



Case Western Reserve University  
Office of Research & Technology Management

# Laws, Policies and Practices Governing Commercialization of Intellectual Property

January 21, 2010

## **Executive Summary**

Case Western Reserve University (“CWRU” or “University”), through its faculty and staff, generates a substantial volume of new intellectual property (“IP”) each year. Both to transfer the benefits of its innovations to society and to obtain financial gains for CWRU and its inventors, CWRU licenses many of its inventions to industry to allow for development and commercial distribution of new products and services. When entering commercial license agreements, CWRU must comply with numerous, and sometimes counterintuitive, legal and policy restrictions that require practices that differ from those of commercial firms. In Section II, this Whitepaper describes the restrictions facing CWRU in detail and, in Section III, explains how CWRU addresses these restrictions when managing and licensing its IP.

CWRU is beholden to six primary categories of obligations and restrictions that affect commercialization of IP. First, CWRU must manage IP in a manner consistent with its academic mission, purposes, and policies. Second, CWRU must satisfy requirements of patent, trademark, and copyright laws to garner value from IP. Third, with respect to IP created with the support of government funds, CWRU must comply with requirements of the Bayh-Dole Act. Fourth, CWRU must honor the terms and conditions of previous sponsorship, collaboration, and licensing agreements with businesses, government and nonprofit sponsors, and other universities. Fifth, CWRU must comply with requirements of tax law governing its tax-exempt status and bonds. Finally, CWRU must consider and address conflicts of interest, which have potential to implicate both academic integrity and legal concerns.

Legal restrictions, policy obligations, and existing contract terms and conditions affect not only the terms of licenses entered by CWRU, but also the terms under which it may accept funding for research. Unlike a business, CWRU must protect academic freedom,

publication rights, and faculty research opportunities. Meanwhile, CWRU may not risk its assets or sustenance to pursue either research funds or licensing revenue. With limited exceptions, CWRU generally does not provide services or products for fees, but instead seeks grants or sponsors for basic research. In addition, CWRU must assure that its licensees will use and commercially distribute CWRU's IP, rather than shelve it to create or preserve a competitive advantage.

CWRU strives to cooperate as fully as possible with industry, but it must balance numerous competing concerns to effectively and appropriately manage its IP. This Whitepaper is intended to shed light on those concerns and promote understanding of the manner in which CWRU meets the challenges they pose.

## **I. Introduction**

CWRU is among the leading universities in the United States for research, collaboration with industry, and the commercialization of IP created in an academic setting. When appropriate, CWRU's IP may be protected through patents, copyrights, trademarks, or other forms of legal protection and, in light of such protection, licensed to industry in return for royalties and/or other consideration, such as equity interests in new ventures. CWRU strives for mutually productive relationships with industry, but it must also balance and comply with numerous interests and legal concerns.

IP created at CWRU that has potential commercial value is managed by CWRU's Technology Transfer Office (the "TTO"). The mission of the TTO is "to assist and lead the successful commercialization of ideas created by people at CWRU."<sup>1</sup> Commercialization promotes CWRU's academic and research mission, reputation, and financial well-being while facilitating the dispersion and practical use of beneficial innovation. Because valuable IP may result from research sponsored (i.e., funded) by industry or government agencies, management of IP must also be considered at the outset of sponsorship supported and managed by CWRU's Office of Sponsored Projects Administration ("OSPA").

In promoting and managing IP, CWRU faces challenges and responsibilities that may differ significantly from those facing commercial organizations. The TTO and OSPA must not only serve and promote the interests of CWRU, as reflected in the University's policies, but also comply with distinctive legal requirements and constraints governing non-profit academic

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<sup>1</sup> CWRU Technology Transfer Website, <http://ora.ra.case.edu/techtransfer/pages/about.htm> (last visited Jan 20, 2010).

institutions—especially when entrusted with research funding provided by private or governmental third parties.

This Whitepaper will identify and discuss the legal and policy considerations governing CWRU’s management of IP and the manner in which it addresses those considerations in the efficient and effective pursuit of its mission and compliance with governing law.

## **II. Legal Constraints Affecting CWRU’s Management of IP**

The legal constraints affecting CWRU’s promotion and management of IP fall into six main categories.

First, CWRU, through its officers, administrators and employees, must preserve academic freedom, academic integrity, and meet fiduciary obligations under state non-profit laws to protect and preserve CWRU’s assets (including IP) in a manner consistent with the University’s purposes.

Second, to preserve potentially valuable IP rights, CWRU must follow protocols required by intellectual property laws. Most significantly, CWRU must assure that inventions are properly documented, that inventions are protected from premature disclosure (which might void potential patent rights), and that patent applications are filed in a timely manner.

Third, CWRU must comply with “The Bayh-Dole University and Small Business Patent Procedures Act” (“Bayh-Dole”),<sup>2</sup> which was enacted in 1980 to promote and establish rules to govern commercialization of IP created with the support of government funds.

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<sup>2</sup> THE BAYH-DOLE UNIVERSITY AND SMALL BUSINESS PATENT PROCEDURES ACT, 26 U.S.C. 200 et. seq. (2006), [http://www.law.cornell.edu/uscode/35/usc\\_sup\\_01\\_35\\_10\\_II\\_20\\_18.html](http://www.law.cornell.edu/uscode/35/usc_sup_01_35_10_II_20_18.html).

Fourth, CWRU must comply with, and assure that new agreements are consistent with, prior contracts including sponsorship, collaboration, and licensing agreements with businesses, government and foundations, and other universities.

Fifth, CWRU must comply with rules governing its tax-exempt status under federal law and its use of facilities financed with the proceeds of tax-exempt bonds.

Finally, CWRU must consider and address conflicts of interest, which have potential both to threaten academic integrity and to raise legal concerns.

Each category of constraints is discussed below.

**A. *Policy and Fiduciary Obligations Affecting Management of University IP***

CWRU’s “core values” include, among others, “scholarship that changes lives and deepens understanding,” “academic freedom and responsibility,” and an “emphasis on sustainability.”<sup>3</sup> Such goals may significantly differ from those of many commercial enterprises. For example, a commercial firm might find it profitable to assemble a portfolio of patents as a means of inhibiting competition, rather than promoting the dissemination of new ideas and technologies. By contrast, CWRU’s mission (as well as legal requirements discussed below) prohibits such non-productive use of valuable IP.

Officials and staff entrusted with oversight of IP as CWRU’s agents, moreover, must manage the IP in a manner consistent with their fiduciary obligations to CWRU and

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<sup>4</sup> See *Cahn v. Antioch University*, 482 A.2d 120, 132 (App.D.C. 1984) (explaining that university deans had fiduciary duties with respect to university funds entrusted to them). See generally RESTATEMENT (THIRD) AGENCY § 801 (“An agent has a fiduciary duty to act loyally for the principal’s benefit in all matters connected with the agency relationship.”).

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contractual obligations to its inventors.<sup>4</sup> In addition, CWRU must comply with policies recommended and adopted by the CWRU Faculty Senate and approved by CWRU's Board of Trustees.<sup>5</sup> Policies that directly affect CWRU's position on corporate interactions include both the CWRU Conflict of Interest Policy<sup>6</sup> and IP Policy.<sup>7</sup>

For example, CWRU's IP Policy, like policies of other major research universities, automatically assigns ownership of most IP created at the CWRU to the university, but it generally requires CWRU to share royalties or other earnings from such IP with the creators.<sup>8</sup> In essence, CWRU's IP policy requires CWRU to protect not only its own interests in IP, but also the IP interests of individual inventors.<sup>9</sup> Meanwhile, CWRU must concurrently protect interests of other current and future faculty members, whose research could be intruded upon by restricting future activities in a research field as the result of a license agreement with industry.

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<sup>4</sup> See *Cahn v. Antioch University*, 482 A.2d 120, 132 (App.D.C. 1984) (explaining that university deans had fiduciary duties with respect to university funds entrusted to them). See generally RESTATEMENT (THIRD) AGENCY § 801 ("An agent has a fiduciary duty to act loyally for the principal's benefit in all matters connected with the agency relationship.").

<sup>5</sup> Case Western Reserve University, Board of Trustees, BYLAWS Article V.2.

<sup>6</sup> Case Western Reserve University, POLICIES ON INDIVIDUAL CONFLICTS OF INTEREST AND INSTITUTIONAL CONFLICTS OF INTEREST (2009), <http://ora.ra.cwru.edu/research/orc/Attachments/COI/COIPolicy2009.pdf> (last visited Jan 11, 2010).

<sup>7</sup> Case Western Reserve University, INTELLECTUAL PROPERTY POLICY (2003), <http://ora.ra.cwru.edu/techtransfer/forms/IntellectualPropertyPolicy.pdf>.

<sup>8</sup> *Id.* (stating [u]nless contractually agreed otherwise in advance, fifty percent (50%) of the Net Income received by the University in the form of royalty payments, or other earnings on the Intellectual Property, shall be given to the creators."). See also *Fenn v. Yale University*, 283 F. Supp. 2d 615, 628-29 (D.Conn. 2003) (holding that faculty member was bound to assign invention to university under the terms of its IP policy); *University of West Virginia Bd. of Trustees v. VanVoorhies*, 84 F.Supp.2d 759, 769-71 (N.D.W.Va. 2000) (holding that inventor was bound by university's patent policy).

<sup>9</sup> *Chou v. University of Chicago*, 254 F.3d 1347 (2001)(confirming automatic assignment of patent rights to University but finding that faculty member could assert claims for breach of fiduciary duty against chair of department and university).

