

Economic Development and Commercialization Subcommittee

Cancer Prevention and Research Institute of Texas

Comments on Intellectual Property Standards And Protection of Confidential Information

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INTRODUCTION

The Cancer Prevention and Research Institute of Texas (“CPRIT”) was established to promote innovation, development and commercialization in the area of cancer research and to enhance the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer. This paper examines ways in which CPRIT can structure intellectual property (“IP”) agreements with grant recipients to encourage private investment and commercialization. We also look briefly at the potential impact application of the Texas Public Information Act (the “Act”) would have on CPRIT grant applications and its effect on future grant proposals.

I. STRUCTURING IP TO EXPEDITE INNOVATION AND ATTRACT INVESTMENT

CPRIT’s enabling legislation provides that the Oversight Committee will establish the standards that govern IP developed from grant awards. First and foremost, these governing standards must comport with the goals and requirements of CPRIT. CPRIT was created to “expedite innovation in the area of cancer research”² and commercialize completed research.³ To fully realize the goals of expediting innovation and commercialization, the Oversight Committee must tailor CPRIT’s IP guidelines so that they do not impede – and if possible attract – private investment, as private investment will play an important role in expediting innovation and bringing research to the market.

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² TEXAS HEALTH & SAFETY CODE ANN. § 102.002.

³ Cancer Prevention & Research Institute of Texas, <http://www.cprit.state.tx.us> (last visited April 29, 2009) (providing that an integral part of CPRIT’s philosophy is the commercialization of completed research).

Before discussing the ways in which the Oversight Committee can structure its guidelines to attract private investment, it is relevant to discuss the rules related to IP in CPRIT's enabling legislation. First, "*all grant awards* must be subject to an intellectual property agreement that allows the state to collect royalties, income, and other benefits realized as a result of projects undertaken with grant awards."⁴ In other words, awards to both public and private entities will be covered by the Oversight Committee's IP guidelines. Second, in determining the rights of the State of Texas, the guidelines must "ensure that essential medical research is not unreasonably hindered by the intellectual property agreement and that the agreement does not unreasonably remove the incentive on the part of the individual researcher, research team, or institution."⁵ In other words, the standards implemented by the Oversight Committee must balance the interests of the State in receiving some return on its investment, but the standards must not unduly burden researchers (including for-profit entities).

A. *Grants to Nonprofit Organizations*

Certain of Texas' public research universities and nonprofit research institutions have already provided their recommendations on how the Oversight Committee should structure its IP agreements. The structure proposed by these institutions is relevant here, as IP agreements between CPRIT and nonprofit institutions should not be structured so as to stifle future downstream investment by for-profit entities looking to commercialize research performed by the nonprofit institutions.

The University of Texas System has proposed a widely accepted licensing structure for grants to academic institutions ("UT's Recommendations").⁶ The basic concepts underlying UT's Recommendations are: (1) IP should be owned by the grant recipients (and the grant recipients will be responsible for IP protection and commercialization), and (2) CPRIT will share in commercialization benefits in the form of licensing revenues.⁷ More specifically, under UT's Recommendations, CPRIT is entitled to 10% of the grant recipient's net IP income based on the percentage of CPRIT funding, and the first payment is required after net income exceeds \$500,000.

As an initial matter, UT's Recommendations follow traditional IP law, that is, IP ownership follows the individual making the discovery/development, and the individual owning the IP (or his or her assignee) is responsible for protecting the IP.⁸ Because UT's Recommendations follow traditional IP law, for-profit companies and investors will be familiar with the regime. For example, the California Institute for Regenerative Medicine has also adopted revenue sharing rules that are similar to UT's Recommendations. The only difference in

⁴ TEXAS HEALTH & SAFETY CODE ANN. § 102.265 (emphasis added).

⁵ *Id.*

⁶ UT's Recommendations have been endorsed by Baylor University, Methodist Hospital, Rice University, Texas A&M University, Texas State University, Texas Tech University, The University of Houston and The University of North Texas.

