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## COMMENT

# The American Models of Technology Transfer: Contextualized Emulation by Developing Countries?

BENTON C. MARTIN†

### INTRODUCTION

The patenting of innovative technology has become an essential part of the U.S. economy, promoted by groundbreaking legislation that allows ownership of technology resulting from research funded by the federal government.<sup>1</sup> Prior to legislation, less than four percent of the tens of thousands of government-funded inventions were licensed to industry, resulting in many technologies failing to reach practical application.<sup>2</sup> Currently, multiple types of research institutions in the United States negotiate an increasing number of licenses every year, resulting in the issuance of more patents and the disclosure of more inventions to technology transfer offices.<sup>3</sup> Even scholars who believe this growth would have occurred eventually without the Bayh-Dole Act (Bayh-Dole) agree that the legislation was important because it “accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing

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† J.D. Candidate, 2010, Emory University School of Law; B.S. Biomedical Engineering, Michigan Technological University. I would like to thank Professor Liza Vertinsky and the staff of the CDC Technology Transfer Office for their helpful insights regarding this Comment. I would also like to thank my wife for her support and patience every time I am engaged in the writing process.

<sup>1</sup> Irene Ribeiro Dubowy, *Subsidies Code, TRIPs Agreement, and Technological Development: Some Consideration for Developing Countries*, 8 J. TECH. L. & POL’Y 33, 57-59 (2003) (discussing the Bayh-Dole Act, affecting universities, and the Stevenson-Wydler Technology Innovation Act, affecting government laboratories, as being the driving factor in making patents a “pillar” of the U.S. economy).

<sup>2</sup> Sen. Birch Bayh, *Bayh-Dole: Don’t Turn Back The Clock*, Address at the Licensing Executives Society 2006 Annual Meeting, (Sept. 12, 2006), *available at* <http://www.lesi.org/BirchBayh/Bayh.pdf>.

<sup>3</sup> AUTM, *Frequently Asked Questions*, <http://www.autm.net/AM/Template.cfm?Section=FAQs> (last visited Apr. 20, 2009) (listing statistics of the increases in licensing, patenting, and invention disclosures).

at universities.”<sup>4</sup>

Clarification of intellectual property ownership has had a substantially beneficial effect on the U.S. economy; many developed and developing countries are considering adopting or have already adopted the U.S. model.<sup>5</sup> Many countries have adopted similar provisions, including a majority of European countries, China, Korea, South Africa,<sup>6</sup> Brazil, and Malaysia.<sup>7</sup> Many developing countries have special concerns relating to Bayh-Dole, specifically, as critics mention, varying degrees of low resources devoted to research funding, lack of “practically oriented universities,” and less established patent systems than the United States.<sup>8</sup>

Granting permission to research institutions to take title and sell technologies to private industry, with a mandate to bring to practical application, was the creative solution Bayh-Dole introduced to fix the problem of government funded technologies sitting on a shelf and not finding practical application.<sup>9</sup> Considering many in research institutions or industry do not have sufficient resources to fund projects and bring the technologies to practical application, it is questionable whether many countries even have the prerequisite problem Bayh-Dole sought to fix. However, many developed countries are beginning to use government funds for research and to prevent the problems Bayh-Dole addressed, attempting “to achieve similar economic success through effectively utilizing the outputs of publicly funded research.”<sup>10</sup>

While some critics feel that instituting Bayh-Dole would create a greater burden due to over-patenting and high costs,<sup>11</sup> others scholars feel that the base strategy of clarification of ownership is important for

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<sup>4</sup> Anthony D. So et al., *Is Bayh-Dole Good for Developing Countries? Lessons From the US Experience*, 10 PLoS BIOLOGY 2078, 2079 (2008), available at [http://biology.plosjournals.org/archive/15457-885/6/10/pdf/10.1371\\_journal.pbio.0060262L.pdf](http://biology.plosjournals.org/archive/15457-885/6/10/pdf/10.1371_journal.pbio.0060262L.pdf).

<sup>5</sup> Michael S. Mireles, *The Bayh-Dole Act and Incentives for the Commercialization of Government-Funded Invention in Developing Countries*, 76 UMKC L. REV. 525, 525 (2007) (“Numerous developing and developed countries are considering adopting or have adopted legislation similar to the U.S. Bayh-Dole Act.”).

<sup>6</sup> Helen Davison, *Public-Private Partnerships: The Role of IPRs*, <http://www.stockholm-network.org/downloads/events/HelenDavison.pdf> (last visited Apr. 20, 2009).

<sup>7</sup> So et al., *supra* note 4, at 2078.

<sup>8</sup> *Id.* at 2082 (mentioning the reasons that Bayh-Dole legislation would likely fail to have the same success in developing countries that it has had in the United States).

<sup>9</sup> *See* Bayh, *supra* note 2 (describing the original problem Bayh-Dole sought to address).

<sup>10</sup> Eugene Lottering, *Pending Intellectual Property Legislation, Based on the Bayh-Dole Act of the USA, Should Help Accelerate South Africa’s Journey Towards a Knowledge-Based Economy*, in INNOVATION FUND ANNUAL REPORT 2006/07, at 6 (2007) (annual report of a group working on Bayh-Dole type legislation in South Africa).

<sup>11</sup> So et al., *supra* note 4, at 2082 (“Based on our review above, we believe it is doubtful that the benefits of legislation closely modeled on BD would outweigh their costs in developing countries.”).

developing countries who seek to increase government funding to research institutions and want the technology produced to be brought to practical application by industry.<sup>12</sup> However, even proponents agree that if Bayh-Dole is to be adopted in developing countries, it must “move beyond” just clarification of ownership to provide a more socially beneficial national innovation policy.<sup>13</sup> Despite criticism, developing countries are likely to continue to attempt and emulate the success of U.S. legislation, especially as countries progress to a point where they are considering federal funding of research. For this reason, it is important to study U.S. legislation to understand how developing countries might realize its positive effects of accelerating practical application of government funded research by utilizing industry. Even more important perhaps is the study of potential safeguards, contextualized to the particular developing country, which could be built into legislation without sacrificing the positive benefits of the Bayh-Dole legislation.

In looking at American technology transfer, it is important to note that different legislation has stimulated technology transfer in universities than technology transfer in government laboratories, and accordingly, the practice of technology transfer in these two entities differs.<sup>14</sup> As foreign governments look to the United States as a model system, it is important for them to understand these differences and enact legislation that will be the most beneficial for their country’s unique history, structure, and goals.<sup>15</sup> The differences in the regulations for the two types of U.S. institutions should encourage developing countries to focus on the specifics of their unique institutions and create legislation appropriate for their unique needs. A few commentators have examined the regulations of university and small business technology transfer and have drawn conclusions on which aspects are beneficial for developing countries,<sup>16</sup> but no commentator has

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<sup>12</sup> Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261, 278 (2006) (“The Bayh-Dole Act fundamentally served to create clarity of ownership of inventions created in the public sector with public funds. This has been the major positive effect of the Act that should be emulated in national policy.”).

<sup>13</sup> *Id.* at 278 (“The adoption of new policy today needs to move beyond Bayh-Dole and the question of IP ownership to provide frameworks for IP management that foster broad innovation.”).

<sup>14</sup> See generally Jack E. Kerrigan & Christopher J. Brasco, *The Technology Transfer Revolution: Legislative History and Future Proposal*, 31 PUB. CONT. L.J. 277 (2002) (discussing key differences in the legislation controlling government laboratories and universities).

<sup>15</sup> See Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States*, 59 ME. L. REV. 259, 261 (2007) (arguing that the Bayh-Dole Act may not be successful in Europe and Japan “because of the differences in the history, practice, and structure of most European and Japanese university systems compared with the U.S. university system.”).

<sup>16</sup> See Mireles, *supra* note 5, at 281 (examining the Bayh-Dole Act and the implications

thoroughly examined the successful aspects of the more highly regulated government agency laboratories to evaluate their potential if adopted by developing countries. Perhaps commentators have overlooked this model of American technology transfer because developing countries have a low percentage of research funded by government and accordingly a low number of government funded laboratories.<sup>17</sup> Some of the distinct provisions warrant closer examination, especially since some developing countries are characterized by an increased level of regulations. Furthermore, no commentary has emphasized how the need for different legislation for different types of institutions within the United States is an example of how developing countries must similarly tailor their legislation to the distinct organization of their research institution and their country's unique objectives.

This Comment will address differences between technology transfer licensing practices in U.S. government laboratories compared to universities, arguing that understanding the need to focus on the specific needs of research institutions and their relationship to the specific country's government is integral to coherent national technology transfer legislation. Part I of this Comment examines the important legislation that has affected technology transfer in universities and governmental laboratories and examines how this legislation has evolved based on the unique needs of the different institutions. Part II uses two examples, Emory University and the Centers for Disease Control and Prevention (CDC) to describe noticeable differences in how licensing works in practice in each type of entity. Finally, Part III analyzes, based on the differences described, the importance of legislation contextualized to the specific country. This final Part proposes which beneficial aspects of the American models developing countries should preserve. It also looks at some specific problems faced by developing countries, such as access to life-saving technology for low-income populations, prevention of anti-commons, and lack of technology transfer resources, and analyzes legislative provisions that could modify the American model to contextualize legislation to address the unique needs of the particular country.

