Ownership of Intellectual Property

As is standard practice among academic institutions, Baylor College of Medicine owns intellectual property developed by its faculty, staff, and students. College personnel are strongly encouraged to educate themselves on the college’s policies regarding intellectual property ownership and disposition. The College’s policy 20.8.01: Research: Inventions and Patents (Baylor login required) describes these policies in their entirety, but key clauses associated with the Patent Policy are as follows:

• **Assignment of Intellectual Property Rights (Section II. A.):** “Baylor Intellectual Property is and shall be regarded as the proprietary property of the College, owned and controlled solely by the College, and all rights thereto shall be determined and administered by the College as provided in this Policy. As a condition of their appointment, employment or enrollment by, or working at the College, or use of facilities made available by or through the College, or in consideration for the compensation or other benefits received from or through the College (including the use of facilities), all College Personnel are obligated to assign and convey, and do thereby assign and convey to the College, all Baylor Intellectual Property Developed by them.”

• **Definition of Intellectual Property (Section X.):** “Intellectual Property” shall mean Inventions, know-how, trade secrets, technology, research data and notes, Copyrightable Works, trademarks, service marks, and trade names.”

• **Definition of Invention (Section X.):** “Invention” shall mean and include, without limitation, any development, discovery, creation, improvement or other advance whether developed as a product of mental processes or as a result of scientific investigation and experimentation, and whether not reduced to writing. Inventions shall include by way of example, but not by way of limitation: drugs, methods of healing or promoting the healing arts, chemical or biological processes or methods, gene sequences, gene therapy, cell lines, vectors, organisms, combinations of matter, computer software, electrical or mechanical devices, and electrical circuits. The foregoing examples shall not in any way limit the scope of this definition (Section X of the Patent Policy).”

The Bayh Dole Act and the Rise of Academic Technology Commercialization: In 1980, Congress passed an act of legislation that made fundamental changes to the ownership and management of intellectual property resulting from federally funded inventions. The Bayh Dole Act enabled recipients of federal research funds to elect title to inventions developed with federal funding. Universities, small businesses and non-profit organizations that receive federal research funds were now able to direct the commercialization of federally-funded inventions. Prior to passage of the Bayh Dole Act, the vast majority of federally-funded inventions were not leveraged and developed by the commercial sector. The public funds research with the expectation that it will lead to the development of new products and services that benefit society, yet prior to Bayh Dole, it simply wasn’t happening.

The passage of Bayh-Dole unleashed a wave of commercialization activity at at academic institutions across the country and spurred the growth and development of university technology transfer. Since the beginning of the Bayh-Dole era, U.S. universities have generated over 4,000 start-up companies and 153 new FDA approved vaccines, drugs and/or new indications for existing drugs were discovered through research conducted in the university setting (source: Association of University Technology Managers). It is not an exaggeration to state that the Bayh-Dole Act singularly spurred the growth and development of the biotechnology industry in the United States. The success of the Act has spawned similar legislation in numerous foreign countries, including most of the developed world’s major economies.
Major provisions of the Bayh-Dole Act include:

- Recipients of federal funds, including universities and small businesses, can elect title to federally-funded innovations.
- Universities are encouraged to commercialize inventions developed with federal research funding, and are specifically encouraged to work with small businesses.
- Universities must share a portion of their commercialization revenue with the inventors of the licensed technology.
- Although universities are permitted to license federally-funded inventions to commercial third parties, the federal government retains a non-exclusive license to practice the invention in the interests of the U.S. government throughout the world.
- The federal government retains march-in rights, meaning it can step in and potentially direct activities related to commercialization of federally-funded inventions.

What to disclose? When to disclose? How to disclose?

- **What to disclose?** If you have developed a technology that solves or addresses an unmet need, you should disclose the technology to the Baylor Licensing Group. Examples of technologies that are frequently disclosed include therapeutic compositions and methods, vaccines, devices, diagnostics, software and smart phone applications, educational materials, as well as research tools such as knockout mice, antibodies, vectors, and cell lines that have been engineered to have special characteristics. Note: For the purpose of this section, the terms “technology” and “invention” may be used interchangeably.

