A Guide to

NDSU'S Intellectual Property

Development Process

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Executive Summary

Intellectual property is a concern for every university. A key part of any intellectual property (IP) discussion involves a better understanding of the many components relating to IP:

- Understanding the roles and needs of researchers;
- Appreciating the various entities within NDSU who deal with IP;
- Following the policies that govern research activities and the protection of any resulting IP;
- Abiding by the state and university rules that outline an employee's obligations;
- Recognizing the university's legal obligations to federal and state entities as well as sponsoring organizations.

Included in this handbook is an outline of the process of the IP development, protection and invention commercialization at NDSU. A second guide, ***A Guide for New Business Ventures at NDSU*** is devoted to those faculty members or employees who want to license their technology from the university to start their own business. Neither guides are intended to be exhaustive compendiums of the activities to be conducted; rather they are to be used as an overview of the more common issues involved in each area. For further details, please contact the appropriate departments indicated or the NDSU Technology Transfer Office (NDSUTTO).

Academic Pursuits

NDSU has an impressive array of highly qualified and skilled researchers, conducting basic and applied research in a wide variety of disciplines. In fulfilling the land grant mission of NDSU, the discoveries over the years have truly advanced scientific knowledge as well as been of benefit to the citizens of our state and society as a whole.

An added benefit to the research has been the discovery of useful, innovative inventions. By protecting the intellectual property involved in those inventions, opportunities have been developed, not only for NDSU, but for the inventors, supporting departments and colleges and interested industries that have been involved in the commercialization of the inventions.

The collaboration between NDSU researchers and the NDSUTTO helps support the research activities, providing protection for intellectual property that may ensue from a research project. It's a key element in the commercial development activities.

Abiding by the Rules

To enable NDSU to meet its legal contractual obligations for intellectual property rights, ***all inventions*** made by any NDSU employee must be disclosed to the university. Disclosure is a legal obligation and condition of employment at the university.

For NDSU to abide by federal and state regulations as well as its other contractual obligations regarding IP, all NDSU personnel (staff, faculty and students) must inform the university of their research products, discoveries and inventions before disclosing them to the public. Such official notification is required in order to determine and implement IP protection strategies. Protection strategies, such as applying for patent protection, may not be possible if a research product is publicly disclosed before the protection is initiated. Please consult the NDSUTTO for more information if you're unsure of what constitutes disclosure.

The NDSUTTO is available to help all NDSU personnel with the process of identifying which protective steps are required throughout the research process. The office can assist you with the preparation and negotiation of legally accepted IP protection measures such as non-disclosure agreements, material transfer agreements, material testing agreements, and inter-institutional research collaboration agreements.

Every inventor is required to assign their discovery to NDSU. NDSU then assigns the rights to its designee: the NDSU Research Foundation (NDSU/RF). With the assignment, the NDSU/RF can pursue further protection and commercialization activities for the discovery. In certain cases, where there is no further interest in pursuing commercial activities, NDSU/RF will, subject to federal government or sponsoring entity rights, return the rights to the invention back to the inventor, according to NDSU policy.

Mandates and Policies

At the time a discovery is made and disclosed to NDSUTTO, the university conducts an equity review that evaluates the funding profile of the invention to determine who may share in the rights to the IP. If the invention is funded in whole or in part by federal funds, the Bayh-Dole Act applies, and the federal government has a right to the invention if they choose to exercise that right.

Other regulations apply because NDSU is a tax-exempt, non-profit educational institution existing under the Constitution and other laws of the State of North Dakota. Buildings and equipment are often financed under tax exempt bonds. In particular, under IRS Rev. Proc. 97-14, NDSU cannot offer a sponsor of research the opportunity to obtain any resulting IP on a royalty free basis. Private business use of these facilities may also have tax consequences for NDSU and/or may affect the university's tax-exempt status.

When a researcher receives third-party research funding, such as sponsored research funds from corporate, consortia or private granting agencies, each funding agreement contains provisions that specifically address intellectual property rights to the resulting research products. The Sponsored Programs Administration office negotiates these third-party funding agreements.

If no outside funding source was involved in the discovery, the university is the sole owner of the resulting IP.

Protecting IP Provides Benefits

With proper IP protection, the potential for commercial development is greatly enhanced. NDSUTTO, in cooperation with the NDSU/RF, is experienced in the commercial development of university IP. By following the steps to protect the research activities and resulting discoveries, research personnel and their colleges may benefit from added recognition, financial return and additional research funding. It's an effective and constructive strategy for everyone involved.

