

## Proprietary Considerations

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On August 9, 2001, U.S. President George W. Bush announced a compromise position on federal funding for human embryonic stem (HES) cell research, seeking a middle ground between the outright ban favored by the Right-to-Life movement and the active pursuit of stem cell research proposed by some scientists and disease advocacy groups. Henceforth, U.S. funds could be used for research with HES cell lines that had already been created as of that date but not to derive new cell lines nor to perform research with cell lines created after that date.<sup>1</sup>

For the next month, until the events of September 11, 2001 eclipsed all other stories, the terms of access to HES cell lines made front-page news in major newspapers across the United States.<sup>2-6</sup> Within this brief window, an unprecedented level of public attention focused on a problem that has been a growing challenge to the biomedical research community for years: how to get beyond a proliferation of proprietary claims and streamline access to research tools for use in biomedical research. However, while other material transfer agreements (MTAs) and patent licenses had typically languished for months on the desks of overburdened technology transfer professionals in research institutions and private firms, negotiations over the terms of access to HES cell lines proceeded briskly under the bright glare of media attention.

The National Institutes of Health (NIH), sponsor of past research on primate embryonic stem (PES) cells and prospective sponsor of HES cell research within the constraints announced by the President, took the lead in negotiating on behalf of the Public Health Service for terms that would apply to all government-sponsored researchers. On the other side were representatives of the technology transfer affiliate of the University of Wisconsin (Wisconsin Alumni Research Foundation [WARF]), the holder of a handful of qualifying cell lines and the owner of broad patents on HES cells. While reporters eagerly awaited updates, the NIH and WARF worked out the details of a memorandum of understanding (MOU) that would permit streamlined access to HES cells by academic researchers for "upstream" research, while allowing WARF to retain control over "downstream" commercial uses of the technology. Other owners of approved HES cell lines subsequently entered into agreements on similar terms.

The supply of HES cell lines that meet the President's criteria has been disappointing. In his announcement, President Bush indicated that the Department of Health and Human Services had identified 64 HES cell lines that met the stated criteria; as of this writing, it appears that fewer than a dozen viable cell lines qualify.<sup>7</sup> Nonetheless, the MOU negotiated by the NIH and WARF, which sets up a zone of relatively free access to HES cell lines for use in noncommercial research, is something of a triumph for the academic research community. This outcome is all the more remarkable because WARF had previously given exclusive commercial rights to a broad patent covering all HES cells to a private research sponsor Geron Corporation.

Notably, the federal government held its own trump card in the negotiations. Before Geron came on the scene, the NIH had sponsored research at Wisconsin that generated an even broader, "parent" patent covering all PES cells. Under the Bayh-Dole Act of 1980, Wisconsin owned this patent. Nonetheless, the government retained certain rights, including a retained license to use the invention for government purposes<sup>8</sup> and "march-in rights" to compel the granting of licenses to applicants on reasonable terms if necessary to achieve practical application of the invention.<sup>9</sup> Although the NIH has not formally invoked these rights in this context, the recitals at the beginning of the MOU state that "the Government has certain use and other rights to the intellectual property comprising the Wisconsin Patent Rights granted by law and regulation," and the prospect that the NIH could invoke these rights if negotiations reached an impasse clearly strengthened the bargaining position of the NIH.

The field of HES cell research is idiosyncratic in many respects. The cautious posture of public sponsors toward funding HES cell research has left this emerging field unusually dependent on private funding for support of early-stage, upstream research, aggravating the usual difficulties in negotiating terms of exchange for research tools. On the other hand, the strong interest of the Bush administration in legitimating the President's compromise position on HES cell research presumably enhanced its motivation to overcome remaining obstacles to research progress, and the extraordinary level of media attention may have constrained unreasonable bargaining behavior on all sides. For all these reasons, it is hardly a representative case study. Nonetheless, its media salience makes it a relatively accessible case study, and, to the extent that the result has been a diminution in proprietary obstacles to noncommercial research, it might even be an exemplary one.

Contrast the position of WiCell with that of other providers of cell lines who do not have such patent rights. Without contractual reach-through rights negotiated at the time they transfer the materials, these providers might have nothing left to bargain with when research using their cell lines yields a discovery that can be developed commercially using other HES cell lines. Thus, the MOU's seemingly even-handed approach might in fact favor WiCell over other cell line providers who have weaker patent positions. However, whatever the commercial implications for other cell providers, from the perspective of academic researchers, the MOU is quite attractive. Given that many or even most of these academic research projects will not yield commercially valuable results, the MOU has significantly reduced the number of MTAs and patent license agreements that have to be negotiated before research may proceed. Moreover, for those research projects that do yield commercially valuable results, the institutions performing the research will be able to retain their own patent rights without reach-through obligations.