Taken together, CWRU's fiduciary and policy obligations prevent it from agreeing to contract terms that might be commonplace in industry. For example, those obligations prevent the University from assuming risks that might be considered routine in industry, such as providing warranties or indemnification in connection with commercial agreements, or to grant royalty-free licenses to useful pre-existing IP (i.e., background IP) in connection with sponsored research agreements.

**1. Coverage and Objectives of CWRU's IP Policy**

CWRU's IP Policy applies to "Intellectual Property," including:

. . . any results having potential commercial value produced by University faculty, staff, and students in connection with activities funded by the University and/or by External Funding or using University employees, facilities, or equipment, including but not limited to any inventions, computer programs or other software, data bases, any information or material subject to copyright under the laws of the United States or any other government, trade secrets (as defined in the Ohio Uniform Trade Secrets Act) and know-how related to inventions.<sup>10</sup>

In a nutshell, CWRU's IP Policy applies to inventions created (i) with support from CWRU's own funds or funds obtained by CWRU from third parties (i.e., "External Funding"), or (ii) with use of CWRU's facilities, equipment, or employees. Like policies of most other universities, however, CWRU's IP Policy expressly does not apply to educational software, books, writings, musical compositions, or similar works.<sup>11</sup>

CWRU's IP Policy states that it is intended:

- A. To promote creative intellectual effort by University faculty, staff, and students for the purposes of developing the commercial value of Intellectual Property.

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<sup>10</sup> Case Western Reserve University, *supra* note 7 at 1.

<sup>11</sup> *Id.* at 1.

- B. To establish principles for recognizing the rights of the creators of Intellectual Property, the sponsors of External Funding, and the University.
- C. To provide means to determine the commercial potential of Intellectual Property and to promote the commercialization of such Intellectual Property for the benefit of its creators and of the University.<sup>12</sup>

When it applies to an invention, CWRU's IP Policy has significant implications to both the University and its inventors. As explained above, for example, CWRU's IP Policy requires a sharing of proceeds from IP covered by the policy between the University and faculty (and certain other) inventors. Although in most instances, the applicability or non-applicability of CWRU's IP Policy to an invention is clear, on occasion determining whether the IP Policy covers a particular invention requires a thorough review of the relevant circumstances.

The coverage of CWRU's IP Policy may, for example, be contested where a faculty member is engaged in outside consulting<sup>13</sup> and asserts that an invention resulted from work performed "wholly on the creator's own time, at the creator's expense and without use of University facilities, staff or equipment."<sup>14</sup> Consulting projects commonly involve matters related to, or similar to, a faculty member's work at the University. Consequently, unless addressed in a timely manner, it may be unclear whether a faculty member developed IP at least in part on University time and/or with University facilities (which would require CWRU ownership of the IP) or entirely separate from the University during an off-site consulting engagement.

To avoid potentially costly disputes over ownership of IP developed by faculty

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<sup>12</sup> *Id.* at 1.

<sup>13</sup> *Id.* at 1.

<sup>14</sup> Case Western Reserve University, *supra* note 7 at 1.

members engaged in consulting,<sup>15</sup> CWRU's IP Policy provides:

. . . to be sure that there is no disagreement over whether Intellectual Property [was created outside the University], for a creator to secure ownership rights with respect to such Intellectual Property, the creator must notify the Vice President for Research and Technology Management, or his or her designee, of the intended disposition of said Intellectual Property, and request and obtain a waiver of University ownership prior to engaging in any commercialization activities of such Intellectual Property, including application to obtain property rights through patenting, etc.<sup>16</sup>

For like reasons, a faculty member should both maintain detailed records and confer with the TTO as soon as possible about potential ownership issues. Indeed, a faculty member commonly has fiduciary and contractual duties to disclose inventions and conflicts of interest that may arise in connection with ownership of, or compensation for, inventions.<sup>17</sup>

## 2. Other Considerations Affecting Management of University IP

The Council on Governmental Relations ("COGR"), an association of research universities, has identified some important incentive and structural differences between universities and industry that affect management of IP, as follows:

- Universities are not pyramidal, well-organized structures. The chancellor or president is the head--in theory--but in reality faculty have a great deal of

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<sup>15</sup> Recently, Stanford University was involved in more than four years of litigation concerning ownership of a patented invention developed by a faculty member who also consulted for a pharmaceutical company. *See Board of Trustees of Leland Stanford University v. Roche*, 583 F. 3d 832 (Fed. Cir. 2009).

<sup>16</sup> *Case Western Reserve University*, *supra* note 7 at 1.

<sup>17</sup> *See Fenn*, *supra*, note 8, 283 F. Supp. 2d at 632 ("By virtue of Dr. Fenn's special relationship with Yale and the trust Yale necessarily had to place in Dr. Fenn, Dr. Fenn owed Yale the duties of a fiduciary, including the duties to make full disclosures and maintain an undivided loyalty. Dr. Fenn breached that duty when he failed to promptly disclose [his] invention to Yale, actively discouraged Yale from preparing and filing a patent application by the statutory deadline while at the same time he was preparing a patent application in his own name, filed a patent application in his own name without notifying Yale, and licensed [his] invention to [a third party] without notifying Yale."). *See also infra* II.F (concerning conflicts of interest).

autonomy and within wide parameters chart their own course. In industry the CEO sets the direction and, as long as he or she retains the trust of the shareholders, determines the focus of the company.

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- Universities have a culture of open communication consistent with the primary mission of creation and transmission of knowledge. Companies often seek to protect knowledge that may create a competitive advantage by maintaining secrecy.
- For universities, production and protection of intellectual property to encourage commercialization is not a cultural norm. It is typically more important for a faculty member to publish than to patent. For industry, generating, protecting and commercializing intellectual property including trade secrets, confers a competitive advantage in their field. Research spending by a company is an investment in future success and profitability. Spending that does not return a benefit to the company is a bad investment.<sup>18</sup>

Such differences require universities to manage IP differently than commercial ventures. For example, universities almost invariably insist upon maintaining ownership of IP in any dealings with industry. COGR explains some of the reasons for this requirement:

- Giving up ownership of inventions may make it impossible for faculty and students to continue to pursue a line of research. A broad patent filed by an assignee may result in a blocking patent that would prevent the faculty member and students from using their own technology for further research.
- Most research at universities is still sponsored by the federal government ... which requires universities to retain ownership of inventions.
- Academic research often requires substantial resources for facilities, equipment, supplies and personnel. It is not unusual for a variety of funding sources to be utilized in a large academic research group. When research is supported within an academic research group with funds from both a corporate sponsor and the federal government, it is ill-advised to promise the company rights that would conflict with the requirements of the other sources of funding, in particular that of federal funding. ...
- If a licensee does not effectively develop the technology or if the license terminates, it will be much easier for the university to enforce diligence requirements or enter into a license arrangement with another party.

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<sup>18</sup> Council on Government Relations, UNIVERSITY INDUSTRY BROCHURE, <http://206.151.87.67/docs/UniversityIndustryBrochure.doc> (last visited Jan 8, 2010).

- Retaining ownership allows the university in some cases to grant non-exclusive licenses to promote broad utilization and maximize use.
- Ownership by the university helps maintain a relationship between the inventor and company scientists engaged in product development. In many cases, follow-on work by the researcher or additional know-how developed in the laboratory need to be transferred in order to make the discovery most useful to the company.
- The right to participate in the distribution of royalties is an incentive to inventors to disclose and invent. Burdensome or one-sided intellectual property provisions can create disincentives for faculty to participate in company sponsored research.
- An industry position that “we paid for it and we own it” ... fails to recognize the significant investment in intellectual capital and resources that have gone into the development of the knowledge that led to the invention.<sup>19</sup>

In addition, and perhaps more importantly, the nature of universities precludes them from assuming risks often attendant to commercial dealings. In commercial licensing transactions, a supplier or licensor of IP may be expected to agree performance specifications, to provide a warranty that the IP does not infringe third party IP, to covenant that the licensor will not work with competing businesses, or to provide other warranties, representations, or assurances. A commercial company may undertake such commitments based on the probable risks and profits associated with commercial sales. Because of commercially-oriented management controls, testing, and the structure of a commercial business, moreover, a commercial firm may be able to minimize risks arising from warranties and service commitments.

Conversely, universities cannot agree to provide performance specifications, warranties or other assurances, because their work is dedicated to fundamental research rather than commercial sales.<sup>20</sup> In managing its IP, a university must not only protect its endowment and assets, but also avoid agreements that impede both future research and unfettered exchanges

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<sup>19</sup> *Id.*

<sup>20</sup> *See infra* Section II.D (concerning universities’ obligation to public purposes and distinguishing basic, or fundamental, research from applied or commercial research).

of ideas that promote scientific advance and the public interest. Indeed, publication of research results is a key distinction between universities and industry emphasized in government regulations that grant exemptions from taxes, certain export controls, and other requirements.<sup>21</sup> Further, as a practical matter, universities typically lack commercial-type managerial control over the creation of IP, testing, and quality control that allow for assessment of the commercial performance of IP and related risks.

For example, the federal government has established stringent export controls on technologies that could be used for military purposes<sup>22</sup> or dual civilian and military purposes.<sup>23</sup> Export controls cover not only physical shipments of information or materials but also transfer of data or information to a foreign national wherever located, including on a university campus.<sup>24</sup>

In view of their academic missions, and also because of the burdens and risks associated with U.S. export controls (including criminal penalties), two exceptions that apply to most university research projects are especially important: the U.S. export regulations do not generally apply to information that is “publicly available”<sup>25</sup> (or in the “public domain”<sup>26</sup>) or that qualifies as “fundamental research.”<sup>27</sup> These exceptions overlap to some extent, as the export regulations define “fundamental research” as “basic and applied research in science and engineering, *where the resulting information is ordinarily published and shared broadly within the scientific community.*” (Emphasis added.)<sup>28</sup>

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<sup>21</sup> *Id.*

<sup>22</sup> INTERNATIONAL TRAFFIC IN ARMS REGULATIONS (“ITAR”), 22 C.F.R. § 120.1 ET SEQ.

