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*FEATURE ARTICLE*

**LOST IN TRANSLATION? THE  
PROMISES AND PITFALLS OF  
ENACTING U.S. BAYH-DOLE  
STYLE LEGISLATION IN INDIA**

*By* ANN WEILBAECHER

**T**he Rajya Sabha, India's Upper House of Parliament, recently began considering a contentious piece of intellectual property legislation modeled after the U.S. Patent and Trademark Law Amendments Act of 1980 (Bayh-Dole Act).<sup>1</sup> The Protection and Utilisation of Public Funded Intellectual Property Bill, 2008 (Indian Bayh-Dole Bill) allows universities, rather than the government, to patent discoveries derived from publicly funded research.<sup>2</sup> The

Indian Bayh-Dole Bill also gives inventors and institutions a share in the royalties and licensing fees generated from the resulting commercial products.<sup>3</sup> While proponents argue that the Indian Bayh-Dole Bill will result in greater interaction among the government, academic institutions and industry, critics caution that the proposed legislation's emphasis on commercialization will threaten the public interest.<sup>4</sup> These critics assert that the purported benefits of the Bayh-Dole Act have been overstated in the U.S., and that the Indian Bayh-Dole Bill has the potential to hinder innovation and access to essential medicines and treatments in India.<sup>5</sup>

## U.S. BAYH-DOLE ACT

The Indian Bayh-Dole Bill is closely modeled after the U.S. Bayh-Dole Act, which gives universities the right to obtain patents on innovations resulting from government-funded research and to issue exclusive licenses on those patents.<sup>6</sup> Journalists and commentators have referred to the Bayh-Dole Act as “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century,”<sup>7</sup> and “the Magna Carta for university technology transfer.”<sup>8</sup>

Proponents report that before the Bayh-Dole Act, thousands of government-funded inventions were collecting dust in university laboratories across the U.S.<sup>9</sup> According to the U.S. Government Accountability Office, the federal government owned 28,000 patents and less than five percent of those patents were licensed to industry.<sup>10</sup> Advocates allege that since its inception, “the overall effect of the Bayh-Dole Act has been to contribute more than \$40 billion annually to the American economy.”<sup>11</sup>

## BAYH-DOLE EMULATION ABROAD

In the hopes of achieving similar benefits, developing and emerging countries such as Brazil, South Africa, Malaysia and China have implemented Bayh-Dole style legislation in the past several years.<sup>12</sup> Scholars, however, express concern that many countries are adopting such legislation based upon faulty assumptions about the Act's efficacy in the U.S.<sup>13</sup> They contend that the Bayh-Dole Act is only one of a number of factors that has led to increased patenting and licensing.<sup>14</sup> Further, scholars suggest that Bayh-Dole style legislation may even

inhibit scientific research and innovation in developing countries because too many patents can lead to overlapping claims and time-consuming disputes.<sup>15</sup>

India is the most recent example of a country considering enacting legislation similar to the Bayh-Dole Act. Scholars question the wisdom of transplanting U.S. style legislation to a country like India, given the different cultural, economic, social, and legal context of modern day India compared with the U.S. in the 1980s when the Bayh-Dole Act was enacted.<sup>16</sup> Shamnad Basheer, an associate at New Delhi's Oxford Intellectual Property Research Center, asks rhetorically, "Does it make sense for India to blindly import such a bill, given that we have a different set of circumstances (in terms of the nature of university research, relationship with industry, cultural specificities) than what prevailed in the US in the '80s?"<sup>17</sup> Basheer recommends that the legislators "study what the specific Indian conditions are and then customize the bill to those conditions."<sup>18</sup>

#### SECRECY OF THE LEGISLATION

The Union Cabinet, India's highest executive authority, approved the Indian Bayh-Dole Bill on October, 31, 2008, before legislators released a draft to the public.<sup>19</sup> Although drafting began in 2005, the Minister of Science and Technology first disclosed the Indian Bayh-Dole Bill in December 2008, just before it was formally introduced to Parliament.<sup>20</sup> Basheer was instrumental in bringing the bill to the public's attention, posting unofficial drafts on his website, *Spicy IP*, and calling for public interest groups and stakeholders to demand transparency.<sup>21</sup>

