Patent strategy: The patent decision-making and prosecution process explained.

Introduction: The goal of the commercialization process is a license that leads to commercial use or development of the technology/invention, and not to obtain a patent per se. We make the decision to file a patent when we believe that patent protection is necessary to stimulate commercial interest in an invention so that we can successfully land a licensee. The types of inventions that we most frequently patent are therapeutics (molecules & methods), devices, and vaccines. The decision to file a patent application on an early-stage, but promising invention represents a calculated risk on our part that we’ll be able to find a licensee for it. In some cases taking that risk is rewarded and we license the invention, and in others it is not, and the underlying reasons vary from case to case. Patent protection, and the exclusivity that comes with it, is necessary to stimulate a company to expend the resources that it will take to develop an invention and to shepherd it through the regulatory approval process.

• What is a patent? A patent is a document granted by a governing body that confers an exclusionary right to an inventor to make, use, and sell the invention claimed in the patent for a set time period. In the United States, the basis for the patent system is described in Article 1, Section 8, Clause 8, of the U.S. Constitution, which states: “The Congress shall have the power... To promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;” The fact that a patent is an exclusionary right means that the patent holder has the right to exclude others from practicing the claimed invention, but it does not guarantee the patent holder the right to practice the invention.

For example, an inventor develops an automated navigation system for a car to allow a car to be operated without a driver. The inventor files a patent application and obtains an issued patent with claims directed to an automobile containing the automated navigation system. Other parties, like car manufacturers, have patents with claims directed to automobiles, so the inventor of the automated navigation system can’t manufacture cars containing the navigation system without obtaining licenses to the third party patents claiming automobiles. But, the inventor has the right to exclude anyone, including these holders of automobile patents, from manufacturing cars containing the claimed navigation system. This is what is meant by the exclusionary right – the patent holder doesn’t necessarily have freedom-to-operate with the claimed invention if there are third-party patents covering other components of a final product, but the inventor can exclude others from practicing his/her claimed invention in a product in the absence of a license agreement with the inventor.

• Basic patent strategy considerations. The goal of the patent prosecution process is to prosecute and obtain claims that would be of interest to a commercial licensee. The patent must add value to the invention in a manner that is necessary to induce commercial investment in it.
  o Claims that describe the invention in ways that are relevant to how it will be marketed and sold (pharmaceutical compositions, formulations, kits, devices, etc.) by a commercial licensee are optimal. We are most likely to receive clearly enforceable claims if the claims cover a composition of matter comprising the invention.
  o Claims that only describe an invention in terms of methods for using it may be more challenging to enforce and easier for third parties to work around. Therefore, they generally aren’t as valuable to a licensee as composition of matter claims.
  o As a matter of practice we don’t patent research tools – genetically engineered mice, cell lines, etc. If the tool is useful, the goal is not to exclude use, but rather to promote it and disseminate the tool widely. This goal is consistent with NIH guidance on the sharing of
model organisms. BCM controls access to the tool, and by pricing the tools realistically, we find the companies will readily pay for access to tools and reagents that add value to their R&D efforts.

- **Patentable subject matter.**

In order for an invention to be patentable, it must meet the following criteria:

  o **The invention must be patent-eligible subject matter:** This provision essentially stipulates that “anything under the sun made by man”, can be potentially be patentable. Non-patentable subject matter includes:
    - Laws of nature.
    - Natural phenomena.
    - Abstract ideas.

  o **The invention must be novel:**
    - The novelty requirement means that for an invention to be patentable, it must not be described in a prior art reference anywhere in the world. If a patent examiner rejects an invention on the basis of novelty, the applicant must describe how the new invention differs from that of the prior art. Many inventions, particularly in the device field where incremental advances are common, will have similarities to inventions described in the prior art, and the patent applicant must describe how their new invention teaches away from the prior art.
    - There is a one-year grace period in the United States, meaning that a U.S. patent application can still be filed within one year of the initial public disclosure of the invention. However, no such grace period exists in most other countries in the world, including European countries. Once an invention has been publicly disclosed, the ability to patent it in most countries of the world is permanently lost.
    - With the recent passage of the America Invents Act (AIA), on March 16, 2013, the United States transitioned from a “first-to-invent” system for awarding a patent to a “first-inventor-to-file” system, which is more consistent with patent law in other countries. What this means to an inventor is that if you invent an invention, and another inventor independently develops the same invention and files a patent application claiming the invention prior to your patent filing date, then the other inventor stands to be awarded the patent.