The WiCell MOU has formed a template for similar MOUs with other HES cell providers<sup>27</sup> and has also set the terms for patent license agreements between WiCell and these providers.<sup>28</sup> Once again, the result is quite favorable for NIH-sponsored HES cell researchers. In effect, NIH has used its bargaining power to consolidate and expand the relatively unrestricted zone for noncommercial research initially set up by the WiCell MOU to cover the use of cell lines from these other providers. Given that the WiCell MOU arguably puts other cell providers at something of a commercial disadvantage, however, one might wonder why these other providers have entered into the framework created by the MOU. The explanation is probably that they have little choice given WiCell's broad patents (and, relatedly, the retained power the NIH has over these patents). Given the scope of WiCell's patents, these institutions may not make, use, or sell HES cell lines within the United States without a license from WiCell. They may also feel that they ultimately stand to benefit from the advances in biologic understanding of stem cells that will come from their use in NIH-funded research. Although they might prefer to provide their cell lines to researchers under agreements that include reach-through rights, at least the NIH-brokered deal provides them with a royalty-free license.

### **Implications for Current Policy Debates: The Assault on Retained Rights**

In negotiations over access to HES cell lines, the NIH never formally exercised its retained rights in the patents held by WiCell. Nonetheless, those retained rights were a significant source of leverage that enabled the NIH to negotiate on behalf of future grantees for relatively streamlined access to HES cell lines to use in noncommercial research. While preserving WiCell's and Geron's control over commercial applications of HES cells, the NIH was able to claim the authority it needed to get six institutions to agree to provide HES cell lines to NIH-funded investigators on reasonable terms, free of

reach-through obligations that might cast a shadow over upstream research in universities.

The retained rights that proved so useful in facilitating access to HES cell lines are currently facing some political opposition. The Integrated Dual-Use Commercial Companies (IDCC), a coalition of large commercial firms with a mission to change federal laws and regulations for the benefit of firms that perform government research and development (R&D) contract work, has argued that many private firms refuse to develop technology for the government because of the risk of losing control over the resulting patents if the government should choose to exercise its retained rights.<sup>29</sup> IDCC has collaborated with the American Bar Association Research and Development and Intellectual Property Committee to draft legislation that would permit research sponsors to waive in advance their retained rights under the Bayh-Dole Act in negotiating the terms of contracts and grants to make government R&D work more attractive to private contractors.<sup>30</sup> They characterize this proposal as providing the government with flexibility so that it may gain access to state-of-the-art technologies.

More accurately, the proposal would permit the government to bargain away at the point of entering into a contract the flexibility that current law reserves to the government at a later stage. When it enters into an R&D contract or grant, the government is negotiating from a position of substantial ignorance. It can only guess what sorts of technologies will be developed under the contract, what patent rights will be obtained on those technologies, how those patent rights will be licensed, and how broadly and effectively the technologies will be disseminated and used. For this reason, the Bayh-Dole Act preserves for sponsoring agencies the right to review the performance of contractors in bringing their inventions to the point of practical application later on and to intervene if necessary, subject to procedural safeguards to protect the expectations of contractors and their licensees.

Although agencies have almost never exercised their retained rights in the 23 years since passage of the Bayh-Dole Act, it may well be that the specter of retained rights deters some private contractors from getting involved in government R&D work. It is virtually impossible to apply a unitary patent policy across the vast and varied terrain of federally funded R&D without leaving some people unhappy. However, as the HES cell case study shows, the retained rights of the government can be a valuable check on behavior that might otherwise frustrate the public interest in dissemination of inventions.

### **Conclusion**

The ethical debate over the derivation and use of HES cells continues to impose serious constraints on the use of HES cells in publicly funded research. Within these constraints, however, the NIH has done an impressive job of ensuring that proprietary considerations—whether they arise from patent rights or from tangible property rights—do not hamper access to HES cell lines by noncommercial academic researchers.

Of particular relevance to current debates over reform of the Bayh-Dole Act, this episode shows that the rarely invoked rights of government research sponsors over patents held by grantees are not merely a vestige of excess caution from an earlier era. These retained rights can give government agencies the leverage they need to promote the utilization and dissemination of technologies that might otherwise get stuck in a gridlock of proprietary claims.

## The General Problem of Proprietary Research Tools

Universities have been struggling for decades about terms of exchange for materials and other inputs into biomedical research that might yield commercially valuable results. In an earlier era, academic norms of free exchange had pressured university scientists to put research results and the biologic data and materials supporting the research results into the public domain. In the late 1970s, as biomedical research started to show commercial potential, these free exchange norms came under increasing pressure.