The secrecy of the legislation has spurred public outcry. "I think it's part of a troubling impunity in which governments feel that they can act in debating these issues that have very important public interest implications," states Ethan Guillen, Executive Director of Universities Allied for Essential Medicines (UAEM), a student-run public interest group.<sup>22</sup> "It's the same trend where governments go behind closed doors and work with industry-minded groups to create these policies that are then foisted upon the public without any real civil society or public interest comment," says Guillen.<sup>23</sup>

Some, however, are not as concerned with the lack of transparency. Naryanan Suresh, Group Editor of India's first biotechnology business magazine, *Biospec-*

*trum India*, points out that there is no set procedure for releasing draft documents before they are introduced to Parliament.<sup>24</sup> In fact, legislators are only required to publicly disclose documents after they are introduced to Parliament, according to Suresh.<sup>25</sup>

While Basheer acknowledges the government acted legally, he asserts that transparency is a “good norm,” especially with legislation that has such import to the public interest as the Indian Bayh-Dole Bill.<sup>26</sup>

## GENERATING WEALTH

Proponents argue that the Indian Bayh-Dole Bill will allow universities to reap financial benefits from their discoveries, and, as a result, jump start scientific innovation in India.<sup>27</sup> According to Suresh, there is widespread support for the Indian Bayh-Dole Bill among biotech experts who believe the legislation could spur innovation in the biotech sector like it did in the U.S.<sup>28</sup> He adds, “In India, scientists are no different from scientists anywhere else in the world” and would be motivated by a bill that allows them to commercialize their research.<sup>29</sup>

Under the Indian Bayh-Dole Bill, scientists would be allowed to retain at least 30 percent of the royalties earned from patents and licenses resulting from government funded research.<sup>30</sup> Universities would retain 40 percent of the net income, and the remaining income would finance the management of intellectual property at the university.<sup>31</sup> Unlike the U.S. Bayh-Dole Act, the Indian Bayh-Dole Bill actually specifies a minimum percentage to which inventors are entitled.<sup>32</sup>

India’s Science Minister, Kapil Sibal, expressed confidence that the bill will be passed, and that it will assist Indian universities to “make millions through patents.”<sup>33</sup> “That statement is pretty deeply misinformed if you think about universities as a whole in the U.S.,” says Professor Matthew Herder, visiting intellectual property law professor at Loyola University Chicago School of Law.<sup>34</sup> “There have only been a few universities that have made a lot of money after Bayh-Dole, and those that have been successful. . . were those that were successful before for the most part.”<sup>35</sup>

According to Basheer, “The costs of operating the technology transfer offices far exceed the money most universities make out of licensing.”<sup>36</sup> He elaborates, “That is why we were very anxious that they disclose the bill at an earlier stage. I think there’s enough empirical evidence to show that . . . a large number of universities would not necessarily make money.”<sup>37</sup>

#### SAFEGUARDS TO ACCESS

The most pressing concern outlined by public interest groups is that the Indian Bayh-Dole Bill will threaten access to the fruits of government funded research. UAEM cautions that the Indian Bayh-Dole Bill will “allow the institutions and their licensees to charge monopoly prices that may place life-saving medicine out of the reach of India’s poorest consumers, denying them the opportunity to benefit from publicly-funded research.”<sup>38</sup> According to Guillen, “The Bayh-Dole Act is at the basis of everything that UAEM is trying to change.”<sup>39</sup>

Guillen expresses concern that the Indian Bayh-Dole Bill contains even fewer safeguards to preserve public access than the Bayh-Dole Act.<sup>40</sup> When the Bayh Dole Act was debated in the U.S., there was an emphasis on preserving public access to the results of publicly funded research.<sup>41</sup> As a consequence, a “march-in right” provision was added whereby if anything was brought to market under unreasonable circumstances, the government could take action.<sup>42</sup> The Indian Bayh-Dole Bill has no such “march-in right” provision.<sup>43</sup>