  o **The invention must be non-obvious to a person having ordinary skill in the art.**
    - If an invention represents an obvious extension or derivative of an invention described in the prior art, it may not be patentable. The invention may face an obviousness rejection if the patent examiner can combine multiple prior art references with the assertion that a person with skill in the art would have been able to develop the same invention be combining the teaching of the prior art references.
    - Obviousness rejections are very common in the patent prosecution process, particularly with regard to inventions in the biotech arena with its heavy concentration of prior art in the scientific and patent literature. However, obviousness rejections can be overcome if the patent applicant can demonstrate
how the invention teaches away from the prior art, particularly if the invention is based on unexpected results that would not have been anticipated by a review of the relevant prior art. Obviousness rejections may also be overcome by technical arguments that describe why the teachings of the references in the combination are incompatible or cannot otherwise be combined.

- **The invention must have a specific, substantial, and credible utility.**
  - This requirement means that the invention must be applicable to some sort of industrial use. The utility requirement is typically not one that comes in to play during the patent prosecution process. If it were difficult to establish a specific, credible utility associated with an invention, we wouldn’t elect to file a patent on it in the first place.

- **The invention must be sufficiently described in the patent application.**
  - **The invention must be enabled:** This requirement means that the invention must be sufficiently described in the specification of the patent application such that a person skilled in the art could make and use the invention based on the description without the need for undue experimentation. The enablement requirement is frequently used as justification by a patent examiner to reject claims in biotech-related patent applications filed by academic institutions in which the patent applicant is attempting to claim a therapeutic composition or method for use in treating a certain human disease, but the invention is lacking conclusive data from relevant animal model systems. The decision to file a patent application in the academic environment is often driven by a pending public disclosure, so we may have to file a patent application in order to avoid a potential loss of rights, but in ideal world, we might wish to wait to file the application until more enabling/supporting data can be developed.

During the examination process, the examiner will often assert that a skilled artisan would have to engage in undue experimentation in order to determine how to practice the claimed invention, and the patent applicant must be able to provide data/evidence (linked to the description of the invention in the specification of the patent application) supporting the contention that the invention can be practiced as claimed. This process frequently results in amendments to the claims of the patent to adjust their scope to parameters that the examiner believes are enabled.

**Recent Supreme Court Cases Impacting Patent-Eligible Subject Matter:**

- **Mayo v. Prometheus:** This case revolved around the measurement of a known metabolite and use of the measurement to determine therapeutic efficacy of a compound. The claimed invention was ruled as being ineligible for a patent because the claims involved interpretation of a known law of nature with no transformative step. The decision is controversial, and has had negative impacts on inventions consisting of claims drawn to diagnostic methods.

- **Association of Molecular Pathology v. Myriad Genetics:** This case involved a series of patents owned or controlled by Myriad Genetics with claims drawn to isolated DNA sequences, and methods to diagnose cancer by examining the sequences for mutations. The Supreme Court held that a naturally occurring DNA segment is not patentable merely because it has been isolated. The
court held that artificially created cDNA molecules are patent eligible because they aren’t naturally occurring.

- **The Bilski case:** This Supreme Court case involved claims directed to a method for hedging risk in commodities trading, but the implications of the court’s decision go beyond the claimed method and state that in order to be patent eligible, the claim must be tied to a machine or apparatus, or must involve a transformative step that transforms a particular article into a different state or thing.

- **Collectively,** these three high-profile cases have had a chilling effect on patent claims drawn to diagnostic methods. In this era of increasingly personalized medicine and increasing use of diagnostic tests to direct treatment, there is concern that these cases may lead to decreased commercial investment in new diagnostic technologies and tests.