⁷ Presentation of The University of Texas System, http://www.cprit.state.tx.us/pdfs/present/sanga_ut_system_090211.ppt (last visited April 22, 2009).

⁸ Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-12.

California's regime is that California receives 25% of licensing revenues over \$500,000, as opposed to the 10% proposed by UT.⁹ For-profit companies will generally be neutral as to the amount of revenues returned to the State (i.e., 10% v. 25%) so long as an increase in the percentage does not result in an increase in the overall royalty rate charged by the university to license out the technology or spin out a new company. As a general matter, however, lower licensing costs should help promote private investment and commercialization.¹⁰

B. Grants to For-Profit Organizations

As previously discussed, CPRIT envisions grant awards to for-profit entities. Grants to for-profit organizations will require additional rules governing IP because for-profit companies are able to generate revenue both through downstream licensing (similar to nonprofit institutions) and through self-commercialization. In other words, IP agreements with for-profit companies must provide rules for returns to the state both from licensing and self-commercialization revenue.

To stimulate private investment, CPRIT should again follow traditional IP licensing conventions when making grants to for-profit entities that receive revenues from downstream licensing. In other words, ownership (and the responsibilities related thereto) should follow the individual (and his or her assignee) making the discovery. In crafting rules to cover downstream licensing, UT's Recommendations again provide a good foundation. In other words, in cases of downstream licensing, CPRIT can structure its guidelines to allow Texas to recover a portion of licensing revenue. By extending UT's Recommendations to for-profit entities that license research, CPRIT would create uniformity in its guidelines and also follow traditional IP law and practices. Uniformity and tradition should help promote commercialization because entities are already familiar with the regime.¹¹

CPRIT must adopt a separate regime to govern for-profit organizations that manufacture (or outsource the manufacture) and sell products derived from their own research, as licensing revenues may not always be applicable. Again following traditional IP licensing practices, a potential approach involves the grant of royalties to the state. Texas already embraces the concept of royalty payments in its Emerging Technology Fund (the "ETF").¹² The ETF affords little guidance on how CPRIT might structure its royalty rates, however, as the ETF provides that the royalty percentage will be "in a specified percentage" to the State of Texas without specifying such percentage or range of percentages.¹³ California's regulations related to its stem

⁹ 17 CAL. CODE REGS. Tit. 17, § 100308.

¹⁰ See generally Guifang (Lynn) Yang & Keith E. Maskus, *Intellectual Property Rights and Licensing: An Econometric Investigation*, in INTELLECTUAL PROPERTY AND DEVELOPMENT 111, 116 (Carsten Fink & Keith E. Maskus eds., 2005) (examining the correlation between licensing costs and IP regulations).

¹¹ The California Institute for Regenerative Medicine follows a similar approach for licensing revenues. For-profit organizations "must pay 25% of Net Licensing Revenue in excess of \$500,000 to the State of California for deposit into the State's General Fund." 17 CAL. CODE REGS. Tit. 17, § 100408.

¹² TEX. GOV'T CODE ANN. § 490.103 ("The contract between the government and a recipient of an award . . . shall provide for the distribution of royalties . . .").

¹³ *Id.*

cell initiative also provide that royalties will be negotiated between the grantee and the state. Unlike the ETF, though, California’s regulations provide that the royalty must be greater than 2% and less than 5% of the net commercial revenue from any CIRM-Funded Patented Invention.¹⁴ The benefit of using a net royalty formula is again familiarity—companies and investors are more likely to come off the sidelines when they are familiar with and know the rules and the royalty rates charged do not discourage further private investment in the grantee.

A grant of royalties is not the only solution available to CPRIT, however. Grants by foreign government-related entities illustrate some alternative solutions. For example, in Bavaria, the Bayerische Beteiligungsgesellschaft invests as an equity partner in companies seeking grant money. This approach could potentially limit private investment, as founders and investors often do not like dilution of their equity interests. On the other hand, investors might be willing to give the state an equity interest in exchange for additional investment (*e.g.*, through ETF). Ultimately, this approach is likely to be viewed by investors as less favorable than a traditional royalty interest, as investors might be leery of sharing a portion of their equity interest with the government or a government-controlled entity.