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to developing countries when adopting a similar provision); Boettiger & Bennett, *supra* note 12, at 525 (same).

<sup>17</sup> See Sonja van Renssen, *Innovation in South Africa: too much, too soon?*, SCIDEV.NET, Apr. 6, 2006, <http://www.scidev.net/en/sub-suharan-africa/features/innovation-in-south-africa-too-much-too-soon.html> (stating that "some 70 percent of research in South Africa is funded by industry, not government").

## I. HISTORY ON THE TECH TRANSFER LEGISLATION

In 1980, the U.S. legislature passed two pieces of legislation aimed at increasing the effectiveness of commercializing technological innovation funded by the federal government.<sup>18</sup> Overall, these initiatives are hailed as one of the greatest successes in U.S. legislation, due to their beneficial effect in helping technology transfer to become a key part of the American economy.<sup>19</sup> As noted previously, as a model for developing countries, commentators criticize the legislation as being merely supplementary to the increased growth already occurring in the United States,<sup>20</sup> but this Comment recognizes that many developing countries are adopting this type of legislation in anticipation of increased development. One key piece of legislation, the Bayh-Dole Act, applies to U.S. universities, small businesses, and non-profits.<sup>21</sup> The other piece of legislation, the Stevenson-Wydler Technology Innovation Act (Stevenson-Wydler) applies to governmental agency research laboratories.<sup>22</sup> Legislators enacted each piece of legislation based on the particular structure of the institution and the unique relationship each has with the government. This Part will examine the legislative history and subsequent amendments to Bayh-Dole and Stevenson-Wydler in order to emphasize the need in the United States to contextualize its technology transfer legislation.

### A. Universities: Bayh-Dole Act

Bayh-Dole is viewed as a success in the United States in fulfilling its purpose of commercializing the results of government-funded research and has been called “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century.”<sup>23</sup> According to one of the Act’s authors, Birch Bayh, prior to the Act’s passage “the U.S. government owned approximately 28,000 patents, [but] less than 4 percent were licensed to industry.”<sup>24</sup> Since the Act’s passage in 1980, “there has been a substantial increase in the number of government-funded inventions that

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<sup>18</sup> See Kerrigan & Brasco, *supra* note 14, at 279-80 (“Congress passed two acts in 1980 that shaped the law of government technology transfer for the years to come: (1) the Bayh-Dole Act, and (2) the Stevenson-Wydler Technology Innovation Act. Although both statutes were enacted to foster technology transfer . . .”).

<sup>19</sup> See, e.g., *Innovation’s Golden Goose*, THE ECONOMIST, Dec 12, 2002, at 3 (calling one of the pieces of legislation “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century . . .”).

<sup>20</sup> So et al., *supra* note 4, at 2078.

<sup>21</sup> 37 C.F.R. § 401 (2000) (implementing 35 U.S.C. §§ 200-212).

<sup>22</sup> Stevenson-Wydler Innovation Act, 15 U.S.C. § 3710 (2006).

<sup>23</sup> Chester G. Moore, *Killing the Bayh-Dole Act’s Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 156 (2006) (citing *Innovation’s Golden Goose*, *supra* note 19, at 3).

<sup>24</sup> Bayh, *supra* note 2.

have been patented and licensed by universities,” largely attributed to Act’s influence.<sup>25</sup> As reported by a website tracking university technology transfer “between FY 1991 and FY 2004, annual invention disclosures increased more than 290 percent (to 18,178), new patents filed increased nearly 450 percent (to 11,089) and new licenses and options executed increased about 510 percent (to 5,329).”<sup>26</sup> Universities’ technology transfer offices have flourished within the framework it created and the only amendment to the Act, in 1984, granted large corporations the benefits of Bayh-Dole.<sup>27</sup>

However, the Act is not without its critics.<sup>28</sup> One criticism of the Act is the use of “march-in rights” as the primary means of protecting the public interest.<sup>29</sup> The Act gives the government the right to require compulsory licensing of inventions under limited circumstances if needed to protect the public interest.<sup>30</sup> The government is permitted to require a research institution “to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible” third party licensee if the governmental agency which funded the research determines that “action is necessary because the [original licensee] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use, action is necessary to alleviate health or safety needs which are not reasonably satisfied by the [original licensee], [or] action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees.”<sup>31</sup> During the adoption of Bayh-Dole, opponents argued that in practice these rights would never be used.<sup>32</sup> This has turned out to be true: despite multiple attempts, “the

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<sup>25</sup> Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1152 (2006) (citing H.R. Res. 319, 109th Cong. (2006)).

<sup>26</sup> AUTM, *supra* note 3.

<sup>27</sup> See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1685-87 (1996).

<sup>28</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) (discussing the “tragedy of the anticommons”).

<sup>29</sup> See Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls?*, 75 TUL. L. REV. 631, 658 (2001) (agreeing that opponents’ objection that march-in rights would never be used has turned out to be true).

<sup>30</sup> Boettiger & Bennett, *supra* note 12, at 261-62 (“Under very limited circumstances, the Act also allowed for ‘march-in’ rights, under which the government can require the compulsory licensing of a patent.”).

<sup>31</sup> 35 U.S.C. § 203 (2006).

<sup>32</sup> Arno & Davis, *supra* note 29, at 658.

[government] has never exercised its march-in rights.”<sup>33</sup>

The other provision aimed at providing access to the public allows the government to retain title to a technology “in exceptional circumstances when the agency determines that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter.”<sup>34</sup> Like march-in rights, the government rarely uses this “exceptional circumstances” provision and scholars argue that more inventions would stay in the public domain if legislators modified the provision.<sup>35</sup> It is important to note that both access provisions, “march-in” rights, and the “exceptional circumstances” also regulate governmental laboratory licensing.

Another aspect of Bayh-Dole that is relevant to our focus is the fact that it does not exempt “experiment use” from patent infringement. This means that researchers cannot use technology to research new inventions without licensing the technology, which potentially makes it more difficult to discover new inventions due to the cost of licensing and fear of infringement. There is also no research exemption in the Stevenson-Wydler Technology Innovation Act, as discussed in sub-Part B.

#### B. *Government Labs: Stevenson-Wydler Technology Innovation Act*

Passed prior to Bayh-Dole, Stevenson-Wydler’s purpose was similar to Bayh-Dole in that it encouraged government laboratories to take an active role in technology transfer, requiring money to be set aside for technology transfer activities.<sup>36</sup> However, commentators argue that Stevenson-Wydler initially provided more flexibility than Bayh-Dole.<sup>37</sup> Critics of Bayh-Dole argue that while Bayh-Dole sought to remove the federal government from the technology transfer equation, Stevenson-Wydler sought to “engage federal agencies actively in the process of technology transfer in cases where there was no contractor to take charge of this mission itself.”<sup>38</sup>

Unlike with Bayh-Dole, Congress has needed to significantly amend

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<sup>33</sup> *Id.*

<sup>34</sup> 35 U.S.C. § 202(a) (2006).

<sup>35</sup> Mireles, *supra* note 25, at 1160 (explaining commentator stances on modifying Bayh-Dole).

<sup>36</sup> FED. LAB. CONSORTIUM FOR TECH. TRANSFER, FLC ORTA HANDBOOK, at A-2 (2007) [hereinafter ORTA HANDBOOK] (“The law requires laboratories to take an active role in technical cooperation and to set apart a percentage of the laboratory budget specifically for technology transfer activities.”).

<sup>37</sup> *See* Kerrigan & Brasco, *supra* note 14, at 279-80 (“The Stevenson-Wydler Act provided substantially more flexibility than the Bayh-Dole Act . . .”).

<sup>38</sup> Eisenberg, *supra* note 27, at 1706 (warning against over-patenting of government funded technologies).

Stevenson-Wydler to help the Act fulfill its proposed purpose, due largely to the unique aspects of technology transfer from a government owned laboratory.<sup>39</sup> Commentators suggest that Steven-Wydler needed these amendments to be successful in allowing commercialization of technologies from government laboratories in the same way Bayh-Dole allowed commercialization of technology from university laboratories.<sup>40</sup> The first amendment to Stevenson-Wydler was actually passed within Bayh-Dole; an amendment that allowed government owned and operated laboratories to issue exclusive licenses to commercial entities, which was included in a different provision of the Act affecting universities, due to the special regulations that had to be laid out due to the limited powers of the federal government.<sup>41</sup>

The next major amendment came in 1986 through the Federal Technology Transfer Act of 1986 (FTTA).<sup>42</sup> The FTFA sought to require federal laboratory scientists to “consider technology transfer an individual responsibility” by including it in performance review and allowing employees to share in royalties.<sup>43</sup> The Act also made the important distinction that “enabled cooperative research and development agreements (so-called ‘CRADAs’) between government owned laboratories, industry, and academia . . . .”<sup>44</sup> A CRADA is an agreement “between one or more Federal laboratories and one or more non-Federal parties . . . toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory . . . .”<sup>45</sup> CRADAs are the only mechanism by which the government can grant patent licenses on an employee’s technology in advance of invention.<sup>46</sup>

Unlike universities, government owned and operated laboratories could not previously receive funds from outside institutions due their nature as a branch of the federal government. CRADAs allows contribution of

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<sup>39</sup> Kerrigan & Brasco, *supra* note 14, at 281 (“By failing to give federal laboratories clear legal authority to enter into such agreements, the Stevenson-Wydler Act catalyzed few technology transfers.”).