**Inventorship on a Patent**

Inventorship is a legal determination, and differs from authorship on a scientific publication.

- **Inventorship on a patent is tied to the act of conception of the invention.** If a person did not contribute to the conception of the invention, they are not an inventor, even if they helped reduce the invention to practice.

- There is **no requirement for reduction to practice in order to be an inventor.** One can make an inventive contribution by contributing to the conception of the invention without being personally involved in carrying out the process of enabling the invention, provided that carrying out this process does not require additional inventive contribution. However, as stated in the section above, in order for a patent to actually issue, the invention must be sufficiently described in the patent to enable a skilled artisan to make and use it.

- **With regard to joint inventorship, if a person contributes to one claim on the patent application, they are an inventor,** and will be an inventor on any subsequent patent that issues that contains the claim to which they made an inventive contribution. Individuals may be joint inventors even if they did not physically work together or at the same time, and even if the type or amounts of their respective contributions to the invention are different. There is no requirement that an inventor make a contribution to every claim on the patent application to be listed as an inventor. An inventive contribution to a single claim is sufficient.

- **Differences between inventorship and authorship.** An individual working under the direction and supervision of a laboratory PI might well be listed as an author on a scientific publication containing data developed by the individual. Let’s suppose this same work leads to the development of a patent application; unless this individual also made contributions to the conception of at least one claim in the patent application, they should not be listed as an inventor.

Additionally, there is **no significance associated with the order in which inventors are listed on a patent application. An individual is either an inventor, or they are not.** This differs from typical practices around the listing of authors on a scientific publication, such that the individual(s) who did the lion’s share of the work are listed first, and the laboratory PI is
often listed last. This convention does not apply to the listing of inventors on a patent. There is no such thing as a “senior inventor”, or a “junior inventor.”

- **Who makes the inventorship determination? Why is it so important?** Because inventorship is a legal determination, this determination is made by outside patent legal counsel at the time that the patent application is being drafted. Verifying correct inventorship is important for insuring the enforceability of the ensuing patent. If the inventorship on a patent is incorrect, it can open the door for a third party to challenge the validity of the patent and potentially overturn it.

The Patent Prosecution Process

Patent Prosecution is a Lengthy Process: As a faculty inventor, prepare yourself for a long journey. The span of time from the date that a patent application is filed until the inventor receives an issued patent (if this happens) is a lengthy one and can encompass a range of years. Some cases can issue in 3-4 years after filing, while more complex cases can take 7-8 years (or more), before the patent is granted. It is very difficult to predict the pendency period when an application is filed. There are ongoing efforts at the United States Patent & Trademark Office to reduce the patent pendency period.

- **Patent Life:** The term of a patent is 20 years from the filing date of the earliest non-provisional U.S. application to which the patent claims priority.

- **Patent Legal Counsel:** Baylor College of Medicine works with outside law firms that have experience in patent drafting and prosecution. These firms are engaged by the BCM Office of General Counsel (OGC), often in consultation with BLG project managers. Outside patent law firms are chosen based on the relevance of their technical expertise to the invention, the quality and value of their service, and their understanding of factors that impact university patenting decisions and strategy. Most outside patent counsel who are engaged by the college have dual backgrounds in science and law (a combination of Ph.D. and J.D., for example). In addition to attorneys, law firms frequently employ Patent Agents (someone who is admitted to practice before the USPTO, but not an attorney) with strong technical backgrounds. Patent agents are often the “troops on the ground” and are frequently responsible for much of the drafting of a patent application, and they are often heavily involved in managing the patent examination process (acting under supervision of a more senior attorney).

- **Provisional Patent Applications:** The first step in the patent prosecution journey will almost always involve the preparation and filing of a provisional patent application. Provisional patent applications are not examined by a patent examiner, but they can useful for establishing the priority date for an invention, to the degree that the invention is described in the provisional application. Like most academic institutions, our decision to file a provisional patent application is often driven by a pending public disclosure of the invention (meeting abstract, poster, or presentation; or a manuscript). Filing a provisional patent application can protect proprietary rights associated with an invention that would otherwise be lost through public disclosure. However, the scope of rights protected under the provisional application limited to the degree that the invention is described in the initial filing. Although a “cover sheet” provisional patent application can be filed as a last minute solution for urgent and unexpected situations, it is to the college’s strong advantage (and yours, as a
faculty inventor) to file a more completely developed application that is facilitated by disclosure of the invention to BLG in plenty of time to craft a fleshed-out application.