CPRIT could also structure the grants in the form of loans.¹⁵ Structuring the grants as loans would avoid the problem of dilution caused by a grant of equity. The European Investment Bank, for example, makes favorable loans to spur development. Assuming the loan must be repaid, investors may still prefer granting royalties, as royalties do not require any repayment in the event the investor is unable to create a commercially viable product. In order to avoid this problem, CPRIT could tie the repayment of loans to the achievement of milestones, so if a product fails along the way, loans are forgiven. Such a plan could be more trouble than it is worth, however, as CPRIT would have to create additional rules to determine milestones, and investors might still worry about the potential consequences of a failed product.¹⁶ Ultimately, the grant of a royalty interest is likely the preferred method of repayment because it does not result in equity dilution and has previously been used by Texas and other states as a viable system.

C. Using Commercialization as a Factor in Awarding Grants

In addition to structuring IP agreements to minimize the impact on private investment, the Oversight Committee should also examine grant applicants’ ability to successfully commercialize research as an important factor in making grant rewards. CPRIT can analyze an institution’s past success in getting research into the market. For instance, companies looking to license IP often target universities with a reputation of being easy to work with.¹⁷ Additionally,

¹⁴ 17 CAL. CODE REGS. Tit. 17, § 100408. “CIRM-Funded Patented Invention” is defined as: “An invention that has been patented under Title 35 of the United States Code, and that resulted wholly or in part from CIRM-funded Research, except in the event the patent has expired, been abandoned or found to be invalid or otherwise unenforceable” *Id.* § 100401(b).

¹⁵ *See, e.g.*, TEX. GOV’T CODE ANN. § 490.10(h) (“[For ETF grants] [t]he governor may make awards in the form of loans. . . .”).

¹⁶ For example, investors could be subject to taxes if the loan is forgiven.

¹⁷ Anthony Waitz & Wasiq Bokhari, *Nanotechnology Commercialization Best Practices* (2003), http://www.quantuminsight.com/papers/030915_commercialization.pdf (“A leading nanotech researcher from HP,

universities with significant commercial success often tend to have a faculty that “engage in a high level of industry consulting and collaboration. Because of [the faculty’s] propinquity to a vast network of friends and colleagues who are entrepreneurs, venture capitalists, and other experts, their opportunity recognition skills are more keenly developed.”¹⁸ Furthermore, successful universities tend to have a technology transfer office with good resources and good industry connections, as these connections help universities recognize the best commercialization opportunities.¹⁹

CPRIT should take a similar approach to examining the ability to achieve commercial success when awarding grants to for-profit entities as well. Often, the most successful for-profit entities are those that have experienced management (who often are serial entrepreneurs), as well as a “well thought-out and compelling business plan.”²⁰ Such a plan would demonstrate that the organization has considered all the major issues, understands the important roadblocks in getting the product to the market, and allows for good communication with potential investors.²¹ As with universities, for-profit organizations with a balanced team of people with strong networks of contacts are most likely to succeed. A balanced team will help ensure that the organization is capable of taking advantage of new opportunities and adapting to new circumstances as needed.²² These factors are certainly not intended to be comprehensive; instead, they are offered to illustrate the types of factors CPRIT should consider when evaluating grant proposals. If CPRIT’s goal of commercialization is to be taken seriously, it must analyze an organization’s potential for commercial success, or else the risk continues that Texas “will continue to rank[] near the top in biomedical research funding, [while only ranking] about 30th in commercialization.”²³

II. CONFIDENTIALITY OF CPRIT GRANT PROPOSALS

One of the primary concerns for grant applicants seeking CPRIT funding is maintaining the confidentiality of the proprietary information included in their grant proposals. Grant proposals often contain information that applicants do not want disclosed to the public. However, CPRIT must abide by public information laws. Grant applicants must weigh the benefits of receiving CPRIT funding against the risks of having their proprietary information disclosed to

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Stan Williams, has publicly stated that his group no longer looks at patents being generated from UC Berkeley due to their previous experiences in trying to license from that university.”)