Proprietary pressures intensified with the 1980 passage of the Bayh-Dole Act. The central goal of the Bayh-Dole Act, which encourages universities to patent the results of publicly sponsored research, is to facilitate commercial development of discoveries arising from such research.<sup>a</sup> The guiding philosophy behind this legislation—that patents and protection from competition are generally necessary to induce commercial investment in developing new technologies—is in tension with the free dissemination norm. Early dissemination before filing a patent application may make an invention unpatentable.<sup>b</sup> Even after a patent application is on file, the logic of technology transfer tends to encourage exclusive licensing, because a nonexclusive license can not provide the hedge against competition that the Bayh-Dole Act envisions as necessary for commercialization.

Although the philosophy of patenting and exclusive licensing to achieve commercial development has some merit, it does not apply uniformly to all university inventions. The problem lies in distinguishing inventions that are best developed through exclusive rights from those that will be more effectively disseminated and used on a nonexclusive basis. Exclusive rights are necessary for commercializing certain types of inventions, such as promising drug candidates that have high development costs. In contrast, many inventions arising in university research can be promptly disseminated

for use by other researchers without substantial additional investment. Exclusive licensing is particularly problematic when, as is increasingly common, a university has a broad patent on a research tool that enables many subsequent paths of investigation. In these cases, exclusive licensing threatens creative development, because the holder of the exclusive right is unlikely to foresee all the follow-on paths. Moreover, subsequent research using these tools is likely to generate additional patents that will provide commercial exclusivity in any emerging downstream products that require substantial private investment.

Exclusive licensing is not only encouraged by the Bayh-Dole Act but university technology transfer officers often see it as most promising of the available options. According to a recent estimate by the Association of University Technology Managers (AUTM), about half of university licenses are exclusive, and 90% of licenses to start-ups are exclusive. Although nonexclusive licensing of broadly enabling research can be lucrative for universities, it may be difficult for university technology transfer officers to foresee these revenues at the time that they initially attempt to market the technology. In the case of an early-stage invention about which little is known, they may mistakenly believe that only one firm is interested and grant an exclusive license, only to determine later that it might have been profitable to license the invention nonexclusively to multiple firms.

Indeed, in the post-Bayh-Dole era, pressure to assert aggressive proprietary claims extends to all upstream research materials, whether or not they are patented. Universities and private firms try to leverage their control over these upstream materials into a percentage of profits from subsequent commercial products. For example, if a university is providing materials such as cell lines to a firm that might develop a commercial product, it may seek reach-through royalties on future product sales. Many firms resist this approach, which they believe overvalues mere research tools relative to the overall work of product development. Most products can trace their provenance to a great many different research materials, and, as more of these materials become subject to reach-through royalties, the prior obligations encumbering a commercial product could mount quickly.

A related strategy that is more common for extracting value from transfers to academic researchers and others who are unlikely to develop a commercial product is for the provider to seek reach-through rights to future intellectual property of the user, such as an option to license future discoveries. Universities view reach-through rights as an undue restriction of their control over the licensing of future discoveries. Moreover, if a university signs enough of these agreements, it can soon find itself committed to inconsistent obligations to assign future license rights or options on the same inventions to multiple institutions. Consequently, just as firms bargain hard to avoid reach-through royalty obligations, universities bargain hard to avoid reach-through license obligations. The net result can be

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restricted access to research materials, even among academic researchers.<sup>c</sup>

Conflicts over patents and MTAs had been a source of growing concern in the biomedical research community and among policy analysts for years before the summer of 2001.<sup>11-13</sup> However, the issue did not catapult into the consciousness of the general public until August 2001, when the controversy over access to HES cell lines captured newspaper headlines.

### The Specific Problem of Proprietary Human Embryonic Stem Cells

Research on HES cell lines presented two special circumstances that aggravated the usual problems with terms of exchange for research tools. First, prohibitions on the use of U.S. government funding for HES cell research forced universities—specifically the University of Wisconsin—to turn to private sponsors at an early stage, compromising its control over the relevant patents long before specific commercial applications came into view. Second, the Bush compromise itself, which limits future use of federal funds to research with existing HES cell lines, greatly enhanced the bargaining power of the institutions that had already developed the approved cell lines.