- **When to disclose?** If the technology is one that may require the preparation and filing of a patent in order to be successfully commercialized (this group would generally include therapeutic compositions and methods, medical devices, and some diagnostics), it is important to disclose the technology prior to any public presentation or disclosure of it. Public disclosure can take a variety of forms, including meeting abstracts, oral presentations, and online and print publications. Many meeting abstracts are published online well in advance of the scientific meeting or conference, making it imperative to disclose the invention to BLG prior to any description of the invention appearing online. Ideally, we’d strongly like to avoid the scenario of a “rush” patent filing to try to beat online publication of an abstract, especially if there are aspects of the invention that haven’t been developed or described, such that we end up filing an application that may not adequately capture and claim important aspects of the invention.

The reason that you should disclose your technology to BLG prior to any public disclosure of the invention is linked to the fact that the ability to patent the invention in most countries in the world is permanently lost once the invention is publicly disclosed. Most countries in the world have a requirement for absolute novelty in order for an invention to be patentable. The United States does represent an exception to this practice, such that a patent application can be filed within one year of the date of the initial public disclosure – this is known as the “grace period.” However, it is important to stress that it is to your advantage, and to the college’s, to file an application before any potential patentability rights are lost through a public disclosure.
**How to disclose?** Submitting your disclosure is a simple process that you can do using BLG’s online disclosure submission application, available here: [https://blg.research.bcm.edu](https://blg.research.bcm.edu), or on the front page of the Baylor Licensing Group website.

Before getting started, you’ll need the following information:

- **The names of the contributors to the technology/invention**, their contact information (if they are BCM personnel, they are searchable with the disclosure submission application), and their respective percentage contribution to the technology.
- **The identities of any funding sources** that were used to support the development of the technology, **including grant numbers**. BLG has reporting obligations to the federal government, and to other funding agencies (CPRIT, for example), such we must have grant numbers associated with the disclosure.
- **A description of the technology**: You may attach manuscripts, abstracts, posters, or other documents that describe the technology that you have developed; or, you may choose to write a description.
- **Public disclosure of the technology/invention**: If the technology/invention has been described in a published manuscript, abstract, poster, or other format, please attach a copy of that document. Prior public disclosure of an invention can impact patentability of your invention.
- **Third party use of the technology/invention**: Has the invention been offered for sale or use to any third party outside of your laboratory? If this was done through an agreement with a third party, we would need to see a copy of that agreement.

Once you have the required information in-hand, submitting the disclosure should require very little time. Once the information is submitted, you and the other BCM contributors will be asked to submit electronic signatures. BLG will coordinate obtaining signatures from any non-BCM developers. Once the disclosure has been submitted and transferred to the BLG database, you will receive an email confirmation and your department chair will be notified as well.

**Disclosure Management: What Happens to Your Disclosure?**

Following submission of the completed disclosure, it will be assigned to a BLG project manager, who will work with you to determine the appropriate commercialization strategy. Each BLG project manager is responsible for managing disclosures from a portfolio of departments. A list of project managers and the departments for which they are responsible is available on the BLG website.

- The typical workflow of the disclosure management process is summarized in “Life Cycle of an Invention Disclosure” graphic. The individual steps in this process are described in detail in this guide (marketing and licensing activities, for example), but this graphic serves to provide a schematic overview of the entire process beginning with the submission of a disclosure and ending with the successful execution of a license agreement or a decision to close the file and cease licensing and marketing activities.
• **Invention Disclosure Analysis: Elements & Purpose.** Once your disclosure is assigned to your BLG project manager, they will initiate the process of coordinating the development of an Invention Disclosure Analysis (IDA) for your disclosure. The IDA is intended to provide the faculty member with an analysis of factors that the commercial prospects of the disclosed technology and it will provide a commercialization recommendation along with a rationale for the recommendation. The IDA is not intended to be an exhaustive analysis of the disclosure, but is intended to be a vehicle to provide high-quality feedback to the PI within a reasonable timeframe after submission. The IDA process will be initiated when the BLG project manager has received sufficient information on the technology to conduct an evaluation. Members of the BLG intern team will assist BLG project managers with the collection of prior art and market information that is relevant to the invention being analyzed.

**Elements of a typical IDA will include:**

- A *description of the technology* being evaluated.