<sup>23</sup> EXPORT ADMINISTRATION REGULATIONS (“EAR”), 15 C.F.R. § 730 ET SEQ.

<sup>24</sup> EAR, *supra* note 23 at 732.2(b)(ii); ITAR, *supra* note 22.

<sup>25</sup> EAR, *supra* note 23 at § 734.3(b)(iii).

<sup>26</sup> ITAR, *supra* note 22 at § 120.11.

<sup>27</sup> EAR, *supra* note 23 at § 734.8(a); ITAR, *supra* note 22 at § 120.11(8).

<sup>28</sup> EAR, *supra* note 23 at § 734.8(a). *See also* ITAR, *supra* note 22 at § 120.11(8).

In view of such export regulations, universities (unlike many private businesses) must be wary of agreements that restrict disclosure of research results, because such restrictions could potentially subject them to export restrictions that might not only impose substantial administrative burdens but also require them to exclude foreign students from research activities. Likewise, and as discussed separately below in Section II.D, a university's tax exempt status and bond financing may depend upon preservation of publication rights for university research.

**B. *Preservation of Intellectual Property Rights***

IP provides a potentially valuable asset for universities and their commercial licensees. University research may give rise to patents, which afford a lawful monopoly over manufacture, use, and disposition of an invention,<sup>29</sup> or copyrights, which grant an author the right to prevent others from reproducing an original work of authorship.<sup>30</sup>

Copyrighted material poses far less a risk of loss than patented material for two reasons. First, a copyright vests in the author of work (or the employer of an author with respect to "work-for-hire") automatically when the work is "fixed in any tangible medium of expression."<sup>31</sup> Although registration of a copyright is necessary for certain rights of enforcement and statutory damages,<sup>32</sup> it is not required for protection generally. Copyrights arise from the creation of an expressive work, so no particular protocols are required to obtain the benefit of the copyright laws.

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<sup>29</sup> See 35 U.S.C. § 271(a) (2006) ("whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent").

<sup>30</sup> See 17 U.S.C. § 106 (2006) (setting forth the exclusive rights of a copyright holder).

<sup>31</sup> *Id.* § 102(a) (2006).

<sup>32</sup> *Id.* §§ 408-412 (2006).

Patent rights, however, can be lost entirely if not adequately protected and pursued. The standard formulation for the patentability of an invention is that it must be “new, non-obvious, and useful.”<sup>33</sup> Most countries outside of the United States require “absolute novelty” for issuance of a patent. Although absolute novelty is not required in the United States, a patent application must be filed within one year of any publication, sale, or other act that places the invention in the public domain.<sup>34</sup> Failure to apply for a patent within one year of such a disclosure will lead to a permanent bar against patentability.<sup>35</sup>

The publication restriction on patentable inventions can be especially challenging in an academic environment, where publication of research results may be both expected and essential to career advancement. For these reasons, CWRU must both encourage and educate faculty about the importance of submitting timely confidential information disclosures to the TTO to enable it to consider filing a patent application, which would preserve patent rights notwithstanding subsequent publication. Likewise, to preserve patent rights, the TTO will enter confidentiality agreements with any potential licensees in advance of exchanging information about CWRU IP.

Another risk to the patentability of inventions in academic institutions was made clear in a 1997 decision of the U.S. Court of Appeals for the Federal Circuit. In *OddzOnProducts, Inc. v. Just Toys Inc.*, 122 F.3d 1396 (Fed. Cir. 1997), the court ruled, in effect, that sharing of confidential information between or among collaborators could preclude both (or all) of the collaborators from patenting a related invention, because the exchanged information would be combined with public information as evidence of “prior art.” Prior art

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<sup>33</sup> This standard is codified in the U.S. Patent law at 35 U.S.C. §§ 101-103 (2006).

<sup>34</sup> *Id.* § 102(b).

<sup>35</sup> *Id.*

refers to the existing body of technical information that is considered in deciding whether an invention is sufficiently novel and non-obvious to qualify for patent protection.<sup>36</sup> Given the importance of collaboration among academic and research institutions for innovation, *OddzOn* could have significantly impeded research advances.

In 2004, however, Congress enacted the Cooperative Research and Technology Enhancement Act (the “CREATE Act”)<sup>37</sup> to overcome the potentially damaging ruling of *OddzOn* and to promote collaborative research. Under the CREATE Act, collaborative research will not prevent patentability if three conditions are met: (1) the inventors must have entered or been subject to a joint research agreement before the date of the invention; (2) the invention must have resulted from activities within the scope of the joint research agreement; and (3) the application for a patent for the invention must disclose, or be amended to disclose, the names of the parties to the joint research agreement.<sup>38</sup> The CREATE Act, moreover, defines a qualifying joint research agreement as “a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.”<sup>39</sup>

In addition to protecting its own IP rights, in some instances a university must be careful to protect the IP rights of its students. As part of their learning experience at a university,

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<sup>36</sup> *Id.* § 102(a) (“A person shall be entitled to a patent unless—(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent”) and § 103(a) (“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains”).

<sup>37</sup> P.L. 108-453, codified at 35 U.S.C. § 103(c) (2006).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* § 103(c)(3).

students may often create IP in coursework or independent projects. In general, university policies make clear that such IP belongs to the student rather than the university. Unless a student is hired for a research project, there is generally no basis for depriving the student of ownership of his or her creations. CWRU specifically addresses student materials in its IP Policy as follows:

Regardless of use of University facilities, student coursework or other Intellectual Property shall belong to the student unless created (a) while student is acting as an employee of the University, (b) while student is engaged in research funded by the University or External Funding, or (c) as part of a class or other academic project involving a commercial entity's intellectual property, provided that it is announced at the commencement of the project that students will not have ownership of Intellectual Property created in conjunction with that project. If faculty or teaching assistants, acting as advisors, assist in the creation of Intellectual Property and are therefore co-creators (with the student as creator), the student may choose to disclose the invention to the Vice President for Research and Technology Management, or his or her designee, and request the services of the Office of Technology Transfer in commercializing such inventions.<sup>40</sup>

In science and engineering programs especially, students may be offered the opportunity to work on “real life” projects involving commercial technologies. Although such projects can enhance a student’s academic experience, they may also raise significant concerns about protection of IP and confidential business information that may be provided by a commercial business for purposes of the project. To address such issues, students must be advised in advance of any restrictions on use of information that may be required for participation in a class or project and, in some instances, required to execute an agreement transferring any new IP to the company providing sensitive research information and/or

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<sup>40</sup> Case Western Reserve University, *supra* note 7 at 11.

protecting confidential commercial information. (CWRU will generally review and/or negotiate the terms of such agreements to prevent inclusion of unreasonable requirements).

In addition to protecting IP created by students, universities must also consider and protect student academic interests that may be affected by university research. For example, sponsored research agreements often require universities to maintain confidentiality of proprietary business information and, sometimes, research results (for a specified period). When such agreements cover research involving students, however, restrictions on the use of information have potential to affect timely completion and publication of a dissertation or thesis. Notably, CWRU requires publication of all doctoral dissertations.<sup>41</sup> For this reason, although CWRU's standard terms for sponsored research provides a university investigator may be required to delay publication of research results that may contain proprietary business information, "such delay shall not, however, be imposed on the filing of any student thesis or dissertation."<sup>42</sup>

### C. *Bayh-Dole Act*

The Bayh-Dole University and Small Business Patent Procedures Act ("Bayh-Dole") was enacted on December 12, 1980 (P.L. 96-517) to promote commercialization of inventions developed with the support of U.S. government funds.<sup>43</sup> Prior to passage of Bayh-Dole, government sponsored research was generally treated as work-for-hire that would belong

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<sup>41</sup> Case Western Reserve University, School of Graduate Studies--FAQ ABOUT ELECTRONIC THESIS DISSERTATION, <http://www.case.edu/provost/gradstudies/current/etd/faqs.html> (last visited Dec 30, 2009).

<sup>42</sup> CASE\_SPONSORED\_RESEARCH\_AGREEMENT\_INDUSTRY.doc, 6.2, [http://ora.ra.cwru.edu/ospa/forms/CASE\\_SPONSORED\\_RESEARCH\\_AGREEMENT\\_INDUSTRY.doc](http://ora.ra.cwru.edu/ospa/forms/CASE_SPONSORED_RESEARCH_AGREEMENT_INDUSTRY.doc) (last visited Dec 30, 2009).

<sup>43</sup> THE BAYH-DOLE UNIVERSITY AND SMALL BUSINESS PATENT PROCEDURES ACT, *supra* note 2.

to the government upon completion. The premise was that such inventions, like government publications, should be publically available and, therefore, were typically licensed by the government on a non-exclusive basis, if at all.<sup>44</sup> Before passage of Bayh-Dole fewer than 5% of federally-owned patents had been licensed to industry for commercial development.<sup>45</sup> This low rate of commercialization likely was due to the absence of uniform government policy encouraging federal agencies to commercialize IP and incentives (such as exclusive licenses) for commercial firms to adopt government-owned technology.

Bayh-Dole sought to promote commercialization of federally sponsored inventions developed by universities, not-for-profit corporations, and small businesses by permitting such organizations to patent their federally sponsored inventions, to take ownership of those patents, and to license them on an exclusive basis to provide more incentive to businesses.<sup>46</sup>

Bayh-Dole covers any invention by a non-profit organization or small business that is “conceived or first actually reduced to practice in the performance of work under a funding agreement,” which are termed “subject inventions.”<sup>47</sup> Subject inventions include inventions that are only partially funded by the federal government. Under Bayh-Dole, a non-

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<sup>44</sup> Council on Governmental Relations, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS, 1-2 (1999), [http://www.cogr.edu/docs/Bayh\\_Dole.pdf](http://www.cogr.edu/docs/Bayh_Dole.pdf) (last visited Oct 22, 2009).

