention.
  18. Pursuant to the funding agreement, the contractor is required to provide the written documents necessary to establish this right.<sup>32</sup> Even if the contractor does not explicitly grant the license, one might infer that the funding agency nevertheless has a license. However, without an explicit license, the funding federal agency may not realize that it has the right to practice the subject invention; it is the filing of the paper copy of this license with the Patent Office that puts the patent on the Governmental Register.<sup>33</sup> There is no clear indication as to the ramifications for failure to comply with this section.
  19. Fifth, the federal agency may require “periodic reporting on the utilization or

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<sup>25</sup> 35 U.S.C. § 202(c)(3).

<sup>26</sup> *Id.*

<sup>27</sup> 37 C.F.R. § 401.14(a)(c)(3) (2003).

<sup>28</sup> 35 U.S.C. § 202(c)(3). This time period may be shortened if the date for a statutory bar has been triggered.

<sup>29</sup> 35 U.S.C. § 102.

<sup>30</sup> There may be scenarios in which the contractor does not comply with the regulations. For example, the contractor may file its foreign applications on the one-year anniversary date of the priority application, rather than within ten months. However, it is unlikely that the federal government would express an interest in filing foreign applications, and not take title to the U.S. application. Further, the federal government always retains its march-in rights.

<sup>31</sup> 35 U.S.C. § 202(c)(4).

<sup>32</sup> 37 C.F.R. § 401.14(a)(f)(1) (2003).

<sup>33</sup> 48 C.F.R. § 27.305-4(b) (2003).

efforts of obtaining utilization.”<sup>34</sup> There is no description of the consequences of failure to comply with this requirement.

20. Sixth, for any United States patent application that is filed concerning a subject invention, the specification must include “a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.”<sup>35</sup> This is the only provision that requires certain action in the Patent Office. Thus, failure to comply with this requirement cannot be remedied by application to the federal agency that provided funding.
21. The patent laws strictly limit what can be added to an application after filing and/or after issuance.<sup>36</sup> Thus, it is unclear whether a contractor should be permitted to remedy a failure to comply with this requirement after the filing of an application or after issuance of a patent.
22. Seventh, in the case of a non-profit organization, (a) rights cannot be assigned without approval of the federal agency that provided funding, except to an organization that has as one of its primary functions, the management of inventions; (b) the contractor must share royalties with the inventors; (c) royalties that are not paid to the inventors must be put into scientific research or education; (d) when possible, licenses should be granted to small firms; and (e) certain additional requirements must be followed concerning the spending of royalties and the administration of licenses for Government-owned-contractor-operated facilities.<sup>37</sup> Again, the ramifications of failures to comply with these provisions are unclear.<sup>38</sup> For example, should an assignment without the permission of the federal agency render the assignment ineffective? Should it divest the assignor and/or the assignee of title?
23. Eighth, a contractor that takes title is still subject to the federal agency’s “march-in rights.”<sup>39</sup> Under these rights, the federal agency may require a contractor “to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable.”<sup>40</sup> If the contractor refuses, the federal agency itself has the authority to grant the license upon a showing of certain conditions: (a) the contractor has not and is not expected to take steps within a reasonable time to achieve a practical application of the invention; (b) there is a need for reasons of health or safety; (c) in order to meet requirements for public use; or (d) there has not been an implementation of

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<sup>34</sup> 35 U.S.C. § 202(c)(5).

<sup>35</sup> 35 U.S.C. § 202(c)(6).

<sup>36</sup> 35 U.S.C. §§ 112, 251-256, 302-314.

<sup>37</sup> 35 U.S.C. § 202(c)(7).

<sup>38</sup> The Secretary of Commerce has established a procedure under which small businesses can lodge complaints if they believe that a nonprofit organization is not meeting the requirements of a preference for small businesses. 37 C.F.R. § 401.7(b) (2003). However, the Secretary has no authority to compel a particular license.

<sup>39</sup> 35 U.S.C. §§ 202(c)(8), 203.

<sup>40</sup> 35 U.S.C. § 203.