- *Citations of prior art* in the scientific and patent literature that are relevant to the invention, along with citation of specific language/passages in the references that may read upon aspects of the invention.

- A *description of the commercial market* associated with the invention, which may contain a list of companies/products that are active in the relevant market, and/or descriptions of competing technologies.
- **Identification of any encumbrances** that may impact our ability to commercialize the disclosed technology. Such encumbrances might consist of obligations to third parties that arise via previously signed agreements, such as MTAs or SRAs.

- A **commercialization plan**, which may result in a decision to prepare marketing materials and begin marketing the invention to potential licensees, and/or to prepare and file a patent application. Alternatively, we may decide that the invention has already been substantially disclosed in the prior art and we may elect not to file a patent or to market it to industry. Each technology will be different, and the commercialization plan for each one will be different as well.

![Diagram: The Invention Disclosure Analysis (IDA) Process]

**FIGURE 2: The IDA Process & Outcomes**

**Typical Commercialization Factors & Strategies for Different Types of Inventions**

Each technology disclosed to BLG will be examined on its own merits, but there are some general factors that impact the commercialization prospects, and our decisions around them, for different classes of technologies:

- **Therapeutic Methods and New Uses for Existing Compounds**: In order for a therapeutic method to be of interest to a potential licensee, they will typically wish to see proof-of-
concept data from a relevant animal model system. If the therapeutic method involves the use of a compound/molecule this is owned by a third party and not BCM, then the likely (and in most cases, the only) prospect for a licensee will be the owner of the compound. There has been much focus and emphasis on developing new uses for existing compounds. For a compound that has already been through the regulatory approval process and has been proven safe for use in humans, there are sound reasons to investigate new uses for it from a patient care standpoint. But, from a commercialization standpoint, *the company that owns the compound will be the primary beneficiary of any new method of use for such a compound that is developed by an academic PI.*

If an academic PI develops a new method of use for an off-patent, non-proprietary FDA-approved compound, it is often very difficult to attract a company to license such a technology because the compound itself is no longer protectable, and enforcing infringement around a new method of use for a non-proprietary compound is challenging at best, particularly if the new method of use can be achieved via “off-label” use of the approved drug.

Technologies involving novel therapeutic methods that are not associated with some sort of proprietary molecule or compound are very tough to successfully commercialize. There must some aspect of the data associated with the new method that is extraordinary in some respect to have a realistic shot at garnering commercial interest.

There are cases in which a new therapeutic method is developed using an existing compound, but a route exists by which potentially proprietary derivatives can be developed. We often will elect to file a patent application under these circumstances, provided that the PI has a plan in place to develop and enable such derivatives, and provided that there is indeed a real prospect for developing derivatives that have not been described or claimed by a third party. We will use outside patent counsel to guide strategy.

- **Therapeutic Compounds or Molecules:** When we receive a disclosure that describes a potentially proprietary composition of matter, our initial focus will be to determine whether the molecule is indeed novel and proprietary, or whether it is based upon a known composition or molecular scaffold. We will also be interested in determining the degree to which derivatives can be made, claimed, and tested. If at all possible, we would prefer to file a patent application once the compounds/molecules have been tested in an appropriate animal model system, so that we can claim both the compound(s) and methods for their use in treating disease.

- **Drug Targets:** Disclosures based on genetic or biochemical evidence that a gene/protein constitutes a route for the development of a therapeutic (a “target”), but lacking any description of a molecule that interacts with and impacts the activity of the target are extremely difficult to successfully commercialize. We do not file patent applications on disclosures that describe drug targets without a description of a molecule that interacts with it. Nor do we file patents with claims directed to screening methods because screening method claims are very difficult to police for infringement and companies won’t license screening method patents. We cannot obtain patent claims to a molecule that interacts with a target without providing an enabled example of such a molecule. There is legal precedent around this issue (*University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004)).
In this high-profile case, the court ruled that a patent held by the University of Rochester that claimed inhibitors to the Cox-2 enzyme without actually providing an example of such an inhibitor was invalid.

It is very difficult to find a commercial partner if all we have to offer is a target without a molecule. Once information about a target is published, any third party can use that information to develop a screen and isolate a molecule. If you have developed data on a target that you believe is proprietary, you may wish to pursue collaborative routes to develop a molecule that interacts with your target. The BCM Center for Drug Discovery may be able to help you identify collaborative routes to isolate a molecule that interacts with your target.