Provisional patent applications must be converted to a non-provisional patent application within one year of the provisional filing date. Additional new data that have been developed during the intervening year can be added to the non-provisional application to more fully describe and support the parameters of the invention. Conversion of a provisional patent application to a non-provisional application is costly, so we will only convert a provisional application if it makes business sense, i.e., we have found or will very likely find a licensee in the near future to pay for ongoing patent costs. If we’ve marketed the invention and received negative feedback from potential licensees, we may elect not to convert the application. Additionally, if data developed during the year between the provisional filing date and the conversion date fail to support the case for continued prosecution (experiments may have yielded negative or inconclusive data), we may elect not to convert a provisional application. The decision to convert is always driven by the degree to which the patent application may add value to the invention in a way that is necessary to secure a licensee.

- **Non-Provisional Applications:** When a decision is made to convert a provisional application, we will frequently elect to file a non-provisional PCT application. The acronym PCT stands for Patent Cooperation Treaty, which is a treaty that has been signed by over 140 member countries, including all major global economic leaders (countries where we might wish to file). Once we’ve prepared and filed a PCT application, this acts as a gateway to provide the patent applicant with the option to enter the national phase of patent prosecution in any PCT signatory country. The national phase entry deadline occurs eighteen (18) months after the conversion date. During this interim period, BLG will normally actively market the invention and seek to execute a license with a commercial partner prior to the national phase entry deadline. The costs associated with continued patent prosecution dramatically ramp up once the national phase of prosecution is initiated.

For inventions that had been publicly disclosed prior to filing a patent application, if we convert to a non-provisional application, we will continue prosecution in the U.S. alone.

- **The National Phase Entry Decision:** The national phase entry decision must be made within 18 months of the PCT application filing date; or 30 months from the initial provisional filing date. At the national phase entry point (actually, a couple of months before the deadline) we will instruct our patent counsel to enter countries where we desire to continue patent prosecution. Entry into foreign countries requires a very substantial investment, and for this reason the college seldom elects to continue foreign patent prosecution into the national phase, unless we have a licensee supporting patent prosecution costs. National stage filing and prosecution in a limited set of countries (U.S., Europe (via the European Patent Office), Canada, Australia, Japan, and potentially China and India) will easily top $150,000 or more. In addition to fees and annuities, translation costs are big driver of foreign patent filing costs. For these cost-driven reasons, we aim to have a licensee in place to support foreign filing and prosecution costs in advance of the national phase deadline. If we’re approaching this deadline without a licensee in place, decisions will have to be made regarding the scope of continued prosecution.

- **The Patent Examination Process:** Once the decision has been made to prepare and file a non-provisional application and continue prosecution, the application will be examined by a patent examiner. The examination process is lengthy - we may not expect to see an Office Action from the patent examiner for two years or more from the conversion date. The examination process, and our odds of successfully obtaining an issued patent, can be impacted by several factors:
The prior art that is relevant to the invention (including the inventor’s own previously published works). If the invention resides in a “hot” area of scientific study, it is likely that multiple citations from the art will be used by the examiner to assert that the invention is not novel, or that it is anticipated by the existing art.

The skill and expertise of the patent examiner – this is a factor over which the applicant has no control. Some examiners will exhibit a good grasp of the elements of the invention, while others may require considerable effort on the part of the applicant to educate the examiner regarding the features of the invention and how it differs from the prior art, etc.

The willingness of the faculty inventor to be actively engaged in the process and work productively with outside patent counsel. The amount of time that a faculty member might be expected to commit to the patent prosecution process will vary with the complexity of the case and the types of objections raised by the patent examiner. An engaged inventor is always a strong asset in the quest to obtain an issued patent with claims that will appeal to a commercial licensee.