<sup>45</sup> United States General Accounting Office GAO, REPORT TO CONGRESSIONAL COMMITTEES: TECHNOLOGY TRANSFER ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 3 (1998), <http://www.gao.gov/archive/1998/rc98126.pdf> (last visited Oct 22, 2009).

<sup>46</sup> *Id.*

<sup>47</sup> 35 U.S.C. § 201(e) (2006).

profit,<sup>48</sup> such as CWRU, may elect to “take title to any subject invention,”<sup>49</sup> and thereafter license the invention for use in industry, provided it satisfies a number of conditions. In particular, a non-profit organization must comply with all of the following:

- Report each subject invention to the funding agency;
- Elect to retain title in writing within a specified time period—ordinarily two years after disclosure;
- Timely file for patent protection;
- Grant the federal government a non-exclusive, non-transferable, irrevocable, paid-up license to use the subject invention throughout the world;
- Actively promote and attempt to commercialize the subject invention;
- Maintain title to the subject (i.e., not assign it to a third party), subject to limited exceptions;<sup>50</sup>
- Share royalties with the inventor;
- Use all net income derived from the subject invention for education and research, after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, for education and research;
- Give preference to United States industry by requiring any licensee to agree to manufacture any product based on the subject invention substantially in the United States (unless the applicable federal agency waives this obligation).<sup>51</sup>

In addition to specifying non-profit organizations’ obligations respecting subject inventions, Bayh-Dole establishes safeguards for the federal government, called “march-in rights,” to assure that useful and/or valuable inventions are properly commercialized.

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<sup>48</sup> Bayh-Dole imposes more obligations on non-profit organizations than small businesses. *See* 35 U.S.C. § 202(c) (2006) (relating to small businesses and non-profits) and § 202 (c)(7) (relating to non-profits only).

<sup>49</sup> *Id.* § 202(a).

<sup>50</sup> Assignment of title to federally-funded inventions is prohibited except (a) to an organization which has as one of its primary functions the management of inventions or (b) with federal funding agency consent. 37 C.F.R. § 401.14(k)(1) (2009).

<sup>51</sup> 35 U.S.C. § 202(e) (2006) (concerning duties of small business and non-profits that acquire patent rights under the Act); 35 U.S.C. § 202(f) (2006) (concerning additional duties of non-profits that acquire patent rights under the Act), and 35 U.S.C. § 204 (2006) (respecting preference for United States industry).

Specifically, under Bayh-Dole, a federal agency is allowed to override the patent holder's exclusive rights under the U.S. patent laws, and grant a non-exclusive, partially exclusive, or even exclusive license to one or more "reasonable applicant or applicants," if the agency determines that such action is necessary.<sup>52</sup> The exercise of "march-in" rights may be deemed necessary, for example:

- where the non-profit organization "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention" in a field;<sup>53</sup>
- to alleviate health or safety needs which are not being reasonably satisfied;<sup>54</sup>
- to meet regulatory requirements for public use of the subject invention;<sup>55</sup> or
- to remedy a failure to comply with the statutory preference to require manufacture of covered products in the United States.<sup>56</sup>

In addition to facing the exercise of march-in rights by the federal government, a nonprofit that fails to comply with an obligation under Bayh-Dole may forfeit its rights to the subject invention.<sup>57</sup> To avoid the exercise of march-in rights, therefore, licenses to IP resulting from federally funded research must include milestones and/or other requirements to assure that the licensee makes meaningful use of the IP in commerce.

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<sup>52</sup> *Id.* § 203; 37 C.F.R. § 401.14(j) (2008).

<sup>53</sup> *Id.* § 203(a)(1).

<sup>54</sup> *Id.* § 203(a)(2).

<sup>55</sup> *Id.* § 203(a)(3).

<sup>56</sup> *Id.* § 203(a)(4).

<sup>57</sup> *Id.* § 202(c)(1). *See also Campbell Plastics Engineering & Mfg., Inc. v. Les Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004) (holding that failure to disclose invention, as required by the Bayh-Dole Act and the parties' contract under the Act, authorized the U.S. Army to take title to the subject invention).

#### **D. *Prior Contractual Requirements***

When entering sponsorship or licensing agreements, universities must also assure that the new agreement complies with prior agreements. Although universities will not enter agreements that impinge on future research or academic programs, some university agreements require protection of non-university interests or proprietary rights.

For example, collaboration agreements or agreements creating a research consortium may impose conditions to protect collaborating parties from unexpected liability. To provide such protection, sponsorship and licensing agreements related to the collaboration or consortium may need to include specified warranty disclaimers, insurance requirements, indemnification or other terms.

Agreements related to university IP may also be constrained by the rights of non-university inventors. Most inventions have more than a single inventor, and many inventions have inventors from more than one institution. Participation in a research consortium may require licenses to be granted to consortium members on specified terms.<sup>58</sup> Likewise, agreements with joint owners of university IP may also require specified terms in licenses for the IP.

Universities, like all other organizations involved in collaborations, must also protect confidential or proprietary information provided by research partners or sponsors pursuant to confidentiality agreements or material transfer agreements.<sup>59</sup>

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<sup>58</sup> See *infra* Section II.E.3 (concerning limited exception to tax-law restriction on granting rights in advance of development of an invention, where invention was resulted from consortium sponsorship).

<sup>59</sup> See *infra* Sections III.C (concerning sponsored research agreements) and III.D (concerning material transfer agreements).

Finally, universities must assure consistency among its sponsored research and licensing agreements. Consistency is necessary for several reasons. Agreements with especially favorable terms might raise concerns under tax laws that prohibit use of university assets from private gain<sup>60</sup> or under conflict of interest restrictions.<sup>61</sup> In addition, inconsistency would invite conflict both within the university and with third party sponsors. Finally, inconsistency may be contrary to obligations related to government or private research grants. For example, federal contracting regulations require consistent treatment of indirect (or overhead) costs of research.<sup>62</sup>

**E. Tax-Exemption Issues**

**1. Tax Exempt Status, Private Inurement and Private Benefit**

Like any tax-exempt entity, CWRU must comply with rules and regulations of the U.S. Internal Revenue Service. Tax-exempt status is provided under 26 U.S. §501(c)(3) (2006) (“Section 501(c)(3)”) for an organization:

- (1) “organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes;”
- (2) “no part of the net earnings of which inures to the benefit of any private shareholder or individual;” and
- (3) “no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation ... [or] any political campaign on behalf of (or in opposition to) any candidate for public office.”

Under these criteria, when a university seeks to “commercialize” technology, it must be especially careful to avoid transactions that would result in private use of its tax-exempt assets.

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<sup>60</sup> See *infra* Section II.E.1.

<sup>61</sup> See *infra* Section II.F.

<sup>62</sup> Circular A-21, C.11, [http://www.whitehouse.gov/omb/circulars\\_a021\\_2004/](http://www.whitehouse.gov/omb/circulars_a021_2004/) (last visited Jan 19, 2009).

Specifically, a university must guard against entering transactions that might be construed as “private inurement” or as conferring a “private benefit.”<sup>63</sup>

Both the “private inurement” and “private benefit” doctrines arise from the obligation of a tax-exempt organization to operate “exclusively” for its tax-exempt purpose (such as a charitable, scientific or educational purpose). Under the private inurement doctrine, no part of the net earnings of an exempt organization may inure to the benefit of any “insider”— i.e., a person in a position to exercise substantial influence over the organization, such as an officer, director, or key employee.<sup>64</sup> Private inurement may also lead to revocation of an organization’s tax-exempt status.<sup>65</sup>

Under the private benefit doctrine, a tax-exempt organization may not allow any private business or individual (whether or not an insider) to accrue more than an insubstantial benefit from the tax-exempt organization’s operations. The main distinction between private benefit and private inurement is that the latter does not require involvement of an insider and will not be violated by an “incidental” benefit to a third party.<sup>66</sup>

Private benefit and private inurement concerns may arise in a variety of contexts involving the creation or licensing of university IP. For example, a private benefit or private inurement may result from granting favorable treatment to a researcher in the allocation of

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<sup>63</sup> U.S. Internal Revenue Service, COMPLIANCE GUIDE FOR 501(C)(3) PUBLIC CHARITIES 2-3 (2009), <http://www.irs.gov/pub/irs-pdf/p4221pc.pdf>. “Private Inurement” and “private benefit” are separate prohibitions of the law governing tax-exempt organizations.

<sup>64</sup> *Id.*

<sup>65</sup> Treas. Reg. §1.501(c)(3)-1(f)(2) (2009) (“Determination of whether revocation of tax-exempt status is appropriate when section 4958 excise taxes also apply”).

<sup>66</sup> U.S. Internal Revenue Service, INTERNAL REVENUE MANUAL - 4.76.3 PUBLIC CHARITIES (2009), [http://www.irs.gov/irm/part4/irm\\_04-076-003-cont01.html#d0e1623](http://www.irs.gov/irm/part4/irm_04-076-003-cont01.html#d0e1623) (last visited Jan 10, 2010).

funding (such as a waiver or reduction of allocations for indirect costs) or to a university spin-off company in the licensing of university IP.<sup>67</sup>

## 2. Unrelated Business Income (“UBI”)

Sponsored research and licensing of IP must address taxable unrelated business income (“UBI”).<sup>68</sup> UBI refers to the income of a non-profit organization that is taxable at the regular corporate tax rate. There are two types of UBI:

- Income arising from the conduct of unrelated trade or business that is regularly carried on;<sup>69</sup> and
- Debt-financed income, which is usually in the form of rent, interest or royalties arising from financed property.<sup>70</sup>

If UBI becomes a “substantial” portion of an organization’s revenue, its tax-exempt status could be revoked.