¹⁸ Carl J. Schramm, *Accelerating Technology Transfer and Commercialization* 6 (2004), http://www.boulderinnovationcenter.com/PDF/Kauffman_Foundation.pdf.

¹⁹ *Id.*

²⁰ Waitz & Bokhari, *supra* note 17, at 3.

²¹ *Id.* at 3-4.

²² *Id.*

²³ Jason Embry, *How Biotech Plan Turned into Political Storm*, March 31, 2009, <http://www.marshallnewsmessenger.com/news/content/region/legislature/stories/03/31/0331grant.html>.

the public. To encourage applicants to submit grant proposals, CPRIT should take every legal measure to protect the proprietary information of grant applicants.

Once a grant proposal is submitted to CPRIT, the proposal becomes the property of CPRIT.²⁴ As a result, the information in the proposal could be classified as “public information” under the Act.²⁵ The CPRIT Open Records Policy states that CPRIT will promptly release requested information unless the information is made confidential by law, or the information falls under an exception to the Act.²⁶

Section 552.110(a) of the Act provides an exception for “a trade secret obtained from a person and privileged or confidential by statute or judicial decision.”²⁷ The Texas Supreme Court defines a “trade secret” as “any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.”²⁸ Furthermore, in making a trade secret determination, the Texas Attorney General considers the six factors outlined in the Restatement of Torts.²⁹ To protect information under the trade secret exception, an applicant must establish a *prima facie* case for the exception by demonstrating that the information meets the definition of a trade secret and by addressing the determining factors.³⁰

Section 552.110(b) of the Act also provides an exception for “commercial or financial information for which it is demonstrated based on specific factual evidence that disclosure would cause substantial competitive harm to the person from whom the information was obtained.”³¹ Information related to organization, personnel, market studies, professional references,

²⁴ Requests for proposals from the Texas Department of Agriculture and the Texas Fund for Veterans’ Assistance contain the following language: “All proposals shall be deemed, once submitted, to be the property of the [government agency] and are subject to the Texas Public Information Act, Texas Government Code, Chapter 552.” TEX. GOV’T CODE ANN. Ch. 552.

²⁵ Under Texas Government Code, section 552.002, public information includes information that is collected, assembled, or maintained under a law or ordinance or in connection with the transaction of official business by a governmental body. Section 552.021 requires public information to be available to the public upon request. *Id.* §§ 552.002, .021.

²⁶ Cancer Prevention & Research Institute of Texas – Open Records Policy, <http://www.cprit.state.tx.us/openrecords.html> (last visited April 22, 2009) [hereinafter CPRIT Open Records Policy].

²⁷ TEX. GOV’T CODE ANN. § 552.110(a).

²⁸ RESTATEMENT OF TORTS § 757 cmt. b (1939); *Hyde Corp. v. Huffines*, 314 S.W.2d 763, 776 (Tex. 1958), *cert. denied*, 358 U.S. 898 (1958).

²⁹ The six factors that the Restatement gives as indicia of whether information constitutes a trade secret are: “(1) the extent to which the information is known outside of [the company]; (2) the extent to which it is known by employees and others involved in [the company’s] business; (3) the extent of measures taken by [the company] to guard the secrecy of the information; (4) the value of the information to [the company] and [its] competitors; (5) the amount of effort or money expended by [the company] in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.” RESTATEMENT OF TORTS § 757 cmt. b; Texas Open Records Decision Nos. 319 at 2 (1982), 306 at 2 (1982) and 255 at 2 (1980).

³⁰ Texas Open Records Letter Ruling OR2002-0746 (2002).