- the preference for using the technology within the United States.<sup>41</sup> Essentially, the march-in rights provide a remedy when the federal agency determines that the public would benefit by forcing the contractor to permit wide use of the technology. This action remains in the discretion of the federal agency.<sup>42</sup>
24. Ninth, any small business firm or non-profit organization, or any assignee, cannot, without a waiver, grant an exclusive right to use or to sell any invention in the United States unless the party that is receiving the rights agrees that “any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.”<sup>43</sup> Here, there are issues as to the ramifications of failure to comply with this provision or whether there is a failure to comply if the assignee fails to agree to the provision, but as a matter of course complies in practice.
25. These issues of ambiguity as to the consequences of, and absence of clear penalties for failure to comply with, the aforementioned requirements are more than theoretical. In 1998, the GAO found that the federal agencies are not enforcing compliance with the Act and instead are in large part entrusting the recipients of the funds with self-compliance. For example, the GAO noted: (1) the agencies “relied on the universities to ensure that all federally funded inventions were meeting the requirements of the law and regulations”; and (2) with respect to certain requirements, the agencies have no data, including whether universities gave a preference to small businesses or how they ensured substantial domestic licenses by exclusive licensees.<sup>44</sup>
26. In 1999, at the request of the Senate Committee on the Judiciary, the GAO sought “to determine whether federal agencies . . . ensure that contractors and grantees are complying with the provisions of the Bayh-Dole Act and Executive Order 12591 on the disclosure, reporting, retention, and licensing of inventions created under federally funded projects.”<sup>45</sup> The GAO concluded that the federal agencies, their contractors and grantees were not complying with these obligations.<sup>46</sup> For example, the GAO found that some inventions had never been disclosed to the federal agency that provided funding.<sup>47</sup>
27. This lax compliance may be explained by a lack of incentive to comply with the

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<sup>41</sup> *Id.*

<sup>42</sup> The “march-in” authority of the government was the subject of the well-known dispute between CellPro and Johns-Hopkins University, and has been well analyzed by many scholars. *See, e.g.,* Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-In Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211 (Winter 2000); Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155 (1999).

<sup>43</sup> 35 U.S.C. §§ 202(c)(8), 204.

<sup>44</sup> GAO/RCED 98-126 at 7.

<sup>45</sup> GAO/RCED 99-242, *Technology Transfer, Reporting Requirements for Federally Sponsored Inventions Needs Revisiting*, at 1.

<sup>46</sup> *Id.* That this compliance is obligatory should go without saying. However, in case there was any doubt, it is reemphasized at 48 C.F.R. § 27.305-2, -3 (2003).

<sup>47</sup> *Id.* at 10.

Act. As discussed above, with respect to 35 U.S.C. § 202(c)(1) - (c)(3), Congress provided that the federal agency may receive title for: failure to disclose the invention to the federal agency “within a reasonable time”;<sup>48</sup> failure to make a written election within two years after disclosure to retain title;<sup>49</sup> and failure to file a patent application prior to statutory bar dates or foreign applications within a reasonable time.<sup>50</sup> But it has remained silent as to the effect of either complete failure to comply with these requirements of Bayh-Dole or gross delays in compliance in the absence of activity by the federal agency. With respect to the remaining requirements, other than those provided for by the “march-in” provision, Congress has been silent as to the effect of either a failure to comply or delayed compliance.

28. In theory, the permissive language allowing for the receipt of title in subsections (1)-(3) of 35 U.S.C. § 202(c) could be viewed as the only requirements that lead to discretion in the federal agency and failure to comply with the other requirements renders a patent invalid. Alternatively, failure to comply with those other requirements could be viewed as a minor infraction, and of no consequence because Congress did not state that failure to comply with them would ever give rise to the federal agency’s receiving title. Both interpretations are problematic.
29. Under the first interpretation, the latter requirements would be more important than the former. However, at least from the federal agency’s perspective, the former requirements seem to be the more substantively important requirements. Under the second interpretation, the second group of requirements would be a “wish list.” But if they are requirements, failure to comply should have consequences.
30. As with any area of uncertainty in the law, ambiguous statutes become the subject of litigation. Particularly in patent law, this inevitably leads to significant legal expenses as litigants attempt to persuade courts to develop the law where Congress has been silent. Before these issues are heavily litigated, congressional action should be taken.
31. Two court cases have touched on how these issues may be approached absent congressional action. In *TM Patents v. IBM*,<sup>51</sup> one of the few cases to address the consequences of the failure to comply with requirements for receiving federal funding, the court explicitly held: “Failure to comply with the conditions of [35 U.S.C.] § 202 results in the Government’s acquiring title.”<sup>52</sup>
32. In *TM Patents*, a graduate student at the Massachusetts Institute of Technology created the invention that was the subject of one of the patents in suit. The parties disputed whether the invention was created through the use of federal funds, but

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<sup>48</sup> 35 U.S.C. § 202(c)(1) .