IP Process Overview

The following overview covers the key events involved in the development, protection and commercialization of an invention. The list depicts the order in which these events typically occur; however, some events may take place simultaneously or in a different order, depending on the needs of the inventors and the university. For ease of use, the following steps are broken into two handy guides:

- ***A Guide to NDSU's Intellectual Property Development Process*** includes those steps that would provide appropriate intellectual property protection for a researcher's discoveries, and is the focus of this guide.

- ***A Guide for New Business Ventures at NDSU*** includes information for faculty or staff who want to license their own technology from NDSU and begin a new company. This information is found on the Technology Transfer website at www.ndsu.edu/techtransfer.

A Guide to NDSU's Intellectual Property Development Process outlines the activities involved in protecting intellectual property.

1. NDSU researcher pursues an academic or sponsored research question. Within the scope of scientific discovery, and prior to the actual creation of an invention or discovery, a researcher may require the assistance of the NDSUTTO in research support, helping maintain the confidentiality of the research in its development stages.

2. Researcher makes a novel discovery and discloses discovery by submitting an Invention Disclosure form to NDSUTTO. For software, there is a Software Disclosure form, while plant breeders should use the Plant Variety Disclosure form. All disclosure forms should be submitted to the NDSUTTO.

3. NDSUTTO initially evaluates the disclosed discovery for commercial potential, as well as patent, copyright or trademark or plant variety protection. This process often involves in-depth discussions with the inventor.

4. Inventor(s) assigns the invention to NDSU. NDSU then assigns the invention to the NDSU Research Foundation (NDSU/RF) in order to protect and commercialize the invention.

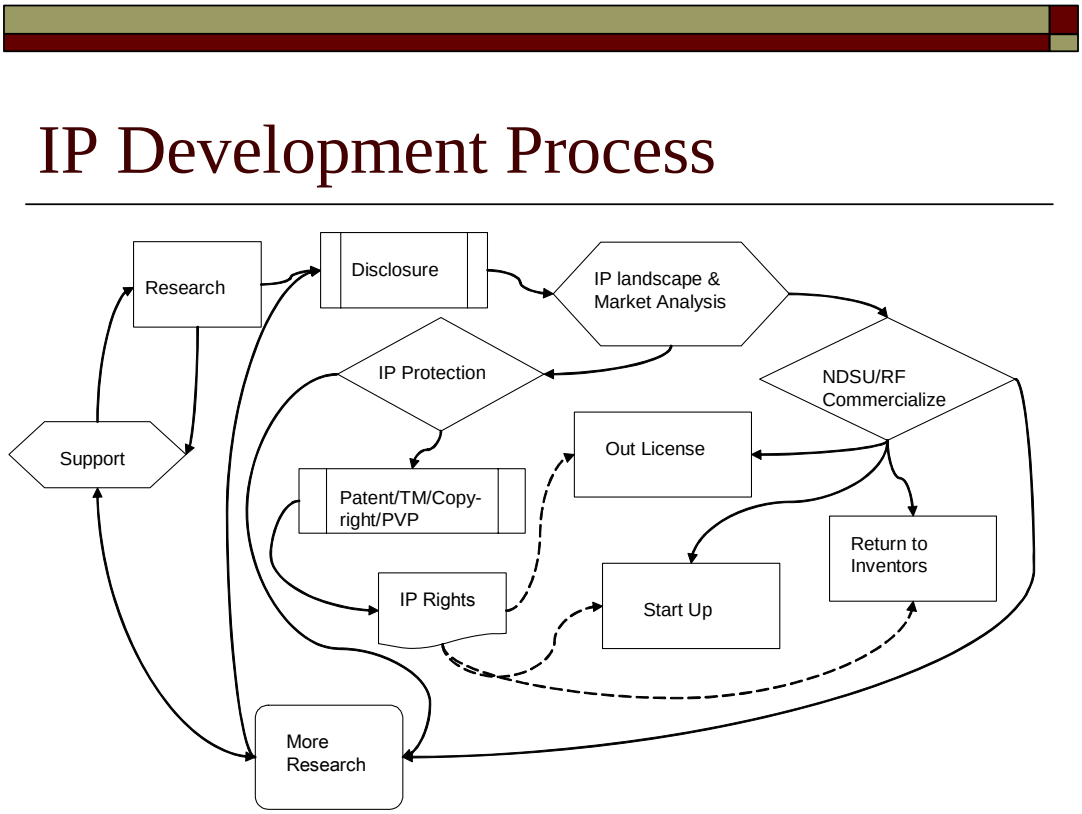
5. NDSU/RF may file a patent application, initially paying all the associated attorney fees and costs of protecting the discovery. Proper protection includes geographic considerations, inventorship and clear delineation of claims from any "prior art" and literature.