³¹ TEX. GOV’T CODE ANN. § 552.110(b).

qualifications, experience and pricing is generally not excepted under Section 552.110(b), but information such as customer lists are protected under the exception.³² This exception to disclosure requires “a specific evidentiary showing, not conclusory or generalized allegations, that substantial competitive injury would likely result from release of the information at issue.”³³

Finally, section 552.101 of the Act provides an exception for “information considered to be confidential by law, either constitutional, statutory or by judicial decision.”³⁴ This exception encompasses information that other statutes make confidential. Consequently, if the CPRIT enabling legislation³⁵ contained a confidentiality provision, the information covered by that confidentiality provision would be excepted from disclosure under the Act. For example, the ETF enabling legislation contains a confidentiality provision that protects all information related to the “identity, background, finance, marketing plans, trade secrets, or other commercially or academically sensitive information of an individual or entity being considered for an award . . . unless the individual or entity consents to disclosure of the information.”³⁶ As a result, much of the information contained in grant proposals to the ETF is protected from public disclosure.³⁷

Unfortunately, the CPRIT enabling legislation does not contain a confidentiality provision. However, the Texas Legislature is considering a bill to amend the CPRIT enabling legislation, which includes a provision regarding disclosure of grant proposal information.³⁸ Under the proposed amendment, the grant applicant’s name and address, the amount of funding applied for, and the type of cancer to be addressed under the grant proposal is public information.³⁹ The proposed amendment also allows CPRIT to publicly disclose “any other information designated by [CPRIT] with the consent of the grant applicant.”⁴⁰ Because the proposed amendment requires the consent of the grant applicant before further information is disclosed to the public, the legislative language seems to imply that grant applicants can prevent CPRIT from disclosing all other information contained in the grant proposal. However, unlike the ETF legislation, the proposed amendment to the CPRIT legislation does not specifically list types of proprietary information protected from public disclosure. Consequently, the

³² Texas Open Records Decision No. 319 (1982); Texas Open Records Letter Ruling OR2008-04621 (2008).

³³ National Parks & Conservation Ass’n v. Morton, 498 F.2d 765 (D.C. Cir. 1974); Open Records Decision No. 661 (1999).

³⁴ TEX. GOV’T CODE ANN. § 552.101.

³⁵ TEXAS HEALTH & SAFETY CODE ANN. Ch. 102.

³⁶ TEX. GOV’T CODE ANN. § 490.057.

³⁷ See Texas Open Records Letter Ruling OR2009-00693 (2009).

³⁸ The Texas Legislature is currently considering H.B. 1358. As of April 30, 2009, the proposed bill has been approved by the House Committee on Public Health but has not been submitted to the entire House of Representatives for approval.

³⁹ See proposed H.B. 1358, which would amend TEXAS HEALTH & SAFETY CODE ANN. Ch. 102 to include § 102.262.

⁴⁰ *Id.*

confidentiality of information supplied to CPRIT in connection with a grant application is not free from doubt.

If the proposed CPRIT clean-up legislation becomes law, CPRIT may wish to consider seeking legal guidance from the Attorney General's office as to whether the enabling legislation as amended falls within Section 552.101 of the Act, which permits withholding of information considered confidential by law. Otherwise, under CPRIT's Open Records Policy,⁴¹ CPRIT would carry the substantial burden, whenever an applicant seeks protection of confidential portions of its application, of having to: (a) request an Attorney General opinion and state which exceptions apply, (b) notify the requestor of the referral to the Attorney General, and (c) notify the grant applicant if the request seeks disclosure of proprietary information. The failure to request an Attorney General opinion within ten business days would result in a presumption that the information is not protected under an exception, unless there is a compelling reason to withhold the information.

CONCLUSION

If CPRIT wishes to make a major impact on the commercialization of research, it must consider the impact its IP and confidentiality guidelines will have on private investment. To best stimulate private investment, CPRIT should enact guidelines that private investors are familiar with, as investors often prefer predictability. Additionally, CPRIT should make a detailed inquiry into a grant recipient's ability to commercialize research, because even the best IP guidelines will not ensure that products will ever reach the market. Finally, CPRIT must recognize a grant applicant's desire for confidentiality, and it must do all it can to protect confidential information within the requirements of the Act.

⁴¹ CPRIT Open Records Policy, *supra* note 26.