<sup>49</sup> 35 U.S.C. § 202(c)(2).

<sup>50</sup> 35 U.S.C. § 202(c)(3).

<sup>51</sup> 121 F. Supp. 2d 349 (S.D.N.Y. 2000).

<sup>52</sup> *Id.* at 368.

the court ultimately concluded that it was created with the use of such funds.<sup>53</sup> The parties did not dispute that the patentee failed to comply with the requirements of 35 U.S.C. § 202, and the court held that such failure to comply meant that the patentee never acquired title and suit could not be entertained on that patent.<sup>54</sup>

33. A similar result appears in *Thermalon Indus., Ltd. v. U.S.*<sup>55</sup> In that case, which involved an invention that was developed with federal funding that was supplied before the enactment of Bayh-Dole, the court held that the government acquired title when the invention had not been disclosed to the government within a reasonable time.
34. These cases provide precedent for the proposition that under the current law, any failure to comply with the requirements of Bayh-Dole should divest the patentee and any of its assignees of power to enforce the patent because they do not have title. However, these cases are not rooted in clear expressions of congressional intent, and they do not address what would happen if rather than no compliance there were delayed compliance, or there were compliance with only some of the requirements of Bayh-Dole. Before more courts attempt to resolve these issues, Congress should make its will known.

### **III. What If a Recipient of Federal Funds Fails to Comply with Bayh-Dole?**

35. Because there is evidence of gross failures to comply with Bayh-Dole and there are ambiguities as to the consequences for failure to comply with the statute, Congress should determine the appropriate consequences and then enact explicit legislation that effectuates its intent. When making its decision, Congress must address whether and when failure to comply or delayed compliance will have any effect, and if so, when the delinquency will divest a patentee of title regardless of whether the federal government takes title.
36. One can hypothesize three primary scenarios: (A) failure to comply with Bayh-Dole divests a recipient of federal funding of title and precludes the recipient or assignee from enforcing the patent; (B) failure to comply with the requirements of Bayh-Dole is forgiven if the recipient rectifies the failure; and (C) failure to comply is forgiven if corrected within a fixed time. In theory, different consequences and modes for rectifying failures could be applied to the different requirements of Bayh-Dole. However, only the basic scenarios are discussed below.

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<sup>53</sup> See *id.* at 352-53.

<sup>54</sup> See *id.* The patentee had actually transferred its interests to the plaintiff. However, the court concluded that the patentee could not assign its interests because it never took title.

<sup>55</sup> 34 Fed. Cl. 414 (1995).

## **A. Failure to Comply Divests the Inventor of Title**

37. One option is to codify the holding of *TM Patents*, and completely divest a patentee of rights for failure to comply timely with Bayh-Dole. This scenario is easy to administer, either the recipient has complied with the requisite obligations or the recipient has not. It might be a fair part of the bargain for receiving federal funds. No party is obligated to receive federal funding or to file a patent application if it receives funding. But if a party wants these funds and wants to file a patent application, it should abide by certain obligations that allow the federal agency providing the funds to evaluate the scope of interest that it should take and to put the world and particularly federal employees, as well as the recipient's competitors, on notice that the federal government has a non-exclusive license.
38. If Congress does agree that *TM Patents* correctly addresses the issue of failure to comply with Bayh-Dole, it should enact specific legislation that indicates this position. However, before making such a policy explicit, Congress should consider whether it would impede its articulated goals. If the consequences of failing to comply are too strict, potential contractors may be discouraged from participating in the process.

## **B. Failure to Comply is Always Curable**

39. Under a second scenario, the failure to comply would always be curable. This would permit contractors whose compliance is delayed to notify the appropriate agency that they have not complied with the applicable laws, but that they nonetheless wish to possess title and to take steps to remedy the situation so that they may acquire title to patents.
40. This option would sanction the regulations promulgated by the Secretary of Commerce as applied to 35 U.S.C. § 202(c)(1) and (2) and expand them to all requirements of Bayh-Dole. In order to encourage compliance, Congress could bar enforcement of any patent until there has been such compliance and limit the collection of damages to periods in which there has been full compliance.<sup>56</sup> From the perspective of the researcher and contractor this system is ideal. However, without severe consequences for failures to comply, there may be limited incentive to do so. For example, a contractor might not expend money to ensure compliance until it sees the potential for a lucrative license.
41. This policy is particularly problematic with respect to the requirement of providing notification to the funding federal agency so that it may make an early decision to take title. One of the reasons to require notification to the federal agency is to permit the federal government to take title when it would be in the