<sup>40</sup> *See id.* at 280 (“The Bayh-Dole Act was less successful primarily because of its burdensome public notice requirements, the limited class of beneficiaries under the Act, and the fact that recently proposed amendments to Stevenson-Wydler and its progeny will likely incorporate the most beneficial components of the Bayh-Dole Act.”).

<sup>41</sup> *See* ORTA HANDBOOK, *supra* note 36.

<sup>42</sup> 15 U.S.C. §§ 1501-1534 (2006).

<sup>43</sup> ORTA HANDBOOK, *supra* note 36.

<sup>44</sup> Mark R. Wisner, *Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193, 193 (1994).

<sup>45</sup> 15 U.S.C. § 3710a(d)(1) (1994).

<sup>46</sup> Kathleen Sybert, Kay Etzler & Ron G. King, *Government Funding and Research Development Collaborations with Biotech Companies*, in *Biotechnology Law 2002: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES* 749, 785 (Practicing Law Inst., 2002).

private funds to government funded research projects<sup>47</sup>—this has been attributed as one of the main successes of government laboratory technology transfer.<sup>48</sup> CRADAs have become the “technology transfer vehicle of choice.”<sup>49</sup> There is potential for creative, contextualized use of CRADAs in developing countries to allow private-public partnerships to fund research on neglected disease and, in return, gain limited control over the type of license issued on the technology.<sup>50</sup>

In addition to the FTTA, Steven-Wydler was also amended by the National Competitiveness Technology Transfer Act of 1989,<sup>51</sup> which “extended the Stevenson-Wydler Act to government owned, contractor operated federal laboratories,”<sup>52</sup> and the Emerging Technologies and Advanced Technology Program Amendments Act of 1991,<sup>53</sup> “which created an Advanced Technology Program which worked with specific industry investors to the Program to sponsor new technologies.”<sup>54</sup> The effect of these amendments was to define which entities would get the power granted in the FTTA, since these organizations also performed research funded by the federal government.<sup>55</sup> It is important to note that in including these entities under the umbrella of Stevenson-Wydler, Congress made a judgment call that these institutions were similar to government owned and operated research laboratories than small businesses or universities.

A few more recent amendments specific to Stevenson-Wydler show the need to allow technology transfer legislation to evolve around the individual structure and circumstances of the particular institution. First, Congress enacted the National Technology Transfer and Advancement Act

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<sup>47</sup> *Id.* (“CRADAs are one of the few mechanisms that the Federal government has to receive non-appropriated funds from the private sector.”).

<sup>48</sup> See Kerrigan & Brasco, *supra* note 14, at 279-80 (describing the importance of CRADAs in making federal laboratories more successful than Universities at technology transfer).

<sup>49</sup> Barbara A. Duncombe, *Federal Technology Transfer*, 37 FED. B. NEWS & J. 608, 610 (1990).

<sup>50</sup> See generally Nathaniel Lipkus, *How to Understand Product Development: Public-Private Partnerships as Vehicles for Innovation in Combating Neglected Diseases*, 10 MICH. ST. U. J. MED. & L. 385 (2006) (discussing the potential for public-private partnerships to address neglected diseases in the context of America’s modern intellectual property environment, which includes CRADAs as an integral part).

<sup>51</sup> 15 U.S.C. §§ 3701-3718 (2006) (amending the Stevenson-Wydler Technology Innovation Act).

<sup>52</sup> Wisner, *supra* note 44, at 193.

<sup>53</sup> Emerging Technologies and Advanced Technology Program Amendments Act of 1991, Pub. L. No. 102-245, 106 Stat. 1992.

<sup>54</sup> Wisner, *supra* note 44, at 193.

<sup>55</sup> See Kerrigan & Brasco, *supra* note 14, at 283-86 (describing the “definitional stage” of technology transfer history which followed the “incentive stage” when CRADAs were created).

of 1995<sup>56</sup> as a response to complaints that CRADAs were taking too long to negotiate because the licensing laws were too flexible (sometimes in excess of one year).<sup>57</sup> The Act grants “assurance” to corporations that they will have sufficient intellectual property rights under CRADAs.<sup>58</sup> The Act also “gives the collaborating party in a CRADA the right to choose an exclusive or nonexclusive license for a prenegotiated field of use for an invention resulting from joint research under a CRADA.”<sup>59</sup> In 1995, Congress enacted the Technology Transfer Improvements Act to provide safeguards against corporation abuse. “The Act provided any party holding an exclusive license to a CRADA invention could be required to transfer its license to a third party in exceptional circumstances, such as when a transfer is necessary to secure health and safety needs” and also that “the Government retained the right to a nonexclusive, non-transferable, irrevocable, paid-up license to practice the invention by or on behalf of the Government for government purposes.”<sup>60</sup> Finally, the Technology Transfer Commercialization Act of 2000<sup>61</sup> required exclusive or partially exclusive licensees “to provide a plan for development and/or marketing of the invention and to make a commitment to achieve a practical application of the invention within a reasonable period of time,” exempting inventions made under CRADA.<sup>62</sup> This Act also highlighted the continued need to lessen the negotiation time for CRADAs by creating clear regulations of ownership, requiring the use of successful provisions from Bayh-Dole to further streamline the negotiation process.<sup>63</sup>

## II. HOW TECH TRANSFER OFFICES LICENSE IN PRACTICE

In practice, the technology transfer procedures of government laboratories and universities differ in many aspects. Ultimately, it is these practical aspects that exemplify the need for developing countries to adopt

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<sup>56</sup> National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 1996.

<sup>57</sup> See Kerrigan & Brasco, *supra* note 14, at 285.

<sup>58</sup> ORTA HANDBOOK, *supra* note 36, at A-4.

<sup>59</sup> *Id.*

<sup>60</sup> Kerrigan & Brasco, *supra* note 14, at 285-86.

<sup>61</sup> Pub. L. No. 106-404, 114 Stat. 2000.

<sup>62</sup> ORTA HANDBOOK, *supra* note 36, at A-4; *see also* 35 U.S.C. §209 (2006).

<sup>63</sup> Hearing on the Department of Veterans Affairs Medical Research Programs: Before the Subcomm. on Oversight and Investigations, Comm. on Veterans' Affairs, U.S. H. Rep., 107th Cong., 2nd Sess. (2002) (statement of Benjamin H. Wu, Deputy Under Secretary for Technology), *available at* <http://www.ogc.doc.gov/ogc/legreg/testimon/107s/wu0919.htm> (“The law sought to remove the procedural obstacles and, to the greatest extent possible, the uncertainty involved in the licensing of Federally patented inventions created in a Government-owned, Government-operated (GOGO) laboratory. This was achieved by applying the successful Bayh-Dole Act provisions to a GOGO.”).

policies contextualized to their particular government and research institutional structure. It is important to note that federal government laboratories are fundamentally more limited than those of universities, due to the government's limited powers in comparison to private industry.<sup>64</sup> This Part will use specific examples, Emory University and the CDC, to examine how technology transfer operates at these two institutions in practice.

#### A. *Universities: Case Study: Emory University*

Started in 1985, Emory University's Technology Transfer Office has been more successful than many university tech transfer offices, having earned over 760 million dollars through 2008 from commercializing Emory inventions.<sup>65</sup> One of the office's biggest success stories is a 525 million dollar deal with Gilead Sciences and Royalty Pharma for an HIV drug developed by one of the school's researchers.<sup>66</sup> Gilead had plans for an Access Program in place for the drug, but was initially unsuccessful due to the poorly designed infrastructure of the drug access program.<sup>67</sup> After advocacy groups heavily criticized the failure of Gilead's plan, the company responded by taking more aggressive steps to ensure that the drug would be available, including issuing non-exclusive licenses and providing information for generic manufacturers.<sup>68</sup> Emory responded by working with student groups calling for better access policies to draft new access guidelines for future deals.<sup>69</sup> This is an impressive step, but these access guidelines are not legally binding and one could envision compromise in the face of well-financed corporate pressure.

In spite of these shortcomings, the Office is clearly proficient in the practice of technology transfer, assisting Emory University with the education of researchers about technology transfer, evaluation of new inventions for commercialization potential, protection of intellectual

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<sup>64</sup> E-mail from Andrew Watkins (Nov. 5, 2008) (on file with author).