6. NDSU/RF continues to explore the commercial marketplace, and assesses commercial value, marketability, intellectual property protection, and the potential for further development.

7. NDSU/RF takes the final step in the process, initiating one of four options:
   a. licenses invention to an outside commercial entity;
   b. requests that inventor complete added research before pursuing further commercialization activities;
   c. releases or returns the invention to the government or inventor according to NDSU policy and any applicable contractual obligations;
   d. licenses the invention to a faculty member's start-up company.

Setting the Stage

The goal of the Technology Transfer Office is to assist NDSU faculty, employees and students as they pursue knowledge through research and academic activities and conceive inventions. Upon assignment, the NDSU Research Foundation then helps in the commercialization of inventions. One of the key areas of support is in the protection and management of the intellectual property. The diagram below outlines the process flow, and illustrates the many avenues in the process, from conducting research through commercialization of an invention.



Research Support Activities

One of the primary services provided by the NDSUTTO is the assistance they provide to researchers while in the discovery process. This behind-the-scenes support is a significant portion of the Technology Transfer Office responsibilities. By supporting the confidentiality of information throughout the research development, the collaborative effort between researcher and the NDSUTTO provides the important initial protection of intellectual property prior to anticipated publication or public disclosure.

Transfer of Research Materials

Many times a researcher will want to have information validated, cross-checked or used in some way by another researcher outside NDSU. The NDSUTTO office can facilitate Material Transfer Agreements (MTAs) that outline the requirements of each party in the collaborative effort, and provide protection of the results. The MTAs can be used when shipping materials out to another organization or when the NDSU researcher needs materials from an outside source. If you're not sure if you need an MTA, call the office or simply request the MTA from the website at www.ndsu.edu/techtransfer.

Inter-Institutional Collaborations

When working with a colleague at another institution or government entity, there needs to be a clear-cut understanding of which researchers are involved and which institution retains control of the intellectual property, which is often jointly owned. The NDSUTTO office can assist in providing the agreements that will protect all parties involved. Request an Inter-institutional Agreement from www.ndsu.edu/techtransfer.

Methods for Disclosing Confidential Information

Before presenting information about your intellectual property to another researcher, sponsoring commercial entity, at a seminar, poster session, or to another person or entity, it may be prudent to protect the information with a Confidential Disclosure Agreement (CDA), also known as a Non-Disclosure Agreement (NDA). The agreement specifies what intellectual property will be discussed, with whom and when. It also prevents the person(s) with whom you're having the discussion from sharing that confidential information with other third parties. Download the request form from www.ndsu.edu/techtransfer.

Researchers should also avoid including un-redacted, enabling information in research proposals which may be accessed through open records or freedom of information acts. It is also advisable to avoid including enabling information in abstracts.

Research Sponsored by External Sources

Because of the expertise of many of the NDSU faculty, outside entities may approach a department or individual to conduct research for a specific project. In other instances, an NDSU employee may request outside funding to support their ongoing research efforts. In either case, research sponsored by non-NDSU organizations should be outlined in a Sponsored Research Agreement (SRA), before commencing the research study. Download the request form from http://www.ndsu.edu/research/spa.shtml. The purpose of the SRA is to ensure proper relationships are maintained with the outside entity, and to protect the rights to intellectual property that may result from the research effort. In some instances a CDA or NDA may be required to enable discussions regarding potential sponsored research work that may lead to an SRA.

Please note that no faculty member is authorized to sign any agreements, obligating NDSU. Only the designated individuals in Sponsored Programs Administration handle all negotiations and have the authority to sign agreements.

Keeping Records

Most research involves lab notebooks, journals or other records of the process involved in the research. Please keep in mind that those notebooks or journals—including any handwritten notes—are vitally important in the establishment of "first to invent" and the roles of various inventors in the development of any discovery. The time taken to record dates, obtain signatures of a department chair or dean as you progress, and even to have a notary signature at key points, is time well spent. Keeping accurate and detailed logs of your research progress is vital, both for the protection of your intellectual property, but also for supporting the claims made in a patent application.