To the extent that royalty payments from licensing IP are “passive income,” they are excluded from UBI.<sup>71</sup> Payments received by a tax-exempt organization from a sponsored research project are also exempt from UBI, but only if the project involves “fundamental research”<sup>72</sup> or is performed for a government sponsor.<sup>73</sup> The IRS explains that “[w]hen an

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<sup>67</sup> Inconsistency in application of indirect costs also has the potential to raise concerns about compliance with federal regulations covering government supported research. See OMB Circular A-21 § C (11), [http://www.whitehouse.gov/omb/circulars\\_a021\\_2004/](http://www.whitehouse.gov/omb/circulars_a021_2004/) (last visited Dec 14, 2009) (requiring a nonprofit educational institution to use cost allocation practices in connection with federal research grants that are consistent with such institution's practices in like circumstances).

<sup>68</sup> U.S. Internal Revenue Service, PUBLICATION 598 (03/2009), TAX ON UNRELATED BUSINESS INCOME OF EXEMPT ORGANIZATIONS (2009), <http://www.irs.gov/publications/p598/index.html> (last visited Jan 10, 2010).

<sup>69</sup> I.R.C. §§ 511, 512.

<sup>70</sup> *Id.* § 514.

<sup>71</sup> *Id.* 512(b)(1) - (5); Treas. Reg. §§ 1.512(b)-1(a) - (d) (2009).

<sup>72</sup> *Id.* § 512(b)(8).

organization is operated primarily to conduct fundamental research (as distinguished from applied research) and the results are freely available to the general public, all income from research performed for any person is excluded in computing unrelated business taxable income.”<sup>74</sup> Further, for a sponsored research project to qualify as fundamental research, it must not involve “activities of a type ordinarily carried on as an incident to commercial or industrial operations.”<sup>75</sup> For example, fundamental research does not include “the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc.” or “research carried on for the primary purpose of commercial or industrial application.”<sup>76</sup>

### 3. Use of Facilities Financed with Tax-Exempt Bonds

CWRU, like many universities, has financed many facilities with tax-exempt bonds. The use of tax-exempt bonds, however, imposes additional obligations on a university. To maintain the tax-exempt status of a bond, a university must avoid private business use of the supported facilities. Loss of tax-exempt status for a bond could be severely damaging, because it might require reimbursement of bondholders for unanticipated income tax and/or make future efforts to use tax-exempt bonds difficult or unduly expensive.<sup>77</sup> For a private tax-exempt

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<sup>73</sup> *Id.* § 512(b)(7).

<sup>74</sup> U.S. Internal Revenue Service, PUBLICATION 598, *supra* note 68.

<sup>75</sup> Treas. Reg. § 1.512(b)-1(f)(4) (2009). Treas. Reg. § 1.512(b)-1(f)(2) states that “[i]n the case of a college, university, or hospital, all income derived from research performed for any person and all deductions directly connected with such income, shall be excluded in computing unrelated business taxable income.” As noted above, however, Subsection (f)(5) makes clear that only “fundamental” research is subject to the exemption.

<sup>76</sup> *Id.*

<sup>77</sup> Council on Governmental Relations, *supra* note 18.

organization, such as CWRU, to preserve the tax-exempt status of such bonds, it must limit private business use of covered facilities.<sup>78</sup>

Under tax law, sponsored research, unless properly structured, may result in private business use of facilities. In 1997, the IRS clarified the rules related to the private business use and created a “safe harbor” for sponsored research agreements. In Revenue Procedure 97-14 the IRS stated that research sponsored by a single company would not constitute private business use of a facility only if it qualified as “basic research,” which it defined as “an original investigation for the advancement of scientific knowledge not having a specific commercial objective.”<sup>79</sup> To confirm that only basic research would avoid private use, moreover, the IRS further stated that “any license or other use of resulting technology by the sponsor is permitted only on the same terms as the recipient would permit that use by any” third party.<sup>80</sup> Thus, under the 1997 guidance, a sponsor of the research could be granted rights to IP resulting from a sponsored research project, only if it paid a competitive price for such rights “determined at the time the license or other resulting technology is available for use.”<sup>81</sup>

Revenue Procedure 97-14 did, however, establish a limited exception to the prohibition against granting IP rights at the outset of a sponsored research project. Specifically, a sponsor participating in a research consortium could be granted a non-exclusive, royalty-free license, only if:

1. the research is performed by an instrumentality of a state or local government or a 501(c)(3) organization;
2. the research is funded by multiple unrelated sponsors;

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<sup>78</sup> I.R.C. § 145(a)(2).

<sup>79</sup> Rev. Proc. 97-14, § 3.01 (1997).

<sup>80</sup> *Id.* § 5.02.

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

3. the subject research organization determines how the research was to be performed; and
4. the subject research organization would own title to any resulting patents.<sup>82</sup>

In 2007, the IRS issued Revenue Procedure 2007-47, which clarified (and liberalized) the safe harbor for avoiding private use of facilities with tax-exempt bonds. Revenue Procedure 2007-47 is generally considered to have modified the safe harbor for cooperative research agreements to allow a non-exclusive royalty-free license to be granted to a single sponsor, provided that the other conditions of the safe harbor are met.<sup>83</sup> In addition, Revenue Procedure 2007-47 made clear that the federal rights normally granted under Bayh-Dole do not constitute private use.<sup>84</sup>

#### **F. *Conflicts of Interest***

Management of university IP must also consider and address a wide range of individual and institutional conflicts of interests. Conflicts of interest are not only specifically addressed in university policies, but also may trigger a wide range of legal issues, including issues related to fiduciary duties, regulatory and funding compliance, tax-exemption, contracts and tort law. A conflict of interest potentially has a broad range of consequences, even when not unlawful or improper in itself, because it may serve as a “red flag” for ulterior motives for a transaction.

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<sup>82</sup> *Id.* § 5.03.

<sup>83</sup> Rev. Proc. 2007-47 §§ 4.01, 6.03 (2007).

<sup>84</sup> *Id.* § 6.04.

Numerous studies have demonstrated that conflicts of interest can affect the integrity of academic research.<sup>85</sup> Further, conflicts of interest can have significant effects, even in the absence of improper motives.<sup>86</sup> For example, one study found that physicians who attended grand rounds sponsored by a pharmaceutical company were more likely to specify use of the company's drug than colleagues who had not attended the session, even though they often could not recall attending the sponsored grand rounds.<sup>87</sup> Another study showed that only 5% of economic analysis of new drugs funded by their companies gave those drugs unfavorable evaluations.<sup>88</sup>

Conflicts of interest that affect management of university IP can arise in a variety of circumstances and may implicate individual faculty members or the university itself. CWRU's Conflict of Interest Policy defines an "individual conflict of interest" as "[a]n outside interest that might adversely affect or appear to a reasonable person to adversely affect an individual's judgment in carrying out University responsibilities, or that might adversely affect or appear to a reasonable person to adversely affect the University's responsibility to the public, the safety of research subjects, or the integrity of research."<sup>89</sup> Even apart from a direct financial interest, a university inventor may have conflicting fiduciary duties. For example, if a university inventor serves on the board of directors of a start-up company or research sponsor, he or she

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<sup>85</sup> See e.g., Justin E Bekelman, Yan Li & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 454-65 (2003).

<sup>86</sup> See generally Bernard Lo & INSTITUTE OF MEDICINE (U.S.), *Conflict of Interest in Medical Research, Education, and Practice* (2009).

<sup>87</sup> R. Springarn, J. Berlin & B. Stom, *When Pharmaceutical Manufacturers' Employees Present Grand Rounds, What Do Residents Remember?*, 71 ACADEMIC MEDICINE 86-88 (1996).

<sup>88</sup> M. Friedberg et al., *Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology*, 282 JAMA 1453 (1999).

<sup>89</sup> Case Western Reserve University, *supra* note 6.

might have duties or responsibilities to the company that conflict with obligations to the university.<sup>90</sup>

CWRU's policy states that "[a]n institutional conflict of interest arises when the financial interests of the University, or a University official acting within his or her authority on behalf of the University, may influence or appear to influence the research, education, clinical care, business transactions, or other activities of the University; when an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University; and when outside activities are inconsistent with an individual's responsibilities to the University."<sup>91</sup> Thus, institutional conflicts may arise when the university itself has a financial interest by virtue of a research sponsorship itself, royalty arrangements or equity ownership in a business, or when university officials serve on the board, or have financial interests in, companies that do business with the university.<sup>92</sup>

As the conduits between the University and industry, the TTO and OSPA sit on the cusp of conflict of interest issues related to research funding and University IP. Indeed, virtually every sponsored research agreement creates a conflict of interest, because of the inevitable desire to perpetuate funding and provide the sponsor with favorable results.

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<sup>90</sup> Compare *Gantler v. Stephens*, 965 A. 2d 695, 708-9 (Del. 2009) ("[O]fficers of Delaware corporations, like directors, owe fiduciary duties of care and loyalty, and that the fiduciary duties of officers are the same as those of directors") with Case Western Reserve University, FACULTY HANDBOOK, Ch 3, Pt I. ART III. B, <http://www.case.edu/president/facsen/frames/handbook/main.html> ("Outside activities must not be permitted to interfere through conflict of interest or otherwise with a faculty member's commitment to the University.").