<sup>65</sup> EMORY UNIV. OFFICE OF TECH. TRANSFER, ANNUAL REPORT FISCAL YEAR 2008, at 6 (2008), available at [http://www.ott.emory.edu/Office/Facts\\_and\\_Figures/OTT%20FY08%20Annual%20Web.pdf](http://www.ott.emory.edu/Office/Facts_and_Figures/OTT%20FY08%20Annual%20Web.pdf).

<sup>66</sup> David Wahlberg, *Emory to Get \$525 Million*, ATLANTA JOURNAL-CONST., July 19, 2005, at A1.

<sup>67</sup> David P. Hamilton, *A 'Good Deed' For AIDS Drug Hits Obstacles*, WALL ST. J., June 30, 2006, at B1.

<sup>68</sup> K. BOWLER ET AL., ENSURING ACCESS THROUGH UNIVERSITY TECHNOLOGY TRANSFER: A CASE STUDY OF THE EMORY-GILEAD EMTRICITABINE DEAL (2006), available at [www.essentialmedicine.org/conferenceblog/wp.content/uploads/presentations/U4EM%20Poster-%20Emory-gilead%20Case%20study.pdf](http://www.essentialmedicine.org/conferenceblog/wp.content/uploads/presentations/U4EM%20Poster-%20Emory-gilead%20Case%20study.pdf).

<sup>69</sup> EMORY UNIV. OFFICE OF TECH. TRANSFER, TECHNOLOGY TRANSFER FOR GLOBAL ACCESS: GUIDING PRINCIPLES (2008), available at [http://www.ott.emory.edu/For\\_Inventors/Policies/Emory\\_Global\\_Access\\_Principles.pdf](http://www.ott.emory.edu/For_Inventors/Policies/Emory_Global_Access_Principles.pdf).

property, marketing of protected technology, license negotiation, license monitoring, collection of distribution of licensing proceeds, facilitation of start-up companies, and other administrative duties related to technology transfer at the university.<sup>70</sup> One distinctive feature of small business and university technology transfer that is obvious from Emory's technology transfer program is the ability to create start-up companies based around new technology, which may allow for easy transition to market for some university technologies.<sup>71</sup> Emory has created a program called Emory VentureLab which "is a start-up assistance program established by the Office of Technology Transfer to shepherd Emory discoveries to market through new venture creation and development."<sup>72</sup> The Emory technology transfer website promotes various start-up business incubators and publicizes Emory's success technology start-up ventures.<sup>73</sup>

A "ready to sign" non-exclusive licensing agreement for Norepinephrine Transporter cDNA, one of several such agreements available at the Office of Technology Transfer's website, provides for termination if the license is breached and that the license is "conditional upon and subject to the U.S. Government Licenses and other rights retained by the United States in inventions developed by nonprofit institutions with the support of federal funds."<sup>74</sup> It notes that these rights are "set forth in 35 USCA § 201 et seq. and 37 CFR 401 et seq.,"<sup>75</sup> but does not explicitly describe the government's march-in rights. This portion refers to a section of the Bayh-Dole Act which allows the federal agency that provided funding for the technology to require that a license be granted to a responsible applicant if the current licensee did not effectively bring the technology to practical application within a reasonable time or if action is needed to solve a "health or safety" issue and was not "reasonably satisfied" by the current licensee.<sup>76</sup>

#### B. *Government Laboratories: Case Study: CDC*

In many ways, CDC's Technology Transfer Office is functionally

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<sup>70</sup> See Emory Univ. Office of Tech. Transfer, Overview, [http://www.ott.emory.edu/Office/About\\_Us/index.cfm](http://www.ott.emory.edu/Office/About_Us/index.cfm) (last visited Apr. 20, 2009).

<sup>71</sup> See Emory Univ. Office of Tech. Transfer, Venture Lab, <http://www.ott.emory.edu/VentureLab/General/index.cfm> (last visited Apr. 20, 2009).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> EMORY UNIV. OFFICE OF TECH. TRANSFER, NON-EXCLUSIVE LICENSE AGREEMENT FOR HUMAN NOREPINEPHRINE TRANSPORTER-EXPRESSING CELL LINE AND CDNA 3, [http://www.ott.emory.edu/For\\_Industry/Ready\\_to\\_Sign\\_Agreements/Emory\\_RSA\\_96064.pdf](http://www.ott.emory.edu/For_Industry/Ready_to_Sign_Agreements/Emory_RSA_96064.pdf) (last visited Mar. 20, 2009).

<sup>75</sup> *Id.*

<sup>76</sup> 35 U.S.C. § 203(1)(a) (2006).

similar to Emory University's Technology Transfer Office, working to evaluate, patent, market, and license new technology.<sup>77</sup> Similar to Emory's office, the CDC office deals with monitoring and collecting money from ongoing licenses.<sup>78</sup> According to the director of technology transfer at the CDC, the largest difference in federal government technology transfer is the fact that there is less flexibility since the federal government has limited power compared to the private sector.<sup>79</sup> For example, universities can take equity in start up companies in exchange for university technology, while regulations prohibit government owned and operated laboratories from executing this type of technology transfer deal.<sup>80</sup> Researchers in government laboratories are also limited in their ability to work for entrepreneurial private enterprises and receive honoraria for serving on the boards of start up companies.<sup>81</sup> In spite of these restrictions, commentators hail the process used in government laboratories as successful for decreasing negotiation time for technology transfer agreements.<sup>82</sup> The CDC also acknowledges, because of its nature as a government agency, that it is able to perform research directed toward the public benefit and government interest, with profitability as a less demanding goal than it may be at university technology transfer offices.<sup>83</sup> The remainder of this sub-Part will discuss additional important distinctions that affect federal laboratories licensing.

The first important distinction that is apparent in the CDC licensing procedure is the encouragement of CRADAs as a means to gain access to technology.<sup>84</sup> While universities can enter into collaborative agreements without much restriction, government laboratories are unable to obtain funds from outside sources without the enabling legislation allowing CRADAs.<sup>85</sup> The CDC website explains that the "primary difference

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<sup>77</sup> See Ctrs. for Disease Control & Prevention, Dept. of Health & Human Servs., CDC-OCSO Tech Transfer: Overview, <http://www.cdc.gov/od/science/techTran/overview.htm> (last visited Mar. 18, 2009).

<sup>78</sup> See *id.*

<sup>79</sup> Watkins, *supra* note 64.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> See Kerrigan & Brasco, *supra* note 14, at 285-86.

<sup>83</sup> Watkins, *supra* note 64 (stating the greatest benefit of licensing from government laboratories compared to university licensing schemes is "our technologies tend to be less early-stage than those of universities and they are often directed more to public health or public economic needs"). Dr. Watkins also added that "[m]uch of the research at a Federal lab is targeted to research areas or multi-disciplinary or multi-industry needs that are not feasible for universities or companies to pursue." *Id.*

<sup>84</sup> See Ctrs. for Disease Control & Prevention, Dept. of Health & Human Servs., CDC-OCSO Cooperative Research and Development Agreements (CRADAs), <http://www.cdc.gov/od/science/techtran/crads.htm> (last visited Mar. 22, 2009).

<sup>85</sup> Sybert, Etzler, & King, *supra* note 46, at 785.

between CRADAs and other CDC research contracts and agreements is that CRADAs provide the collaborator with an advance option to negotiate an exclusive license to inventions made under the CRADA” and this “exclusivity gives the commercial partner an advantage in the marketplace along with a window of opportunity for full development and marketing of the resulting product.”<sup>86</sup>

The Director of the CDC’s Technology Transfer Office seems to view CRADAs as a limiting factor in federal technology transfer, claiming universities “engage much more easily in sponsored research with commercial entities, many of which do not require any intellectual collaboration from the company,” while most federal agencies “are limited to collaborative research with commercial partners via the Cooperative Research and Development Agreement.”<sup>87</sup> However, private industry requested this type of inflexibility, as according to Jack E. Kerrigan and Christopher J. Brasco, “[i]ndustry’s message to Congress became quite clear: business was no longer willing to invest in CRADAs unless rights under such agreements were clearly defined and easily secured.”<sup>88</sup> Congress responded by clarifying the rights obtained by private industry collaborations through CRADA use.<sup>89</sup> Congress safeguarded public benefit from the technology through use of the access provisions such as “march-in” rights.<sup>90</sup> Industry has responded positively to the decrease in negotiation time by heavily using CRADAs to fund research and transfer technology from government laboratories to the public sector.<sup>91</sup>

The second key distinction is the CDC model licensing agreement requires adherence to a Commercial Development Plan as required by 37 C.F.R. § 404.5.<sup>92</sup> The license states that “Licensee shall use its reasonable best efforts to introduce the Licensed Products into the commercial market or apply the Licensed Processes to commercial use as soon as practicable. ‘Reasonable best efforts’ for the purpose of this provision shall include, but not be limited to, adherence to the Commercial Development Plan.”<sup>93</sup> While the contents of the Commercial Development Plan are negotiable, the

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<sup>86</sup> Ctrs. for Disease Control & Prevention, *supra* note 84.