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<sup>56</sup> One could establish a plan in which regardless of whether there has been compliance, the contractor may enforce the patent. However, this would render the statutory provisions a true wish list. If this is the will of Congress, then it should simply delete the requirements from the United States Code.

interest of the government and/or the public. If a contractor is always forgiven for a failure to comply by being allowed to do so at a later date, the contractor in possession of an invention has a significant incentive not to comply with its disclosure obligations when the invention is likely in the government's interest to acquire. Instead, the contractor could try to procure a patent and license it, and if anyone raises the failure to comply with Bayh-Dole as an issue, it could comply at that time. This would provide the contractor with the opportunity to receive royalties for at least some period of time. Further, because many inventions are often most desirable when they are first invented, the contractor could hope that by the time that the federal government learns of the patent, it is not interested in the invention.

### **C. Failure to Comply is Curable for a Limited Time**

42. Under a third scenario, the failure to comply with Bayh-Dole could be curable for a limited time, but any failure would render the subject patent unenforceable until the deficiency is remedied. This would be a compromise between the other two options. It would allow the compliance failure to be rectified, depending on the scope of, reason for, and time for the failure. However, to encourage contractors to comply with the requirements, contractors would lose their abilities to enforce their patents, though not necessarily be divested of title, until such time as they have remedied compliance failures.
43. This would provide the fairest method, permitting time for curing failures to comply with the Bayh-Dole requirements, but at the same time, giving notice to the recipients of federal funds that these requirements are not optional. A proposed legislative framework appears below. Under this framework, it is assumed that all the requirements of section 202(c) are important enough to divest a contractor of title.

## **IV. Proposed Legislation**

44. Below are proposed amendments to the United States Code. Additions to existing language are underlined and deletions are denoted with brackets.

35 U.S.C. §202

...

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate and each small business and nonprofit organization shall comply with the following:

- (1) That the contractor disclose each subject invention to the Federal agency within [a reasonable time] two months after it becomes known to contractor personnel responsible for the administration of patent matters, and

that the Federal Government may [receive] elect to claim title to any subject invention not disclosed to it within such time: *Provided*, That if the Federal Government elects to take title, it shall do so within nine months of receiving the disclosure of said invention. If the contractor makes the disclosure after the two month period, but the Federal Government does not elect to take title, in order for the contractor to retain title, it must comply with 35 U.S.C. § 213(c).

- (2) That the contractor make a written election within two years after disclosure to the Federal agency [(or such additional time as may be approved by the Federal agency)] whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further*, That the Federal Government may [receive] elect to claim title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights, within such times, if such election by the Federal Government is made within nine months of the expiration of the aforementioned two year period. If the contractor makes the election after the two year period, but the Federal Government does not elect to take title, in order for the contractor to retain title, it must comply with 35 U.S.C. § 213(c).

...

- (4) With respect to any invention in which the contractor elects rights, [the Federal agency shall have] the contractor shall provide in writing within six months of issuance of any patent that cover such rights, confirmation that the Federal agency possesses 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: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement,

arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and protection.

- (5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information, as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code; and further *Provided*, That said periodic reporting requirements shall not be requested more than once per year.
- (6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor at the time of the filing of each non-provisional, continuation, continuation-in-part and divisional application that appears within in a patent claim of priority for which there was development of an invention that was funded pursuant to this Chapter, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.
- ...
- (8) The requirements of sections 203 and 204 of this chapter, which must be recognized in a written document whenever there is any transfer of rights from a contractor.

### 35 U.S.C. § 213

(a) A small business firm or nonprofit organization that is party to a funding agreement shall have standing to enforce a patent under 35 U.S.C. § 271 if and only if the small business firm or nonprofit organization has complied with all requirements set forth under 35 U.S.C. § 202(c)(1)-(c)(8).

(b) A small business firm or nonprofit organization that is obligated, but fails, to comply with the requirements of 35 U.S.C. § 202(c)(1)-(c)(5), (c)(7) and (c)(8) shall have standing to enforce a patent if the small business firm or nonprofit organization:

(1) submits a petition to the funding Federal agency for and receives a waiver of the timeliness of these requirements and avers that the failure was due to inadvertence and not intentional and the requisite information or confirmation of the requisite event is by the date of the petition submitted to the applicable Federal agency; and

(2) demonstrates that the failure was not of more than three years from the date by which the recipient should have complied with the obligation; and

The Federal agency shall not unreasonably withhold a waiver, but the Federal agency may in its discretion determine that it should, for reasons of public interest or out of equity, acquire title to the invention, thereby precluding the small business firm or nonprofit organization from enforcing the patent at issue. Denial of a petition under this subsection shall be reviewable in accordance with the process for reviewing adverse decisions under 35 U.S.C. § 202 and 204 as authorized by 35 U.S.C. § 206.