<sup>91</sup> Case Western Reserve University, *supra* note 6.

<sup>92</sup> Association of American Universities Task Force on Research Accountability, REPORT ON INDIVIDUAL AND INSTITUTIONAL FINANCIAL CONFLICT OF INTEREST, 11-12 (2001).

Individual conflicts of interest may arise in connection with commercialization where, for example, a university inventor (i) has an equity interest in a start-up or other company seeking to license university IP, (ii) has research funded by the licensee; or (iii) has a consulting relationship with the licensee. Likewise, institutional conflicts may arise in connection with commercialization, where the university holds or is granted an equity interest in the licensee; controls a seat on the licensee's board; has officials with financial interests in, or fiduciary responsibilities to, the licensee, and so on.

Most research universities, including CWRU have recognized that while disclosure of a conflict is a necessary first step, many conflicts must be more actively managed. As explained by the Institutes of Medicine in a recent report:

A physician's or researcher's disclosure of financial relationships, either to the institution or to a broad audience, is a necessary step for identifying and avoiding or managing conflicts of interest, but it also has important limitations. First, disclosure alone does not resolve conflicts of interests or prevent the harms that may result from a conflict. Second, some evidence suggests that the disclosure of a conflict of interest may have little effect or may even be counterproductive in some circumstances.<sup>93</sup>

In addition to disclosure, effective management of conflicts of interest affecting university research and IP may require review, mitigation, monitoring, and in some instances, prohibition.<sup>94</sup>

When government funding has supported research, effective management of conflicts are not only required as a matter of academic integrity but also federal regulation.<sup>95</sup> As part of, or in

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<sup>93</sup> Lo and Institute of Medicine (U.S.), *supra* note 86 at 77; American Association of Medical & Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit, THE SCIENTIFIC BASIS OF INFLUENCE AND RECIPROCITY: A SYMPOSIUM (2007).

<sup>94</sup> Lo and Institute of Medicine (U.S.), *supra* note 86; Council on Governmental Relations, RECOGNIZING AND MANAGING PERSONAL FINANCIAL CONFLICTS OF INTEREST (2002), <http://206.151.87.67/docs/UniversityIndustryBrochure.doc> (last visited Jan 10, 2010).

<sup>95</sup> See 42 CFR 50 Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought), <http://ecfr.gpoaccess.gov/cgi/t/text/text->

addition to, a conflict of interest management plan tailored to an individual faculty member's situation, CWRU prohibits a conflicted individual from participating in negotiations on behalf of, or averse to, the University when the other party is an organization in which the individual has a financial interest or fiduciary duty. This restriction may, standing alone, reduce the likelihood of successful negotiations.

In 2009, CWRU adopted new policies for individual and institutional conflicts of interest.<sup>96</sup> The new CWRU conflict of interest policies specify disclosure and management requirements affecting the administration of both sponsored research and commercialization of IP. Under CWRU's policy, review and approval of an individual conflict of interest may mandate a management program that includes:

- a. Requiring the individual to recuse him/herself from particular business decisions.
- b. Requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (such as the Office of Research Compliance, IRBs, IACUCs, subjects, state and federal officials, research sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of the individual's research laboratory, journals to which manuscripts about the professional audiences with whom the research or other activity is discussed orally or in writing).
- c. Requiring the individual to refrain from participating in certain activities or aspects of activities relating to the research project (such as requiring IRB members with conflicts of interest in connection with research protocols to recuse themselves from deliberations on those protocols, or, where compelling circumstances exist to allow certain research stages or activities to proceed despite a conflict of interest, restricting the individual's roles to those stages and

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idx?c=ecfr&sid=a99ca1825187397c7687efea0072a6f8&rgn=div5&view=text&node=42:1.0.1.4.21&idno=42 (last visited Jan 11, 2010); OFFICE OF MANAGEMENT AND BUDGET, Circular No. A-110 -- Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, <http://www.whitehouse.gov/omb/rewrite/circulars/a110/a110.html> (last visited Jan 11, 2010); NATIONAL SCIENCE FOUNDATION, Grant Policy Manual NSF 05-131\_5. Grantee Standards, [http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510) (last visited Jan 11, 2010).

<sup>96</sup> Case Western Reserve University, *supra* note 6.

activities, including establishing a point in time for stopping participation and strategies to keep the individual's involvement at a minimum).

- d. Requiring the activity to be approved by additional individuals or entities (such as deans, department chairs, or program chairs).
- e. Requiring others to review academic decisions in which the individual participates.
- f. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).
- g. Requiring the individual to reduce, modify, or eliminate a financial interest (including divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments).
- h. Requiring the individual to vacate a position.
- i. Prohibiting the individual from disclosing confidential institutional information or channeling discoveries to an outside entity.
- j. Prohibiting the research from taking place at the University.
- k. Requiring continued oversight of the activity by the Conflict of Interest Committee.<sup>97</sup>

Likewise, review and approval of an institutional conflict of interest may mandate

a management program that includes:

1. Isolating the individual from involvement in research or decision-making regarding research.
2. Requiring the individual to reduce, modify, defer, waive, or eliminate the financial interest that is the source of the conflict, such as equity holdings, royalty income, stock options and milestone payments.
3. If recusal would preclude the individual from fulfilling the responsibilities of a University position, requiring the individual to eliminate the holdings or vacate the position.
4. Requiring the individual to recuse him- or herself from institutional decisions regarding the outside entity that is source of conflict.
5. Requiring the individual to make periodic written disclosure of the conflict to all administrators, faculty, non-faculty employees, and students under individual's supervision, to the Office of Research Compliance, IRBs, IACUCs, subjects, state and federal officials, research sponsors, coinvestigators, colleagues, junior colleagues, students, trainees, members and prospective members of the

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<sup>97</sup> *Id.* at 5-6.

individual's research laboratory, journals to which manuscripts about the research are submitted, and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing.

6. Appointing independent individuals or committees to oversee high-level administrative decisions (e.g., financial decisions, space allocations, appointments and promotions) in which the individual participates.

7. Prohibiting the research from taking place at the University.

8. Eliminating, reducing, or modifying the University's financial stake in an outside entity or research project.

9. Enhancing or creating firewalls or other conflict-management systems to separate financial and research decision-making.

10. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).

11. Preventing the individual from serving as the principal investigator, co-principal investigator, or investigator on the research project.

12. Protecting students, trainees, junior colleagues and/or non-faculty employees by preventing or limiting their participation in the research project, preventing or limiting them from working in newly-formed companies involving conflicted superiors, informing them of the potential conflict, giving them access to senior faculty and non-faculty employees to review questions or concerns, having academic decisions outside the research activity made or reviewed by independent individuals, and recusing the conflicted individual from the chain of authority over salary, promotion, and space allocation decisions.

13. Prohibiting the individual from participating in institutional negotiations with the outside entity except as the University directs.

14. Prohibiting the individual from serving on the board of directors of the outside entity, or as an officer, member of the scientific advisory board, member of a speakers' bureau, or consultant.

15. Prohibiting the individual from disclosing confidential University information.

16. Prohibiting the individual from channeling discoveries to the outside entity.

17. Prohibiting the university from accepting research grants from companies founded by the individual.<sup>98</sup>

As suggested by the diverse management options and issues related to conflicts of interest, each sponsored research or licensing agreement is evaluated in light of its unique

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<sup>98</sup> *Id.* at 9-10.

circumstances, which may include the significance of the conflict of interest (such as the size of the individual's financial interest), whether the individual is uniquely qualified by virtue of expertise and experience to conduct the research project, whether the research could not be conducted as safely or effectively without that individual, and whether the degree of risk imposed on research subjects.<sup>99</sup> In turn, each plan of management for an individual or institutional conflict may impose a different set of constraints on a university research agreement or IP license.

### **III. Best Practices for University Management of IP**

In view of the legal and policy issues that face CWRU and other universities, CWRU has established best practices respecting its management of IP that enable it to promote commercialization while complying with its legal and policy obligations. CWRU's IP practices are discussed below in the context of the main types of IP-related agreements entered by CWRU under the auspices of the TTO and OSPA: (1) Licensing Agreements; (2) Confidentiality Agreements; (3) Sponsored Research and Industry Collaboration Agreements; and (4) Material Transfer Agreements.

#### **A. CWRU Licensing Practices**

In view of the legal and policy restrictions affecting its efforts to license CWRU IP to industry (and thereby promote its commercialization), the TTO has adopted licensing practices that include the following:

- CWRU maintains ownership of IP, rather than assigning it outright to industry. This practice is required for most research funded by the federal

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<sup>99</sup> *Id.* at 4, 8.

government and accords with the University's academic and research missions.<sup>100</sup>

- CWRU licenses must clearly define the IP subject to license and the parties' respective rights to any IP that may result from continued research and development.<sup>101</sup> To avoid circumvention of license and royalty obligations, CWRU will require a licensee to comply with the terms of the license with respect to "derivative" technologies it develops during the term of the license (although under appropriate circumstances the licensee may have ownership of any such derivatives).
- CWRU only licenses pre-existing technology (with the exception of certain permitted option or non-exclusive rights that may be granted in connection with sponsored research, discussed above, where such rights fall within the safety zone for basic research performed in facilities financed with tax-exempt bonds).<sup>102</sup> CWRU does not generally license inventions on an exclusive basis in advance of creation, because to do so would, in effect, be both contrary to Revenue Procedure 2007-47, discussed above, and tantamount to performing commercial "work-for-hire," rather than basic research, and therefore would be inconsistent with its tax-exempt purposes.<sup>103</sup>
- CWRU requires licensees to meet milestones, both developmental and commercial, that reflect reasonable diligence and investment activities aimed at achieving practical use and dissemination of the licensed technology... CWRU, moreover, requires its licensees to apprise the University of their achievement of such milestones; such oversight is required by both Bayh-Dole (to avoid the exercise of federal "march in" rights) and CWRU's tax-exempt mission.<sup>104</sup>
- CWRU's licenses are generally restricted to a specified field of use, rather than granted with unlimited rights. Universities are generally concerned about the ability of a licensee to commercialize the IP in all fields of use and "[i]n fact such full development is rarely realized in practice."<sup>105</sup>
- CWRU grants licenses based upon the fair market value of the IP, and CWRU cannot give more favored terms to faculty-owned or local companies. Any license at less than fair market value could subject CWRU to potential

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<sup>100</sup> See *supra* II.A, II.B.