<sup>87</sup> Watkins, *supra* note 64.

<sup>88</sup> Kerrigan & Brasco, *supra* note 14, at 285.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 286.

<sup>92</sup> 37 C.F.R. § 404.5(a)(1) (2008) (“A license may be granted only if the applicant has supplied the Federal agency with a satisfactory plan for development or marketing of the invention, or both, and with information about the applicant’s capability to fulfill the plan. The plan for a non-exclusive research license may be limited to describing the research phase of development.”).

<sup>93</sup> CDC Model Licensing Agreement § 801, <http://www.cdc.gov/od/science/techTran/forms/pla-non.pdf> (last visited October 22, 2008).

plan's existence requires the licensee to be upfront about intentions for the technology. The license then requires the licensee bring the technology to "practical application within a reasonable time as specified in the license," and also "continue to make the benefits of the invention reasonably accessible to the public."<sup>94</sup> The CDC is legally enabled to terminate the license if the licensee does not fulfill its commitments outlined in the plan or if "[t]ermination is necessary to meet requirements for public use."<sup>95</sup>

There are a few other areas where the restrictions on federal government labs are noticeable. One is the requirements for public notice imposed on federal agencies by the Bayh-Dole Act.<sup>96</sup> Government owned and operated laboratories are required to give notice of available technologies to the public several months before the institution can license a technology—a cumbersome requirement.<sup>97</sup> It is interesting to note that these restrictions likely prohibit government laboratories from structuring a deal like the Gilead-Emory deal. For the Gilead deal, Emory took the stream of royalty payments for the technology as an upfront payment. The FTTA caps the maximum amount of royalty payments an inventor can receive at \$150,000.<sup>98</sup>

### III. POLICY CONSIDERATION FOR DEVELOPING COUNTRIES

The most important point to make clear is that it is difficult to make "generalizations concerning developing countries, which have widely differing economic conditions."<sup>99</sup> Regulations in these countries will need to look different than regulations in the United States; for example, "[t]he US is a country where entrepreneurs can find venture capital [and] where there are patent attorneys with the skills to help with patent prosecution," while "in developing economies there may be limited licensing opportunities within the domestic market."<sup>100</sup> Even within these countries, there are various different types of institutions and government styles. The United States has small businesses, universities, government owned and

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<sup>94</sup> 37 C.F.R. § 404.5(b)(5) (2008).

<sup>95</sup> 37 C.F.R. § 404.5(b)(8)(i)-(ii) (2008).

<sup>96</sup> See Kerrigan & Brasco, *supra* note 14, at 280-81 ("The Act further placed limitations on the licensing of government-owned technology by subjecting such procedures to lengthy public notice requirements and by granting only government-owned, government-operated laboratories (GOGOs) the authority to license such inventions.").

<sup>97</sup> See 37 C.F.R. §§ 404.4, 404.7 (2008).

<sup>98</sup> See 15 U.S.C. § 3710(c)(3) (2006); see also ORTA HANDBOOK, *supra* note 36, at 7-6.

<sup>99</sup> Mireles, *supra* note 5, at 532.

<sup>100</sup> Gail E. Evans, *Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries*, 34 AM. J.L. & MED. 175, 191 (2008).

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operated laboratories, and government owned and contractor operated laboratories, and has a federalist, democratic, capitalist government. Some developing countries have institutions like universities and government laboratories, but many do not have the same federal and state structure as the United States and their political systems range from democratic to socialist to communist. The need for different strands of legislation in the United States for its different types of legislation emphasizes the need for developing country governments to closely scrutinize how Bayh-Dole's provision would operate within their specialized structure, rather than bluntly adopting Bayh-Dole.

A recent effort to develop Bayh-Dole-like legislation for South Africa is representative of how a developing country could begin to analyze its specific needs.<sup>101</sup> This effort set out six guiding principles specific to the needs of South Africa to guide in creation of South Africa's technology transfer legislation.<sup>102</sup> These principles are as follows:

1. A consistent approach to ensure protection of IP developed with public funds;
2. Benchmark against good practice globally and contextualised for national and regional efficacy;
3. Identify key rights, functions & obligations;
4. Good balance between incentives and control;
5. Certainty in terms of publicly financed IP;
6. Must not hinder private-public collaborations.<sup>103</sup>

These guidelines highlight some of the key issues that were important to South Africa in drafting legislation. If other developing countries were to lay out their principles, some may be very similar to South Africa's and others may be very different, just as the United States has created different regulations for its institutions. Countries in mid-development phase, similar to South Africa, with strong universities and increasing government funding towards research may have similar principles, while less-developed countries, without the strength of South Africa's underlying structure, would have a drastically different set of guidelines. It is likely that if these less-developed countries actually laid out their guidelines, they would opt out of enacting Bayh-Dole legislation completely.<sup>104</sup>

Governments will need to contextualize Bayh-Dole to the needs of

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<sup>101</sup> McLean Sibanda, Executive Dir. Innovation Fund of S. Afr., , Patents and Their Role in Development and Global Health, Presentation for Emory Law School Seminar (Nov. 5, 2008) (on file with author).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *See* So et al., *supra* note 4, at 2078 (2008) (reviewing some of the general needs of less-developed countries and concluding that Bayh-Dole would be more detrimental than beneficial).

developing countries. Just as Congress sought the same basic effect in legislation affecting both universities and government laboratories in the United States, to obtain commercialization of government funded technology in developing countries, their governments will need to draft legislation carefully tailored to fit the particular needs of that country, its structure of government, and the structure of its institutions. This Part discusses some key provisions that could be included in a strategy adopted by a developing country. This Part is not intended to be conclusive of all the strategies a developing country could use, and is merely meant to suggest areas of flexibility in the original Bayh-Dole legislation that could be used to tailor it to a specific country's needs. First, it examines the core benefit of Bayh-Dole that a majority of developing countries adopting similar legislation should preserve. It then looks at the potential for licensing preferences to aid the attainment of country goals and priorities. It then addresses the potential for developing countries to use CRADAs to reduce negotiation costs and clarify the rights of collaborators, with a special emphasis on the potential for private-public partnerships as collaborators. Finally, it examines suggested solutions to problems with technology transfer within developing countries, including management of limited resources in the technology transfer sphere, prevention of an anti-commons effect, and an adequate provision of access to essential medicines for the country's low-income population.

#### A. *Clarification of Property Rights and Ownership*

While some have argued that Bayh-Dole was not as substantial an incentive of economic growth as some have claimed it is, one resounding benefit of Bayh-Dole in the context of its adoption by developing countries is the clarification it provides of ownership of inventions.<sup>105</sup> It has been noted that Stevenson-Wydler's initial inadequacy was primarily caused by its failure to "give federal laboratories clear legal authority" to enter beneficial licensing agreements for the transfer of its technology.<sup>106</sup> As a result, in "the seven years following the enactment of Stevenson-Wydler, the Government entered into only thirty-four technology transfer agreements."<sup>107</sup> Along with the invention of the CRADA came clear authority for government agencies to enter into technology transfer

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<sup>105</sup> See Boettiger & Bennett, *supra* note 12, at 278 ("The Bayh-Dole Act fundamentally served to create clarity of ownership of inventions created in the public sector with public funds. This has been the major positive effect of the Act that should be emulated in national policy."); So et al., *supra* note 4, at 2078 (arguing that Bayh-Dole was not as successful as suggested, but did provide clarity of ownership).

<sup>106</sup> Kerrigan & Brasco, *supra* note 14, at 281.

<sup>107</sup> *Id.*

agreements.<sup>108</sup> It is clear from this example that legislation enacted in developing countries should clearly, explicitly grant authority to research institutions to own the products of their research, and enter into agreements to license the technology. Guiding principles one, three, and five of the South African guiding principles primarily focus on building clarity of ownership and rights into South African technology transfer law.<sup>109</sup> The existence of clear ownership regulations reinforce guiding principles two and four, by allowing for clarity of benchmarks, and creating a steady framework where balancing of incentives and control can occur.<sup>110</sup> This is the primary reason why Bayh-Dole is such an attractive option for developing and developed countries, and is why more developing countries should continue to adopt similar legislation.