During the examination process, the patent applicant can expect to have their claims denied by the patent examiner. The process of patent examination really boils to a negotiation between the applicant and the examiner to determine the scope of the claims of the eventual issued patent. Faculty inventors can expect to work with outside patent counsel to craft responses to the examiner in our effort to get claims to issue. The outside patent counsel that the college engages will have technical expertise that is relevant to your invention, but as the inventor, your depth of knowledge and expertise related to the invention and your field of study will be essential to secure a successful outcome.

• **Restriction Requirements & Office Actions:** The first communication that we can expect to receive from the patent examiner (an “Office Action”) will most often be a Restriction Requirement. The patent examiner will review the claims of the patent application, and if he/she believes that the claims represent more than one distinct invention (a pharmaceutical composition vs. a method of using it, for example), the examiner will divide the claims into distinct groups (the process of restriction). The patent applicant must then choose a single claim group to pursue through continued prosecution. The remaining claim groups may also be prosecuted at a later date in separate patent applications called divisional applications.

The applicant’s response to the Restriction Requirement will be followed by a series of Office Actions, during which the patent applicant can generally expect to have their claims denied by the patent examiner. Claims may be rejected on the basis of obviousness, lack of enablement, lack of novelty, or for other reasons. Our experience with prosecuting patents in the biomedical sphere is that claim rejections based on obviousness and/or lack of enablement are very common. Our outside patent counsel, working in collaboration with the faculty inventor, will prepare a response to the Office Action. The response the Office Action will state the reasons why we believe the examiner’s objections to our claims should be overcome and a patent should be granted. This process will often involve amendments to the claims of the application (typically narrowing their scope) to address the examiner’s concerns and to craft the claims into a form that the examiner will
allow to issue. The examination process is, at its core, a negotiation between the examiner and the applicant. Not every patent application will result in an issued patent. There are cases in which the process by which the claims are amended to place them in a position where they will be allowed by the examiner results in claims that are so narrow in scope that they are of minimal value to a licensee.

- **Notice of Allowance and Issuance**: If the examination process results in a determination by the examiner that the claims are allowable, the examiner will issue a Notice of Allowance. The applicant must then pay a patent issuance fee for the patent to be granted. If the applicant wishes to prosecute any divisional applications, this process must begin prior to issuance of the parent application.

### The America Invents Act (“AIA”) and Patenting Practices at BCM

- On September 16, 2011, the Leahy-Smith America Invents Act (“AIA”) was signed into law by President Obama. The major thrust of this patent reform legislation was to more closely harmonize U.S. patent law with that of the rest of the world. Key changes associated the AIA include:
  - **Transition from a “first to invent” system to a “first-inventor-to-file” system**. This change went into effect on March 16, 2013, and gives priority for granting a patent to the first inventor to file a patent application. This means that the determination of whether an invention is novel or non-obvious will be based on the prior art that existed on the date that the patent application was filed, and not on the date that the invention was actually conceived. Inventors still have a one-year grace period during which the inventor’s own public disclosures or the disclosures of third parties who obtained their information from
the inventor may not be used as prior art if the disclosures occurred within 12 months of the filing date of the patent application.

- **New post grant review procedures**: Post grant review means that a person who is not the patent owner may request that the USPTO examine the validity of an issued patent within 9 months of the date of issuance, but this change impacts patents filed under the new “first-inventor-to-file” system. Assertions of patent invalidity may be based on grounds of lack of novelty, obviousness, insufficient written description of the invention, or lack of enablement. These proceedings will be administered by the Patent Trial and Appeal Board.

- **Will the AIA change patenting practices at BCM?** The AIA will not significantly change our patenting practices. There is little advantage to be gained by filing a provisional patent application earlier, particularly if the claims of the patent application are not sufficiently enabled by the written description of the invention in the specification of the patent. Nothing is gained by filing an insufficiently enabled patent application. As is often the case in the academic environment, a pending public disclosure of an invention will often trigger the decision to file a patent application. But, the potential to receive patent claims that will add value to the invention and potentially enable us to land a commercial partner will always be the crucial factor in the decision to file.