Both of these circumstances arose because of the ethical controversy surrounding HES cell research. Such research is ethically controversial because extracting HES cells requires destroying a fertilized human egg. Since 1995, Congress has put language in its appropriations bills prohibiting the NIH from funding research in which human embryos are created or destroyed. Despite these prohibitions, the U.S. federal government has, from the outset, been the primary sponsor of embryonic stem cell research using nonhuman tissue. In the 1990s, the NIH funded pioneering work by Dr. James Thomson and his colleagues at the University of Wisconsin that succeeded in deriving embryonic stem cells from rhesus monkeys and macaques. Consistent with the broad discretion to patent enjoyed by grantee institutions under the Bayh-Dole Act,<sup>14</sup> WARF sought to patent this advance and ultimately obtained a very broad patent.<sup>15</sup> Indeed, although the Wisconsin researchers had not, at the time of application, done work on humans, the patent application, which was granted in 1998, covered *all* PES cell lines.

To actually work with HES cells, however, the Wisconsin researchers had to look beyond federal funding. Dr. Thomson and his colleagues, therefore, set up a separate laboratory to work on HES cells and secured private funding from Geron

<sup>c</sup>In a recent article reporting the results of a survey of academic geneticists, Eric Campbell and his colleagues<sup>10</sup> found that almost half of all academic geneticists had been denied access to additional data or materials regarding published research by their academic colleagues. Campbell and his colleagues specifically point to the complexity and restrictiveness of MTAs as a factor that inhibits sharing.

Corporation, a small biotechnology company based in Menlo Park, California.<sup>16</sup> In November 1998, the Wisconsin researchers succeeded in isolating HES cells, and WARF filed a second, subsidiary patent application with claims specifically drawn to HES cells. A broad patent based on this application, which covers all HES cell line, not just the particular cell lines derived with Geron funds, was issued on March 13, 2001.<sup>17</sup> The HES cell patent relies on precisely the same scientific disclosure as the prior patent that covers PES cells and is, therefore, merely a subset of this initial patent.

When the NIH sponsors research, universities enjoy considerable latitude to deploy the resulting patent rights as they wish, subject to the right of the sponsor to intervene if the resulting inventions are not being used. In contrast, when private companies sponsor research, they usually demand at least an option to acquire an exclusive license to the resulting patents. Operating within these constraints, WARF initially granted Geron exclusive rights to develop therapeutic and diagnostic products based on six important differentiated cell types derived from HES cells—heart, bone, nerve, pancreatic, blood, and cartilage cells. Following widespread media attention to this exclusivity, as well as to litigation,<sup>18,19</sup> the parties agreed to narrow Geron's exclusive license to products involving nerve, heart, and pancreatic cells. Wisconsin retained the right to distribute HES cell lines for research purposes, but Geron's exclusive commercial license constrains the terms of these research licenses.

The Bush administration introduced another important constraint by setting limits on which cell lines NIH-funded researchers could use. This restriction greatly increased the bargaining power of the holders of cell lines on the approved list, inasmuch as researchers who did not like the terms offered by approved cell line holders could not avoid these terms by simply making their own new cell lines. In particular, the bargaining power of WARF was enhanced. The Bush compromise ensured that even if the WARF patents were invalidated—or simply ignored, an illegal practice in which academic scientists nonetheless often indulge<sup>d</sup>—NIH-funded researchers would still be bound by WARF's restrictions on its tangible cell lines.

### The National Institutes of Health's Role

As of August, 2001, the prospects for research access to HES cell lines did not look promising. Indeed, even today, most U.S. researchers remain extremely frustrated with their limited access to HES cell lines. Nonetheless, although the present situation is a far cry from the scientific community's normative ideal of free access, the NIH has played a constructive role by intervening aggressively on behalf of its grantees to set terms of access to the approved HES cell lines. Thus far, the NIH has signed MOUs with six institutions that hold cell lines meeting the administration's ethical criteria: WiCell Research

<sup>d</sup>Some university scientists assume that their research is exempt from infringement liability, but the courts disagree.<sup>20</sup>

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Indeed, in the post-Bayh-Dole era, pressure to assert aggressive proprietary claims extends to all upstream research materials, whether or not they are patented. Universities and private firms try to leverage their control over these upstream materials into a percentage of profits from subsequent commercial products. For example, if a university is providing materials such as cell lines to a firm that might develop a commercial product, it may seek reach-through royalties on future product sales. Many firms resist this approach, which they believe overvalues mere research tools relative to the overall work of product development. Most products can trace their provenance to a great many different research materials, and, as more of these materials become subject to reach-through royalties, the prior obligations encumbering a commercial product could mount quickly.

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The NIH's ability to strike a favorable deal for academic researchers depended critically on the fact that it had previously funded *some* research on embryonic stem cells and, therefore, retained some authority to oversee deployment of the resulting patents. The case of HES cells, therefore, underscores not only the importance of public funding but also the importance of the retained rights of the government under the patents obtained by grantees.

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