On the other hand, developing countries seeking to adopt similar legislation in order to build their economies, rather than merely to clarify ownership of rights, might need to adjust their goals. Governments should carefully study and understand their economy and the direction it is headed to determine if the acceleration possibly provided by Bayh-Dole clarification of ownership would have an effect. Commentators note that “university licensing offices barely break even” and that technology transfer licensing “accounts for less than 5% of total academic research dollars.”<sup>111</sup> This resulted in concern of the “anti-commons” effect discussed later and has caused top American universities “to recognize the difficulties that overly aggressive proprietary behavior can engender.”<sup>112</sup> Despite these concerns, “it is rare that technologies develop without some form of exclusive protection” and because it is important that technology reach the marketplace, “patent exclusivity is often justified.”<sup>113</sup> Since clarification of technology ownership and support of technological innovation increases commercialization of government-funded inventions and also increases a country’s economic growth, developing countries should still consider adoption of Bayh-Dole legislation with appropriate country-specific safeguards.<sup>114</sup>

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<sup>108</sup> See *id.* at 282 (“The CRADA for the first time gave federal laboratories clear authority to enter into technology transfer agreements.”).

<sup>109</sup> See Sibanda, *supra* note 101 (discussing guiding principles for South African Bayh-Dole-like legislation).

<sup>110</sup> See *id.* (discussing guiding principles for South African Bayh-Dole-like legislation).

<sup>111</sup> So et al., *supra* note 4, at 2079.

<sup>112</sup> *Id.*

<sup>113</sup> Bess-Carolina Dolmo, Note, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 154 (2001).

<sup>114</sup> See So et al., *supra* note 4, at 2082 (“While policies supporting technological innovation and diffusion contribute to economic growth and development, the appropriate sets of policies to harness public sector R&D are highly context-specific.”).

### B. Utilizing Licensing Preferences to Further Country Objectives

Another benefit of Bayh-Dole and Stevenson-Wydler may be the preference for small businesses and domestic manufacturing.<sup>115</sup> Development of domestic industry and production of technology designed for local needs is an important part of building technology as a force in a country's economy.<sup>116</sup> However, it has been acknowledged that many low income countries do not yet have the capacity for much domestic manufacturing and this provision would need to be modified in preference to domestic benefits rather than manufacturing.<sup>117</sup> Michael S. Mireles has proposed a tiered approach for developing countries: first giving preference to licensees that would do research and development in the country, manufacturing in the country, and use the technology for the country's benefit; second giving preference to licensees that would manufacture in the country and use the technology for the country's benefit; and finally, if neither of those could be met, giving preference to licensees that would use the technology to substantially benefit the country.<sup>118</sup>

The South Africa project used preferences in another unique way: as a way to help correct for social injustices within the country. Besides including a similar small business preference, the legislation also included a preference for "black-owned" companies.<sup>119</sup> South Africa has a history of economic, political, and legal discrimination of its black citizens.<sup>120</sup> This makes the potential for empowerment that could occur through having a preference for black owned businesses very attractive to South African policy makers looking to right their country's wrongs. There is no real enforcement mechanism for this preference, but its mere existence will likely have an effect on technology transfer practice in South Africa. Developing countries facing similar social injustice situations should consider the potential effect technology transfer preferences could have on correcting these problems. Perhaps countries with a history of suppression of women could make the bold move of expressing a preference for female owned and operated companies, since "putting power" in the hands of women is the best way to improving their lives within a country.<sup>121</sup> The

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<sup>115</sup> See Boettiger & Bennett, *supra* note 12, at 277.

<sup>116</sup> *Id.*

<sup>117</sup> Mireles, *supra* note 5, at 543.

<sup>118</sup> *Id.* at 543-44.

<sup>119</sup> See Sibanda, *supra* note 101.

<sup>120</sup> See generally Kevin Hopkins, *Assessing the World's Response to Apartheid: A Historical Account of International Law and its Part in the South African Transformation*, U. MIAMI INT'L & COMP. L. REV., Special Issue 2002, at 241.

<sup>121</sup> See Olivia Wood, *Ten Worst Countries for Women*, TORONTO STAR, Mar. 8, 2008, at A1 (discussing how advocates agree that "[p]utting power in women's hands is the biggest challenge for improving their lives in every country, advocates agree.").

creativity and political will of the country's policymakers are the primary limitations for the possibilities for this type of provision.

C. *Adoption of CRADA-Like Provisions in Government Operated Laboratories*

Legislation permitting the use of CRADAs may also be an innovative step for some developing countries to consider, especially if they have many government owned and operated institutions. While some would argue that this would cause an unnecessary restriction of freedom to collaboration, a proposition needing further investigation, legislation specifically encouraging external funding and collaboration with research institutions may be beneficial. In fact, corporations lobbied for the United States to pass the National Technology Transfer and Advancement Act of 1995 because they were dissatisfied with the long negotiation period involved with entering CRADAs caused by the uncertainty of terms.<sup>122</sup> Requiring that institutions who heavily contribute to research receive a primary say in licensing decisions could be a creative way to involve public-private partnerships in the innovation process. Public-private partnerships vary greatly amongst different countries, but many countries,<sup>123</sup> including South Africa, have strong humanitarian-focused public-private institutions that the government wants to encourage, rather than discourage.<sup>124</sup>

A CRADA-like provision could require that research institutions give external institutions who invest funding an option for an exclusive or non-exclusive license, which public-private partnerships could use to promote developing country goals and humanitarian purposes.<sup>125</sup> The benefit of this type of requirement is that it would clarify and decrease the cost of the negotiation process. This would allow humanitarian-oriented organizations, which may not have the resources to carry out an expensive negotiation process, to get a substantial benefit for contribution of resources. However, it may have to be specifically limited to humanitarian-oriented corporations

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<sup>122</sup> Kerrigan & Brasco, *supra* note 14, at 285 (“Before the Act, the laws were so flexible regarding the intellectual property rights of parties to a CRADA that laborious negotiations were necessary every time a CRADA was proposed. For example, at the 1995 hearings on technology transfer, a DuPont executive testified that his company’s negotiations for a single CRADA often took more than one year. Industry’s message to Congress became quite clear: business was no longer willing to invest in CRADAs unless rights under such agreements were clearly defined and easily secured.”).

<sup>123</sup> Davison, *supra* note 6.

<sup>124</sup> See Sibanda, *supra* note 101 (stating that ideal licensing regulations “[m]ust not hinder private-public collaborations”).

<sup>125</sup> See generally Lipkus, *supra* note 50 (discussing the potential for public-private partnerships to address neglected diseases in the context of America’s modern intellectual property environment, which includes CRADAs as an integral part).

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because otherwise corporate licensees may dictate the use of university inventions. This danger is one issue that the new South African legislation was aiming to avoid by “prevent[ing] industry from negotiating sole ownership rights over research it has contributed little funding to, and . . . enabl[ing] the government to negotiate access to inventions for the public good, such as new HIV/AIDS drugs,”<sup>126</sup> and accordingly, a CRADA-like provision may need to be narrowly drafted to avoid this problem.

As an example, the Global Alliance for Vaccines and Immunization (GAVI Alliance) is a public-private partnership working to promote immunization in over seventy of the most impoverished countries.<sup>127</sup> Two key features of the GAVI Alliance are that it has developed unique and effective funding strategies and its members include governments of developing countries.<sup>128</sup> Access to willing foreign government participation, increased funding for neglected diseases, and access to health data of developing countries are all important resources that a humanitarian-oriented public-private partnership, like GAVI, could provide as contributions to research institution projects focusing on a neglected disease. Though GAVI may not have the resources to negotiate beneficial collaboration agreements, CRADA-like regulations streamlining humanitarian collaborations with research institutions may allow GAVI to more easily contribute to research, with a promise that it would gain control of the licensing for the new technology that is developed. This power would ensure that GAVI is able to create a license that would be the most beneficial for humanitarian purposes. Despite this possible creative use, CRADAs have been a successful technology transfer device<sup>129</sup> and are a potential provision to be considered by developing countries when creating new technology transfer legislation, as long as they are not used to discourage public-private partnerships from contributing to research. The adoption of a CRADA-type provision depends on the particular structure of the country’s government and institutions. Governments with institutions facing slow or expensive negotiations for outside funding, or bogged down by heavy regulations, may particularly want to consider a CRADA-like provision.

#### D. *Central Management of Technology Transfer Offices*

Many developing countries do not have a high percentage of experts in the area of intellectual property and technology transfer that would allow

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<sup>126</sup> Renssen, *supra* note 17.

<sup>127</sup> See GAVI Alliance Fact Sheet (2008), [http://www.gavialliance.org/resources/15\\_EN\\_Achievements1\\_final\\_2.pdf](http://www.gavialliance.org/resources/15_EN_Achievements1_final_2.pdf) (last visited Oct. 22, 2008).