Guillen asserts, however, that the “march-in right” process has been “imperfect and extremely flawed” in the U.S., because the government has never invoked these “march-in rights.”<sup>44</sup> Herder notes, “What we don’t know is if there are cases where a license was disseminated broadly because the government said they were going to invoke march-in rights behind the scenes.”<sup>45</sup> He elaborates, “If they have been used behind the scenes, it can still be a valuable tool.”<sup>46</sup>

Basheer contends that in an earlier draft of the legislation there was a clause specifying that the compulsory licensing provisions under the Indian Patent Act would apply to the Indian Bayh-Dole Bill.<sup>47</sup> Compulsory licensing would have a similar effect as “march-in rights” in that the government could use patented discoveries for a limited period without the consent of the patent

holder.<sup>48</sup> This clause, however, did not appear in the publicly released version of the Indian Bayh-Dole Bill.<sup>49</sup>

When asked about the removal of the compulsory licensing clause from the Indian Bayh-Dole Bill, Herder speculates, “If the real goal in adopting this legislation is to attract investment from foreign firms because of a familiarity with a Bayh-Dole like regime, then having a compulsory licensing provision would be a cost because it is totally foreign in the U.S.”<sup>50</sup> He further explains, “Most of the free trade agreements the U.S. has entered into since the 1980s have been conditioned on getting rid of compulsory licensing regimes.”<sup>51</sup>

According to Basheer, the removal of the compulsory licensing clause effectively has no impact on the bill.<sup>52</sup> Provisions of the Indian Patent Act would apply to the Indian Bayh-Dole Bill even if it is not explicitly written into the new legislation.<sup>53</sup> Basheer emphasizes that the compulsory licensing provisions in the Indian Patent Act are less than ideal and have many bottlenecks towards implementation.<sup>54</sup> Thus, Basheer recommends stronger public access safeguards in the Indian Bayh-Dole Bill, with wider compulsory licensing norms, including removal of the three-year wait time to invoke compulsory licenses in some cases.<sup>55</sup>

Further, Basheer recommends non-exclusive licensing provisions, particularly with regards to platform technologies, to ensure greater access to the results of publicly funded research.<sup>56</sup> Guillen agrees, stating that UAEM recommends, “global access licensing internationally, to ensure that publicly funded discoveries, medicines and health technologies are available at a low cost in developing countries.”<sup>57</sup>

#### OVER-EMPHASIS ON PATENTING

Yet another problem is the strong emphasis on patenting to the exclusion of other forms of knowledge dissemination. As a rationale for adopting the Indian Bayh-Dole Bill, proponents frequently note that only three percent of patents filed in the Indian patent office were filed by Indian universities.<sup>58</sup> However, according to Guillen, “This is not a good metric to go by because just patenting something tells you nothing about whether the discovery should have been patented, how it is eventually licensed and used, or if it was actually licensed to the right company and will eventually benefit the public.”<sup>59</sup> More-

over, legal scholars argue that an over-emphasis on patenting fails to recognize the importance of other avenues of knowledge dissemination, such as publications, conferences, and the training of students.<sup>60</sup> Of particular concern is whether a strong emphasis on patenting will lead to a weakened commitment to open science, manifested in publication delays, secrecy and withholding of data and materials.<sup>61</sup>

#### FUTURE OF THE BILL

With upcoming Indian elections in May 2009, the future of the Indian Bayh-Dole Bill is unclear. According to Basheer, the Upper House has submitted the bill to a Parliamentary Standing Committee, which usually takes four to six months to receive submissions and give their report to the Parliament.<sup>62</sup> Basheer expects the Indian Bayh-Dole Bill to be enacted, even if a new administration is elected.<sup>63</sup> Guillen concurs, noting that there is widespread support among the government and industry groups.<sup>64</sup>

Legal scholars and public interest advocates believe that in the world's largest democracy, the Indian government should widen the debate to hear public interest perspectives.<sup>65</sup> They argue that this open approach will make it easier to learn from the experience of the Bayh-Dole Act in the U.S. and to draw the right lessons for India.<sup>66</sup>

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#### NOTES

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