(c) A small business firm or nonprofit organization that is obligated, but fails to comply with the requirements of 35 U.S.C. § 202(c)(6) shall have standing to enforce a patent under 35 U.S.C. § 271 if the small business firm or nonprofit organization:

(1) petitions the Director for Patents for a Certificate of Correction under 35 U.S.C. § 255 within four years of the earliest filing date to which the application claims priority if a patent has issued, or during pendency of the application that led to the issuance of the subject patent, filed an amendment within four years of the earliest filing date to which the application claims priority or if the subject patent issue off of an application that is a continuation, divisional or continuation-in-part patent application filed as an amendment within four years of the earliest priority date or at the time of filing such application if such application is filed after the four year period, whichever is later, provided that the requisite statement is included in all patents and



applications to which priority is claimed in compliance with section 202(c)(6) or 213(c); and

(2) demonstrates in the petition or amendment of (c)(1) that the mistake was either made by the Patent Office, or if made by the applicant, avers that it was not made in bad faith.

Denial of a petition under subsections 35 U.S.C. § 213(c)(1) and (c)(2) shall be reviewable under the procedures for reviewing other requests under 35 U.S.C. § 255 or denial of entry of an amendment or correction as applicable. Nothing in this subsection shall preclude a request for a Certificate of Correction under 35 U.S.C. § 254 at any time during the life of the patent.

(d) Any petition that is filed under subsection (b) or (c) above shall be deemed granted if it has not been acted upon within nine months.

(e) If a small business firm or nonprofit organization fails to comply with 35 U.S.C. § 202(c)(1)-(c)(5), (c)(7), (c)(8), but files and is granted a waiver under section (b) above or is issued a Certificate of Correction under subsection (c) above or under 35 U.S.C. § 254, the small business firm or nonprofit organization shall be precluded from recovering damages or otherwise enforcing the patent for activities prior to the time that the petitions have been acted upon favorably by the applicable Federal agency or the Patent Office.

#### 35 U.S.C. § 214

A patent for which funding for any of the underlying research and development was provided in accordance with this Chapter will be deemed dedicated to the public if a contractor fails to comply with Bayh-Dole and fails to remedy the failure as provided for in 35 U.S.C. § 213 if the Federal agency has not elected to acquire title.

45. The legislation proposed above strikes a balance between forgiving innocent mistakes and motivating contractors to comply with Bayh-Dole. The proposed amendments to 35 U.S.C. §202(c) would set definitive timeframes in which compliance would be required. Proposed section 213 would provide: (1) mistakes of failure to comply with Bayh-Dole are to be forgiven if remedied within a limited time; and (2) during any time for which there has not been full compliance, the contractor and its assignees would be prohibited from collecting damages or obtaining an injunction in a patent infringement suit. Section 214 would make clear that the federal agency cannot indefinitely forgive failures to

comply with Bayh-Dole.

46. The proposed amendments to subsection 202(c) would set definitive timetables in which there must be compliance. By clarifying when the clock starts ticking for compliance failures, it will be easier to determine when to impose penalties.
47. The proposed amendments to subsection 202(c)(1) would require disclosure of the invention to the funding federal agency within two months after the appropriate contractor personnel had knowledge of the invention. This amendment would codify the regulations established by the Secretary of Commerce in 37 C.F.R. § 401.14. The subsection would also be amended to be consistent with proposed section 213 in that upon receiving a late disclosure the federal agency may elect to take title, but must do so within nine months, which is longer than the time period currently embodied in funding agreements. Additionally, it explicitly states that even if the federal government were to elect to take title, the contractor would retain title only if it were to comply with proposed section 213(c), which is discussed below. The proposed amendments to subsection 202(c)(2) would, like certain of the amendments to subsection 202(c)(1), make the provision consistent with proposed section 213.
48. Subsection 202(c)(3), which provides that compliance must occur before statutory bar dates, would not need to be amended since failure to comply with it would, by definition, divest the contractor of patent rights.
49. The proposed amendments to subsection 202(c)(4) would require that the contractor provide written notice of the federal government's license within six months of the issuance of the patent. This would allow for a reasonable amount of time for the patentee to notify the federal agency, but would also allow the agency to record the license in the Patent Office within a relatively short time after the issuance of the patent.
50. The proposed amendments to subsection 202(c)(5) would limit the burden of the reporting requirements. Because, under the proposed amendment, failure to comply with this provision could divest the contractor of title, it is proposed that the burden of compliance should not be too cumbersome. This is consistent with the current regulations.<sup>57</sup>
51. The proposed amendments to subsection 202(c)(6) would clarify that compliance with inserting the requisite language into the patent application must occur at the time of filing the earliest application in a patent family for which there was funding and in each application, within any chain of priority. Thus, it would need to be made in each parent application, as well as in any applications that claim priority to that parent application. Proposed section 213(d) would provide a window in which this could be rectified if there were a failure to insert the appropriate language in the application.