<sup>101</sup> See *supra* II.B.

<sup>102</sup> See *supra* Section II.E.3.

<sup>103</sup> See *supra* Section II.E.

<sup>104</sup> See *supra* Sections II.A, II.B, and II.E.1.

<sup>105</sup> Government University Industry Research Roundtable: Industrial Research Institute, INTELLECTUAL PROPERTY RIGHTS IN INDUSTRY-SPONSORED RESEARCH: A GUIDE TO ALTERNATIVES FOR RESEARCH AGREEMENTS 12 (1993), [http://www.nap.edu/catalog.php?record\\_id=10009](http://www.nap.edu/catalog.php?record_id=10009) (last visited Oct 31, 2009).

tax penalties or other adverse tax consequences under the “private inurement” and “private benefit” doctrines,<sup>106</sup> or contradict conflict of interest rules.<sup>107</sup>

- CWRU requires commercial licensees to bear the expense of pursuing and maintaining patent protection (or other forms of IP protection), which commonly secure the commercial value of IP.
- Every CWRU license to IP must disclaim all warranties (i.e., grant rights to IP only “as is, where is”), provide for indemnification of CWRU<sup>108</sup> in the event of a lawsuit arising from the licensee’s use or disposition of the IP, and require the licensee to maintain adequate insurance coverage. CWRU, like many other universities, does not grant warranties and requires indemnification for numerous reasons, including:
  - Much CWRU IP relates to leading edge research, which has not been alpha and beta-tested.
  - CWRU does not maintain commercial-type managerial controls over faculty and inventors as would a private business.
  - Upon licensing, CWRU loses effective control over the circumstances in which the IP will be disseminated to the public.
  - CWRU cannot put its endowment and assets at risk because of the commercialization of an item of IP (or even group of items). CWRU’s resources serve all past, present, and future faculty and students, and it would be contrary to the prudent administration of CWRU’s resources to place them in jeopardy for any single commercial relationship.<sup>109</sup>
- CWRU generally prohibits a licensee from assigning license rights to CWRU IP without CWRU’s consent. This provision guards against transfer of IP to a firm that will not be able to develop it or to patent “trolls,” who acquire IP for the sole purpose of pursuing legal claims against alleged infringers but not to transfer CWRU IP to society.
- CWRU licenses include a provision that preserves CWRU’s ability and the ability of affiliated institutions (and in some instances other non-profit research institutions) to continue to use the IP for non-commercial research. This provision seeks to prevent commercialization of IP from impeding continued pursuit of CWRU’s academic and research missions.

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<sup>106</sup> See *supra* Section II.E.1.

<sup>107</sup> See *supra* Section II.F.

<sup>108</sup> Likewise, CWRU does not indemnify licensees for claims arising from use of CWRU IP, due to the economic risk.

<sup>109</sup> See *supra* Section II.A.

- CWRU licenses address the manner and location in which disputes must be addressed. In the absence of such a provision, the parties may engage in a costly dispute over where disputes must be addressed, what state's or country's law will govern disputes, and the like.
- CWRU licenses provide for termination by CWRU or an elimination of exclusivity in the event that the licensee fails to meet milestones or payment obligations, but do not provide licensees a right to terminate for convenience. Such termination provisions promote meaningful commercial development of CWRU IP and discourage efforts to enter license agreements directed at forestalling competition.<sup>110</sup>

#### **B. *Preservation of Patent Rights***

As explained above, protection and promotion of CWRU's IP assets require safeguards against the unintended loss of patent rights through publication or disclosure of an invention in advance of filing for patent protection.<sup>111</sup> For this reason, CWRU's IP Policy specifically provides:

In order to achieve protection and commercialization of Intellectual Property, the creator shall provide the Vice President for Research and Technology Management or his or her representative [i.e., the TTO] with a statement disclosing the Intellectual Property and the circumstances under which the Intellectual Property was conceived with particular reference to (a) whether the project or program from which the Intellectual Property derived was financed in whole or in part by a grant or contract, and if so, the name of the funding entity, (b) whether the Intellectual Property falls within the creator's activities and responsibilities for the University, and (c) whether University funding, equipment, staff or physical facilities were employed in the process of developing the Intellectual Property. This should be done as soon as the creator is aware of the novelty and potential value of the Intellectual Property.<sup>112</sup>

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<sup>110</sup> See *supra* Section II.C, II.E.

<sup>111</sup> See *supra* Section II.B.

<sup>112</sup> Case Western Reserve University, *supra* note 7.

Upon submission of a complete invention disclosure, the TTO is required to decide whether to pursue commercialization within 120 days.<sup>113</sup>

If the TTO decides to pursue commercialization, it will consider filing for patent protection, identify market opportunities, and communicate with potential licensees. Whether or not to seek patent protection, which can be quite costly, will depend upon a number of factors, including the extent of “prior art,” the scope of potential patent protection, and the extent of likely industry interest.

Discussions with potential licensees will generally proceed in stages that protect the IP, while permitting further evaluation of the technology and the qualifications of the licensee. First, the parties will commonly enter a confidentiality agreement (or non-disclosure agreement) that protects the IP and parties’ respective interests during the review and negotiation period. Second, the potential licensee will be expected to provide a business plan that allows for review of its objectives and conformity of the proposed relationship with CWRU interests. Next, the parties will typically enter a “term sheet” that specifies the key economic terms of a proposed license, which provides the basis for negotiation and execution of a final license agreement that is consistent with CWRU legal and policy requirements.

From both a legal and economic standpoint, confidentiality is generally essential to the commercialization process. As a legal matter, a confidentiality agreement may preserve the patentability of the IP<sup>114</sup> and provide for recourse in the event of a misappropriation or

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<sup>113</sup> *Id.* Under the CWRU IP Policy, if the TTO decides against commercialization of an invention, upon the request of the creator IP rights for commercialization may be released to the creator to pursue on his or her own.

<sup>114</sup> *See, e.g., Allied Tube and Conduit Corp. v. John Maneely Co.*, 125 F. Supp. 2d 987, 990 (D. Ariz. 2000) (“[B]ecause the letter was sent to distributors, rather than end users to whom the distributors sold, and was marked confidential, the letter was not accessible to the interested

unpermitted use of sensitive information. As an economic matter, and because of the legal protections, confidentiality may be necessary to maintain the value of the subject IP.

CWRU's confidentiality agreements address the following key issues:

- The confidential information must be clearly described. In the absence of a clear definition, the protections of the agreement may be easy to evade or difficult to enforce.
- In some instances, it may be necessary for all confidential information disclosed by or to CWRU to be clearly marked as such. The administrative burden of complying with such a requirement must be considered in advance.
- A confidentiality agreement should articulate clear restrictions on who is permitted to review the confidential information, and under what circumstances or safeguards. For example, the agreement may provide that only certain employees may view the information and they may use the information only for purposes of considering a collaboration agreement with CWRU. The agreement may also require that each individual execute a copy of the agreement or be subject to a comparable agreement.
- In most instances, CWRU will not permit subsidiaries or related companies to have access to CWRU's confidential information, unless those companies are specifically identified and agree, in writing, to the terms of the confidentiality agreement, so that CWRU will know who has its information.
- A confidentiality agreement should make clear that it (i) does not include any conveyance or license of intellectual property rights (with the limited exception of the right to use the information for the purpose set forth in the agreement); (ii) does not provide any warranties related to the information; and (iii) does not obligate the parties to enter into a subsequent license or other agreement.
- A confidentiality agreement should expressly provide that a breach would allow CWRU to obtain injunctive relief (e.g., a court order prohibiting further use or dissemination of the information). In the absence of such a requirement, the time and expense (the cost of a prolonged court proceeding) required for obtaining such relief may be increased.

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public and does not constitute a publication [that would trigger the one-year bar].”); *Garrett Corp. v. U. S.*, 190 Ct. Cl. 858, 877, 422 F.2d 874, 877 (1970) (“To be a ‘publication’ under the statute, a document must, among other things, be accessible to the public.”).

### C. *IP Rights in Sponsored Research Agreements and Industry Collaboration*

University-industry relationships can be an important source of IP—either as the result of industry sponsorship of research or collaboration between university and industry researchers. In either case, clear delineation of IP rights can be critical to both avoiding disappointed expectations or future disputes and complying with law and policy.

Sponsored research agreements with commercial firms (as distinct from government sponsors) can raise legal concerns related to private use of charitable assets or facilities financed with tax-exempt bonds.<sup>115</sup> Commercial firms may expect sponsored research agreements to include specified deliverables, assignment of resulting IP through work-for-hire requirements, warranties, royalty-free rights to background IP, or other commercial terms. While such terms may be routine in commercial service agreements, they can be inimical to a university's need to preserve tax-exempt treatment for sponsorship of its faculty members' work. For example, granting royalty-free rights to background IP in connection with sponsored research would be inconsistent with both a university's tax-exempt status and fiduciary obligations to the university and inventors of the background IP.<sup>116</sup>

Further, sponsored research agreements have the potential to conflict with a university's mission to promote publication and dissemination of the results of its research. The Emeritus Director of Sponsored Programs at MIT explains:

In seeking support from industrial and corporate sponsors, the institution needs to be aware of the range of significant issues that must be addressed relative to such sponsorship. For example, support from industrial sources is generally of shorter duration and less stable for long-term basic (or fundamental) research projects than from federal sponsors. The work tends to be more directed than funding via grants and cooperative agreements

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<sup>115</sup> See *supra* Sections II.E.1 and II.E.3.