- **Diagnostic Tests/Biomarkers:** The key question to answer regarding the commercial prospects of a diagnostic test or biomarker is: “How will the information gained from this test inform the patient’s healthcare professional and change the course of treatment?” If the test doesn’t change the patient’s course of treatment or clinical outcome, then its commercial prospects are probably insignificant. If indeed the diagnostic test does change the course of treatment, then the focus of the evaluation will shift to the identification of aspects of the test that are proprietary (novel sequences, antibodies, reaction conditions, etc.).

Additionally, a recent case decided by the Supreme Court (Mayo v. Prometheus) held that measurement of a metabolite and the use of that measurement to guide treatment did not constitute a patentable invention because the test revolved around measurement of a metabolite existing in the natural state without any transformative step. The outcome of this case has thrown patents with claims directed to diagnostic methods into a state of confusion, and companies have become more hesitant to license diagnostic technologies.

Because of Baylor’s extraordinary strength in the genetics of rare diseases, particularly neurological disorders, we do receive disclosures of diagnostic tests for these rare disorders. Our current practice is to rarely, if ever, patent diagnostic tests to rare genetic disorders. The target markets and patient populations are often very small with limited commercial prospects. Additionally, patient access to these tests has become a prominent issue via the activity of patient advocacy groups, such that the exclusivity associated with patenting the test may run counter to the focus of advocacy groups who desire broad dissemination of such tests.

- **Medical Devices:** Our evaluation of the commercial prospects associated with a medical device technology will revolve around obtaining answers to the following questions?
  - Is the device design technically feasible? Does a prototype of the device exist? Are there means to develop/test the prototype?
  - If a prototype has been developed, has it been tested in an appropriate animal model system?
  - Is the device novel & proprietary? Does the device represent an incremental improvement of an existing device approach, or is it a new design? Ease of workaround may be a significant issue if the device is more incremental vs. completely novel.
o How does the device differ from other current solutions for the same application? How does the new device stack up against the “gold standard”?

o Is the device technically feasible?

o Does the device depend on or interface with other technologies/devices in order to be used? Does the device require software to work? If so, who owns these other required technologies?

o Is the device cost-effective? Can it produce an improved patient outcome at a lower cost than other current solutions on the market?

• **Research Tools**: Research tool technologies include tangible materials such as mouse models, cell lines that have been engineered or selected to have specialized characteristics, expression vectors, bacterial strains, etc. If the tool that you've developed is popular with your academic colleagues, there is a good probability that it may be of interest to scientists in industry as well. We don’t patent research tools – the goal of research tool licensing is to promote the broad adoption and use of the tool via a non-exclusive licensing strategy. Companies will readily pay for access to research tools that will add value to their research programs. Licensing a tool saves the company the time and resources that it would have to commit if it were to decide to independently develop the same (or a similar) tool.

A peer-reviewed publication that describes the use of a tool is often the best route for marketing a tool to industry. We frequently coordinate our marketing efforts to coincide with publication of manuscript that describes the tool.

• **Software/Smart Phone Applications**: Software technologies are frequently protected by registration with the U.S. Copyright Office vs. filing a patent application. The software development cycle is typically very fast, whereas the patent prosecution process takes years, and by the time that a patent issues, the claims may no longer be relevant to the current version of the software. Registering the code with the copyright office is generally the preferred route for protecting a software application against potential third party infringement. There may be cases in which the software is built around a proprietary algorithm that may warrant patent protection, but this is generally the exception and not the rule.

In terms of commercial prospects, our evaluation will focus on the aspects of the software that differentiate it from competing software applications. What features and capabilities does the software application have that others lack?

In recent years, we've begun receiving disclosures from smart phone applications. We are encouraged to see these new digital innovations from the BCM research and clinical communities. However, most of these apps tend to be of interest to very specialized niche markets, and generally don’t represent significant commercial opportunities. They are often best disseminated on marketing channels such as iTunes. There has been active discussion about different strategies to commercialize smart phone apps in the academic technology transfer community, and we are also exploring and considering suitable solutions for healthcare related apps developed at BCM.
FIGURE 3. Technology Commercialization at BCM