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<sup>57</sup> 37 C.F.R. § 401.5(f) (2003).

52. No amendments are proposed to subsections 202(c)(7). Subsection (c)(7) refers to certain obligations that attach at the time of events such as an assignment or receipt of royalties. Thus, failure to comply at the time of the event would be a triggering event for breach of the obligations under Bayh-Dole.
53. Subsection (c)(8) incorporates the provisions that permit for “march-in” rights and requires assignees to acknowledge the preference for United States industry. The proposed amendment would require that these rights must be acknowledged in writing whenever there is a transfer of rights. This would include assignments and licenses. Failure to put the information in the assignment or license would be a triggering event.
54. Subsection (a) of proposed section 213 would make explicit that a recipient of federal funds may recover damages if the recipient complies with the conditions set forth in 35 U.S.C. § 202(c).
55. Subsection (b) of proposed section 213 would address breaches of the seven subsections of section 202(c) that pertain to behavior in relation to the federal agency that provides funding. It would require that if the contractor were to fail to comply timely with the requirements of (c)(1) - (c)(5) and (c)(7) and (c)(8), it would have a grace period of three years. The contractor would then be required to request forgiveness of the failure to comply. In response to the request, the federal agency would, either for reasons of the public interest or out of equity, be permitted to divest the contractor of its rights.
56. Subsection (c) of proposed section 213 would provide a window for remedying a breach of 35 U.S.C. § 202(c)(6), which pertains to activity in the Patent Office. It would explicitly authorize the PTO to issue a Certificate of Correction in order to add the requisite language to the patent if the request is made within four years of filing of the earliest priority document. An applicant would not be able to correct errors by including language in a pending continuation application beyond that date. If the parent application were still pending, it would simply be amended, provided that the request is made within four years of the filing of the earliest application. These amendments would only be required if the error was not the fault of the Patent Office. Any Patent Office error would be forgivable for the life of the patent.
57. Subsection (d) of proposed section 213 would provide that any petition that is not acted upon within nine months would be deemed granted. This would permit the contractor to have closure on the issue of an attempt to remedy a delinquency.
58. Subsection (e) of proposed section 213 would provide that no damages could be collected if and until there were compliance with sections 202(c)(1) - (c)(8). This provision would provide an incentive for compliance even if an initial deadline were missed. It also makes clear to parties that are potentially going to be accused as infringers what the limits on their liability may be, and when they may be excluded from practicing an invention.

59. Proposed section 214 would establish that even when the federal government does not wish to take title, the contractor could nonetheless lose title. This provision would take into account that there is little incentive for federal agencies to take title to inventions out of retribution against a delinquent contractor, since the federal agency always possesses a license. By making clear that at some point in time, it is not within the funding federal agency's discretion whether the contractor is divested of title, there may be more incentive for the contractor to comply with its obligations.

## **V. Conclusion**

60. To provide contractors and accused infringers with certainty, amendments to Bayh-Dole are necessary. Before the courts are forced to develop a doctrine, Congress should set forth a clear policy. In order to avoid frightening small businesses and non-profit organizations away from participation and to create adequate incentives for compliance, a balance must be struck. If a requirement is important enough for Congress to legislate it, then failure to comply with it should have a clear consequence.

61. As discussed above, it is proposed that there should be three basic tiers of compliance. First, full compliance should continue to permit contractors to enforce their patents. Second, failures to comply that are rectified within a short timeframe should be forgiven. However, within this timeframe, until there is full compliance, the contractor should not be permitted to collect damages from infringers or to obtain injunctions against them. Third, gross delinquency should divest a contractor of title. Thus, after a fixed time period, in the cases in which the federal government does not elect to take title, the patents that were paid for by the public should be dedicated back to the public.