<sup>116</sup> See *supra* Sections II.A and II.E.2.

from the federal government (although not much different than the restrictions placed on some contract activities supported by the government) and there tend to be more deliverables required (including more frequent progress reports). Although there are fewer cited regulations than in federal awards, certain terms and conditions (notably related to ownership and management of intellectual property and to restrictions on publication) are far more difficult to negotiate and often cause extensive delays in finalizing research agreements.<sup>117</sup>

Efforts to impose restrictions on publication of research results can be especially problematic as such restrictions may be contrary to both university policy and legal requirements for tax-exempt "fundamental" research.<sup>118</sup>

In view of the foregoing issues, CWRU's practices with respect to the IP aspects of sponsored research agreements include:

- Sponsored research must be consistent with CWRU's academic and research missions.
- Sponsored research must comply with CWRU's conflict of interest policy and regulations related to conflicts of interest.<sup>119</sup>
- Although a sponsor may be granted the right to review findings in advance of publication (and to seek redaction of confidential information provided by the sponsor to CWRU), a sponsor will not be granted any right to delay publication for more than a reasonable time for such review (typically no more than 60 days).<sup>120</sup>
- If students are to be involved in a sponsored research project, the sponsor must commit funds or resources of sufficient duration and focus to align with requirements for effective instruction and learning. Likewise, a sponsor may not restrict any publication of a student dissertation.<sup>121</sup>

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<sup>117</sup> Julie T. Norris, *Research and Sponsored Programs*, in COLLEGE AND UNIVERSITY BUSINESS ADMINISTRATION, 18-10 to 11 (6th ed. 2000).

<sup>118</sup> *Id.* See also U.S. Internal Revenue Service, PUBLICATION 598, *supra* note 68 (explaining that "[w]hen an organization is operated primarily to conduct fundamental research (as distinguished from applied research) ... the results are freely available to the general public").

<sup>119</sup> See *supra* Section II.F.

<sup>120</sup> See *supra* Section II.D.

<sup>121</sup> See *supra* Section II.A.2.

- CWRU's rights to IP created during a sponsored research project must be clearly specified. CWRU will have ownership of all IP created solely by its faculty and staff and any IP jointly created with the sponsor.<sup>122</sup>
- In some instances, consistent with the safe harbor set forth in Revenue Procedure 2007-47, CWRU may grant a royalty-free, non-exclusive license to IP created pursuant to a sponsored research agreement of \$100,000 or more.<sup>123</sup>
- In lieu of license rights, CWRU may grant sponsors exclusive options to negotiate to acquire IP licenses at fair market rates. Options must, however, have a specified term and a clear termination point so that CWRU may pursue alternative paths to commercialization if a license agreement with the sponsor is not reached.
- Any license rights granted to project sponsors must be subject to the same licensing terms respecting disclaimers of warranties, indemnification, insurance, dispute resolution, etc. as other license agreements.
- Information provided by CWRU to sponsors concerning new IP must be subject to confidentiality requirements (set forth in the sponsored research agreement and/or a separate confidentiality agreement).<sup>124</sup>

Collaborations between CWRU and industry raise many of the same issues as sponsored research but are further complicated by the greater prospects for jointly created IP or IP created entirely by the industry participant(s). Accordingly, collaboration agreements must also clearly delineate the parties' rights respecting IP.

A recent case involving Stanford University and the Roche pharmaceutical company illustrates the problems and long term disputes that may result from a failure to enter a clear agreement governing IP that may result from collaborative research. In *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.* 583 F.3d 832 (Fed.Cir. 2009), the U.S. Court of Appeals for the Federal Circuit recently held, after four years of litigation, that Stanford University had no rights to a patent concerning a test to detect HIV infection that resulted from a collaboration between a Stanford Research Fellow and Roche, a

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<sup>122</sup> *Id.*

<sup>123</sup> *See supra* Section II.E.3.

<sup>124</sup> *See supra* Section II.B.

for-profit company. The court found in favor of Roche (the successor to the original company) notwithstanding Stanford's IP Policy, an assignment of the invention by the Research Fellow to Stanford, and Bayh-Dole. The court based its decision on a conflicting assignment of invention by the Research Fellow to the for-profit company, which the court concluded operated automatically to transfer title to the IP and took precedence over his assignment to Stanford. Both the dispute and outcome could likely have been avoided had Stanford entered a written collaboration agreement with the pharmaceutical firm that delineated their respective rights.

**D. *Material Transfer Agreements***

Material transfer agreements ("MTAs") involving exchanges between universities and industry raise many of the same issues as industry sponsored research.<sup>125</sup> A university receiving materials from industry ordinarily will seek to (1) avoid restrictions on academic freedom and publication; (2) secure ownership of IP and research results; (3) limit indemnification of the provider; and (4) avoid creating conflicting obligations with other sources of funds or materials for the relevant research.<sup>126</sup> In some instances, however, a university must agree to protect proprietary materials provided by a for-profit sponsor from disclosure to, or use by, third parties.

On the other hand, research materials developed with, or used in research supported by, the National Institutes of Health ("NIH") are subject to regulations that promote distribution to third parties for research purposes. In February 2003, NIH issued a final policy statement stating that "all investigator-initiated applications [funding] with direct costs greater

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<sup>125</sup> See generally, Wendy D. Streitz & Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133 PLANT PHYSIOLOGY 10 (2003).

<sup>126</sup> Council on Government Relations, MATERIAL TRANSFER IN ACADEMIA (2003), [http://www.cogr.edu/docs/MTA\\_Final.pdf](http://www.cogr.edu/docs/MTA_Final.pdf) (last visited Oct 22, 2009).

than \$500,000 in any single year will be expected to address data sharing in their application.”<sup>127</sup>

This statement followed NIH’s 1999 *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (“NIH Guidelines”), which provides guidance for complying with NIH requirements for disseminating materials while also complying with Bayh-Dole.<sup>128</sup>

The NIH Guidelines, moreover, highlight the differences between material transfers among non-profits and transfers involving industry. COGR explains the role of the NIH Guidelines as follows:

The *Principles and Guidelines* recognizes the difficult balance between NIH funding recipients’ rights to disclose and publish their research findings, the right of the scientific community and public at large to access and share the research results, the right of providers to preserve proprietary rights to research tools, and the right of recipients to retain title to inventions made with NIH funds while assuring their utilization and commercialization for public benefit. *The Principles and Guidelines* implies a high level of diligence on the part of institutional officials both to educate and advise faculty and manage the process of disseminating and importing research tools. Institutions must carefully oversee interactions (such as industry-sponsored research agreements and exclusive licenses) that have the potential to restrict sharing and thereby contradict the *Principles and Guidelines*.<sup>129</sup>

In brief, the NIH Guidelines require non-profit institutions to share publicly-funded materials freely with other non-profits (through use, for example, of the Uniform

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<sup>127</sup> *Id.*

<sup>128</sup> Department of Health and Human Services, National Institutes of Health, PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH FED. REG. 99–33292 (1999).

<sup>129</sup> Council on Government Relations, *supra* note 127.

Biologic Materials Transfer Agreement)<sup>130</sup> and to limit agreement to restrictions imposed by industry providers. The Guidelines state that recipients of NIH funding should:

### **1. Ensure Academic Freedom and Publication**

Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant coauthorship or copyright to the provider of a material. Reasonable restrictions on collaboration by academic researchers involved in sponsored research agreements with an industrial partner that avoid conflicting obligations to other industrial partners, are understood and accepted. Similarly, brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from a sponsor or the provider of a research tool is not inadvertently disclosed. However, excessive publication delays or requirements for editorial control, approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable.

### **2. Ensure Appropriate Implementation of the Bayh-Dole Act**

... [L]icenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product.

...

### **3. Minimize Administrative Impediments to Academic Research**

... Recipients should develop and implement clear policies which articulate acceptable conditions for acquiring resources, and refuse to yield on unacceptable conditions. ... Reach-through royalty or product rights, unreasonable restraints on publication and academic freedom, and improper valuation of tools impede the scientific process whether imposed by a not-for-profit or for-profit provider of research tools. While these Principles are directly applicable only to recipients of NIH funding, it is hoped that other not-for-profit and for-profit organizations will adopt similar policies and refrain from seeking unreasonable restrictions or conditions when sharing materials.

### **4. Ensure Dissemination of Research Resources Developed With NIH Funds**

...Unique research resources arising from NIH-funded research are to be

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<sup>130</sup> Department of Health and Human Services, National Institutes of Health, UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT (UBMTA) Fed. Reg. 95-5644 (1995).

made available to the scientific research community. Recipients are expected to manage interactions with third parties that have the potential to restrict Recipients' ability to disseminate research tools developed with NIH funds. ...<sup>131</sup>

CWRU's practices with respect to MTA's are consistent with legal requirements and the NIH Guidelines.

#### **IV. Conclusion**

As a result of legal and policy constraints, CWRU must balance numerous competing objectives and requirements that affect its management and commercialization of IP. As discussed above, CWRU has adopted IP practices that have enabled it to promote its missions and comply with legal requirements, while facilitating commercial and practical use of its innovations.

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<sup>131</sup> Department of Health and Human Services, National Institutes of Health, *supra* note 129.