<sup>128</sup> See *id.*

<sup>129</sup> See Duncombe, *supra* note 49, at 610.

every university or government laboratory to have a high-functioning technology transfer office. One proposed solution, due to a scarcity of intellectual property experts, is creating regional or technology specific technology transfer centers in a developing country, rather than institutional-based centers.<sup>130</sup> Some scholars have even pushed for the adoption of a national system that oversees research and technology transfer.<sup>131</sup> While the national approach may be too much, its been argued that the regional approach “affords economies of scale in sustaining the large costs and limited revenues of patent portfolios and the ability to invest the profits from any “blockbuster” inventions in the broader technology transfer infrastructure. The structure also has the potential to sustain a “commons” of technologies in specific areas by aggregating IP and managing unified portfolios of technologies under a common set of objectives.”<sup>132</sup> However, commentators point out that institutional technology transfer offices do much more than simply managing patents and leaving at least limited responsibilities in the hands of institutions may be important.<sup>133</sup>

As an example of a country utilizing a national intellectual property management regime, Nigeria’s National Office for Technology Acquisition and Promotion has been “mandated to assist in the commercialisation of R&D results and to promote the IP system as a source of generating income.”<sup>134</sup> The office is involved on a national level with “Evaluation/Registration of Technology Transfer Agreements, Promotion of Intellectual Property, Technology Advisory and Support Services, Commercialization of R&D Results, Research Industry Linkage, Production of Compendium Management Information System, Publication of Project Profiles on R&D Results.”<sup>135</sup> This office is able to coordinate the research and development efforts of the country’s universities, including training

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<sup>130</sup> See Boettiger & Bennett, *supra* note 12, at 275.

<sup>131</sup> See generally Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373 (2007) (arguing that the United States should establish a national system due to the failures and misuses of technology transfer by universities).

<sup>132</sup> Boettiger & Bennett, *supra* note 12, at 275.

<sup>133</sup> *Id.* at 276 (citing Rosemary Wolson, *Intellectual Property Tools, Innovation and Commercialisation of R&D: Options to Assist Developing Countries in Positioning Themselves to Reap the Benefits of a Stronger Intellectual Property Regime, with Special Reference to the Role of Intellectual Property Management in Research Organizations, “Intellectual Property Rights (IPRs), Innovation, and Sustainable Development” in Eastern and Southern Africa* (Cape Town, South Africa 2004).

<sup>134</sup> Davison, *supra* note 6.

<sup>135</sup> Obi C. Adiuku-Brown, Executive Officer of Nat’l Office for Tech. Acquisition & Promotion, Welcome to NOTAP, <http://www.notap.gov.ng/about.php> (last visited Mar. 22, 2009).

leaders of localized technology transfer offices.<sup>136</sup> Countries with lower levels of funding and few trained intellectual property experts should consider this approach. The possibilities of the structuring of the technology transfer program are nearly limitless and governments should carefully analyze the needs of their country's research institutions.

E. *Prevention of an "Anti-Commons" Effect*

The Federal Circuit recently held that virtually no research exemption exists in America, in either universities or government laboratories.<sup>137</sup> Commentators such as Rebecca Eisenberg have strongly argued that America, without a research exemption, issues patents so frequently and easily that it has inhibited research institutions from development of further innovation and technology because advancement would mean infringement.<sup>138</sup> This has been termed the "tragedy of the anti-commons."<sup>139</sup> Michael Mireles argues that adoption of a Bayh-Dole type of provision in other developed countries, such as Japan and the United Kingdom, could result in over-patenting and other impediments to the development of beneficial research within the United States.<sup>140</sup>

Developing countries, when examining their particular needs, may want to be careful to avoid the "anti-commons" problem due to an increased need for access to essential medicines in lower income countries.<sup>141</sup> When research institutions leave technology in the public domain, it is easily available for generic manufactures to sell at an affordable price, but the anti-commons effect creates a lack of technology in the public domain and drives up the price of technology.<sup>142</sup> One suggested solution to the anti-commons problem is to require research institutions to decide in advance which funding agreements will result in patentable technology and which will not.<sup>143</sup> Critics dismiss this idea on the grounds that it is unworkable to

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<sup>136</sup> Nat'l Office for Tech. Acquisition & Promotion, Establishment of IPTTOs, [http://www.notap.gov.ng/iptto\\_index.php](http://www.notap.gov.ng/iptto_index.php) (last visited Mar. 22, 2009).

<sup>137</sup> See *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

<sup>138</sup> Heller & Eisenberg, *supra* note 28; see also Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW. & CONTEMP. PROBS. 289, 310 (2003).

<sup>139</sup> Heller & Eisenberg, *supra* note 28.

<sup>140</sup> See Mireles, *supra* note 15, at 276-82.

<sup>141</sup> Boettiger & Bennett, *supra* note 12, at 281 ("Finally, the potential to block research because of problems in access to research tools appears to be an unintended, but actual, result of the Bayh-Dole Act. This plays out in terms of directly slowing or stopping fundamental research but may also prevent research targeted towards non-commercial or humanitarian applications of technology.")

<sup>142</sup> *Id.*

<sup>143</sup> Rai & Eisenberg, *supra* note 138, at 294 (proposal to implement this solution by eliminating the "exceptional circumstances" provision of Bayh-Dole).

expect anyone to make that type of determination.<sup>144</sup>

Another suggested solution viewed favorably by scholars is the inclusion of at least a limited research exemption in the legislation passed in developing countries.<sup>145</sup> One option is to require that “[a]ll researchers whose work is supported by federal funds should have a limited, royalty-free license to make and use for research purposes all inventions developed with federal funds.”<sup>146</sup> This option essentially creates a governmental patent pool that gives researchers supported by governmental funds access to other inventions funded by governmental funding.<sup>147</sup> A variation of this approach is to require “those receiving government research funding . . . to consider the option of licensing patented inventions to a ‘technology trust,’ that is, a commons that would ensure designated inventions remained available to all interested parties on predetermined terms.”<sup>148</sup>

While this is beneficial in the sense that it allows further research and potential creation of new life-saving technologies, the downside is that it creates uncertainty and drastically reduces the value of licensing agreements.<sup>149</sup> This is because a large pool of researchers could use a technology for free and find a new technology that might replace the one the licensee has paid to license, making the license nearly worthless.<sup>150</sup> One way to limit the effect of this would be to decrease the size or types of technology allowed in the patent pool. For example, the free license granted by the government could be limited to researchers using the free license to work on neglected diseases. It is important to note that all these types of patenting pooling create difficult antitrust and economic issues,<sup>151</sup> including risks of collusion, limited utility, or high costs.<sup>152</sup> Due to the

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<sup>144</sup> See Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 393, 440-42 (2006) (“[T]he Rai and Eisenberg proposal would fail in implementation.”).

<sup>145</sup> Mireles, *supra* note 5, at 531 (2007) (“Some provisions that may be modified by developing countries include a research exemption to increase access to government-funded inventions.”).

<sup>146</sup> *Id.* at 534 (quoting Pulsinelli, *supra* note 144, at 442-43) (citing Boettiger & Bennett, *supra* note 12, at 278 (“Development of new policies should consider the inclusion of a well-reasoned research exemption for university researchers’ use of proprietary IP.”)).

<sup>147</sup> Pulsinelli, *supra* note 144, at 442-46 (discussing the implementation of this type of government patent pool).

<sup>148</sup> So et al., *supra* note 4, at 2081.

<sup>149</sup> Pulsinelli, *supra* note 144, at 446 (“Under my proposed Bayh-Dole license, however, [the licensee]’s power would have been greatly diminished.”).

<sup>150</sup> *Id.* (using stem-cell research as an example).

<sup>151</sup> See generally Philip B. Nelson, *Patent Pools: An Economic Assessment of Current Law and Policy*, 38 RUTGERS L.J. 539 (2007) (discussing the anti-trust and economic difficulties arising from patent pools).

<sup>152</sup> Bradley J. Levang, Comment, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 251 (2002) (“The risks of collusion,

increased need for access to new life-saving medicine in developing countries, policy-makers in these countries should seriously consider a limited expansion of the research exemption allowed in Bayh-Dole, but they will also have to remember the countervailing dangers.

F. *Provide a Suitable Access Licensing Provision*

Advocates in the United States are strongly pushing for a reevaluation of the access provisions in Bayh-Dole. When developing countries try to contextualize this legislation to their own needs, high levels of low-income individuals and high rates of disease may pronounce this issue. As discussed previously, “march-in rights” and “exceptional circumstances” provisions have largely been unsuccessful in the United States.<sup>153</sup> “March-in rights” may very likely be more effective in a country whose government is more willing to intervene than the U.S. government. In fact, South Africa decided to reserve “walk-in rights” for the government to license a technology to a third party if the original licensee fails to use the license or fails to disclose the license to the state.<sup>154</sup> In these cases, hopefully the country’s governments will be willing to intervene when needed, but due to the failure of these provision in the United States, developing countries, especially those with federalist governments that are similarly hesitant to intervene with industry, may want to consider alternative legislative approaches to providing access to life-saving technologies.

One alternative approach to solve these issues is to work within the framework of the licensing statutes by creating licensing language favorable to the underprivileged.<sup>155</sup> As an example, multiple scholars have pointed to licensing language developed by the Public Intellectual Property Resource for Agriculture and Universities Allied for Essential Medicines designed to ensure that universities and other research institutions reserve rights to allow access for “humanitarian commercial development that benefits the poor and underserved.”<sup>156</sup> Commentators have noted that allowing research institutions to reserve rights would dramatically undercut the worth of the

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disagreements, high costs, and limited utility will prevent many patent pools from being widely adopted by biotechnology companies.”).

<sup>153</sup> Boettiger & Bennett, *supra* note 12, at 279 (“Enforcement of compliance with the legislation may need to diverge from Bayh-Dole’s ‘march-in’ rights. ‘March-in’ rights under Bayh-Dole has not been employed as a mechanism for enforcement of compliance with the legislation. In addition, the inclusion of ‘march-in’ rights has the potential for creating uncertainty in IP rights ownership and therefore may discourage industry involvement. New policies should carefully balance the relative strength of ‘march-in’ rights and the uncertainty they create for technology commercialization.”).

<sup>154</sup> See Sibanda, *supra* note 101 (discussing South Africa’s “walk-in” rights).

<sup>155</sup> See Boettiger & Bennett, *supra* note 12, at 265 (providing examples of how “the patenting and licensing discretion allowed by Bayh-Dole can be used strategically”).

<sup>156</sup> Mireles, *supra* note 5, at 532-33 (citing Boettiger & Bennett, *supra* note 12, at 265).

patent when the product's main market is humanitarian uses.<sup>157</sup> Accordingly, the researchers who seek to do research for low-income populations would have to operate with the knowledge that they would not recuperate any of the costs of eventually marketing the invention. Proposed regulatory schemes should seek to avoid punishing licensees willing to take a risk on drugs aimed at developing country markets. This is also the downside of the "negative milestones" approach that some commentators have suggested, which takes money away from the licensee if they fail to achieve certain commercialization goals by specific dates laid out in the license.<sup>158</sup>

Requiring the use of legally enforceable Commercial Development Plans may be a more successful strategy than reserving rights to research institutions for humanitarian use. Requiring Commercial Development Plans as is done for exclusive or partially exclusive licenses in government agency licensing<sup>159</sup> would grant a licensee full rights to the technology, but would provide research institutions a mechanism for holding corporations accountable to proposed access plans. Legislation could even require that Commercial Development Plans for technology that may have a potential life-saving effect include a provision for how the licensee is going to make the technology available to the low-income population. This is favored by scholars, who argue that "at the very least, when inventions have foreseeable applications in resource-poor regions, a plan for access in those regions should be explicitly incorporated into technology licensing." Some would push for broader provisions, applicable to all licenses resulting from government-funded research.<sup>160</sup>

Under a Commercial Development Plan approach, if the licensee failed to take reasonable efforts to see this plan through, the research institution is not left, as was the case with Emory, with media and public pressure as its enforcement mechanism. Instead, the research institution would have the power to void the license and issue a new license to party who would provide access. While this does create some uncertainty and decrease the value of the license, the fact that an industry partner sets the terms would likely make this an attractive option. While similar to "march-

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<sup>157</sup> *Id.* at 533.

<sup>158</sup> *Id.* at 536 ("The use of negative milestones would also be helpful to ensure that technology that is exclusively licensed will be commercialized.").

<sup>159</sup> 35 U.S.C. § 209(a)(3) (2006) ("A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention . . . only if . . . the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable.").

<sup>160</sup> *See* So et al., *supra* note 4, at 2081 ("Licenses to government-funded inventions should presumptively include access-oriented licensing provisions that address humanitarian needs in other countries.").

in rights,” this option would give enforcement power to research institutions, which have closer ties to the licensee and the technology and may be in a better position to ensure that provision of access. This approach would also require upfront honesty about provisions for access to low-income populations during the licensing process, which may have helped with Emory’s Gilead situation and address the transparency concerns raised by scholars.<sup>161</sup> This approach would also provide a safeguard for countries who would have to market to the industry outside of their country to utilize the Bayh-Dole framework. These countries could use Commercial Development Plans to require a specific plan to allow the the country reasonably priced access to the technology, with the threat of withdrawal of license if the foreign industry licensee fails to return a benefit to the country. Accordingly, developing countries, seeking to balance encouragement of technology transfer as a keystone of their economy and assurance of access to life-saving technology for the underprivileged, should consider this approach.

The required Commercial Development Plan approach has gained some foothold in the United States outside of federal agencies: a recent California state agency, the California Institute for Regenerative Medicine (CIRM), has utilized this approach in the progressive new regulation it adopted into state law regarding transfer of technology discovered using funding granted by the CIRM.<sup>162</sup> CIRM has applied this regulation to exclusive licenses with non-profit organizations and for-profits organizations.<sup>163</sup> The provision requires that licenses “shall include terms for commercial development plans to bring the invention to practical application” which includes “commercial development milestones and benchmarks so that development can be assessed and monitored.”<sup>164</sup> The regulation then requires research institutions to monitor the achievement of benchmarks and commercial development activities of licensees and gives research institutions authority to “take administrative action to modify or terminate license rights where necessary.”<sup>165</sup> CIRM’s regulations provide a model for designing this type of provision in the future.

Another suggestion has been to adopt the “open licensing” approach.<sup>166</sup> This approach, like licensing practices on free software, “uses

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<sup>161</sup> *See id.* (“The legislation should ensure transparency in the patenting and licensing of publicly funded research.”).

<sup>162</sup> *See* CAL. CODE REGS. tit. 17, §§ 100306, 100406 (2009) (governing non-profits).

<sup>163</sup> *See id.*

<sup>164</sup> CAL. CODE REGS. tit. 17, §§ 100306(c), 100406(c)(3) (2009).

<sup>165</sup> CAL. CODE REGS. tit. 17, § 100306(g)-(h) (2009).

<sup>166</sup> *See generally* Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005); *see also* Mireles, *supra* note 5, at 533 n.27 (mentioning the Kapczynski “open licensing”

proprietary rights to secure freedom for an open class of potential users, rather than to secure exclusivity for a closed class of licensees.”<sup>167</sup> It encourages research institutions to use what it calls an “Equitable Access License” which basically aims to allow generic competition to lower the cost in developing markets through enabling the licensee to utilize the technology, but specifically securing “freedom to operate” for generic manufacturers.<sup>168</sup> Developing countries must balance the downside, a decrease in the value of licenses aimed at humanitarian or developing markets, by attempting to grant “fair royalties” to the licensee for allowing the open licensing.<sup>169</sup>

### CONCLUSION

The needs of developing countries are unique and diverse with particular government and research institution structures. The United States has responded to different types of institutions by creating technology transfer legislation specifically adapted to that institution’s particular needs. While two lines of legislation governing government laboratories and universities both seek to encourage the commercialization of the technology resulting from government funding, each has unique provisions, discussed in this Comment, which tailor the regulations to meet the particular needs of each institution in reaching the objective of commercialization.

If developing countries are seeking to pass legislation that attempts to harness the beneficial effect of giving research institutions clarification of ownership and authority to license technology funded by the government, these countries need to realize the highly specified nature of this legislation. These countries will need to closely examine the direction their economy is heading, the structure of their government, and the primary type of research institution within their countries. These countries will also need to weigh the benefits and pitfalls of the American legislation and also examine the provisions specially designed for particular institutions. For countries with highly regulated institutions, more closely compared to government owned and operated laboratories in the United States, provisions like CRADAs, which lower negotiation time and costs for outside input into the institution, and Commercial Development Plans, which encourage transparency in negotiations and clear objective for use by the public, could be beneficial. For countries with institutions similar to American universities, less

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approach as a possible solution to the problems caused by applying Bayh-Dole to developing countries).

<sup>167</sup> Kapczynski et al., *supra* note 166, at 1090.

<sup>168</sup> *Id.* at 1090-94.

<sup>169</sup> So et al., *supra* note 4, at 2081 (“One such provision is an open license for production and sale of end products in (or to) developing countries in exchange for a fair royalty.”).

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restrictive legislation may be preferred.

The unique needs of developing countries will depend on the country, but many will want to create modifications to the Bayh-Dole legislation that helps to contextualize it to a country facing higher disease and poverty rates. This may include different utilization of licensing preferences to further particularized national objectives or possibly more allowance of research exemptions to help spur burgeoning research sectors. It may also include special structuring of technology transfer guidance, perhaps regional or national oversight of the commercialization process, in order to ensure the licensee uses technology for the public's benefit. Finally, it may include access provisions better calculated to work in the specific country, whether this involves "march-in rights" paired with increased governmental willingness to intervene or other innovative strategies, such as mandatory creation of a plan for use of the technology for humanitarian purposes.

Whatever provisions the country ends up adopting, if a country decides to enact legislation modeled on Bayh-Dole, the country must carefully study the particular needs of its own country. Even within the United States there is diversity in the regulations governing how the technology resulting from government-funded research is commercialized. The individual needs of the unique institutions found in the United States and the special way each institution interacts with the structure of the U.S. government is the basis for this diversity. Likewise, developing countries must become acutely aware of their form of government and the institutions in their country. Instead of bluntly adopting Bayh-Dole as it exists in the United States, these countries must specially tailor their legislation to properly regulate their varied research institutions in order to attempt to achieve their country's distinctive national goals and objectives.