According to NDSU policy, the lab notes, research data, analysis, journals, or any other information collected during the research (just as the equipment in the lab itself), belongs to NDSU. Inventors—including faculty, staff and students—are encouraged to keep copies of the information for their own personal files. However, the original materials are to be left with the university.

Outside Activities

Outside professional activities that contribute to the employee's profession and/or to the general public are encouraged and supported by the university. However, the outside activities (such as consulting) may place NDSU personnel in situations involving Conflict of Interest or Conflict of Commitment with their university obligations. Consulting projects need to be disclosed to the University Provost's office, and NDSU personnel should check with the NDSU General Counsel's office or the Office of Sponsored Programs Administration ***before*** signing any consulting agreements so as to not compromise the employee's intellectual property obligations to the university.

In some cases, the research may involve a significant amount of time or use of university resources. Before agreeing to the project, be sure to review the policies. See http://www.ndsu.edu/policy/al_index.htm for added information on these and other related policies, or see Appendix 1.

Research Discoveries: Now What?

The discovery has been made, and you want to tell the world (i.e. publish in a journal, present at a seminar, use the information in a thesis, share with a colleague at another university, report to the sponsoring company or government entity or post it on the department website). After all your time and hard work invested in the discovery, don't give away the intellectual property! Take a moment to protect your invention.

Invention Disclosure: When and Why?

Once a discovery is made, take the time and effort to complete the Invention Record/Application for Patent Screening form and send it to NDSUTTO. To protect your intellectual property, it's critical to keep results confidential until a patent application or other IP protection has been filed. This includes not presenting at seminars, displaying posters, publishing findings, discussing the details with anyone outside your research team or even presenting a thesis until the application is filed. With timely reporting of inventions to the NDSUTTO, the NDSUTTO will make every effort to ensure that protecting your invention does not delay your publication schedule.

Please help in the process by allowing adequate time to complete the review of your invention and then to file the appropriate patent paperwork—a minimum of several weeks would be very helpful, and reduce the costs to the university for getting the application filed.

Just download and complete the form at http://www.ndsu.edu/techtransfer/ and then plan a time to talk to one of the licensing associates about the appropriate protection of your discovery. An invention disclosure provides a summary description of the invention, including:

- Short descriptive title;
- Simple description of the invention;
- Date of the invention;
- Summary of the ways the invention could be used;
- Names of all inventors;
- Names of others to whom the invention has been disclosed;
- Publications, posters, seminars or presentations in which the invention has been disclosed;
- Funding sources supporting the research that led to the invention.

Be sure to complete the form thoroughly and exactly, including collecting all relevant information from other inventors, getting signatures of the other inventors, listing

appropriate grant numbers and agencies that may have sponsored the research, etc. Without a complete disclosure, the NDSUTTO may be unable to help you protect your discovery.

Why Disclose?

Federal granting agencies require that a researcher disclose any invention or discovery to their Technology Transfer Office before publishing, as one of the requirements of receiving the grant. By completing the disclosure, the inventor remains in compliance with the federal mandates.

In addition, there are other potential benefits to making the disclosure. For example, when a disclosure is deemed patentable, benefits could include:

- Enhanced recognition among academic peers and potential industry partners. The increased visibility of having successful patents may lead to added sponsored research, joint ventures or other opportunities.
- Added publication opportunities resulting from the publication of the patent.
- Income generation. Revenue from licensing or royalties is shared with the inventors of record as well as the department and college.

Evaluating the Invention

Every invention disclosure is carefully evaluated at the NDSUTTO. The following outlines the various steps in the evaluation process.

Inventor(s) Interview

To properly evaluate the invention, an NDSUTTO licensing associate needs to meet with the inventor(s) to find out more about the discovery, from patentability to commercial possibilities. The interview needs to be scheduled ***before*** any type of protection can be obtained for the invention, since the university needs to verify the patentability of your discovery. A thorough understanding of the invention is helpful in determining patentability and commercialization. Because of patent law requirements, inventors will also need to show the “utility” of their discovery—does the idea actually work when put into practice? Patent law does not allow the protection of ideas: the ideas must be shown to function as predicted when actually used as described. Your licensing associate may help identify areas where added research may need to be completed to add utility to the discovery.

To gain an adequate understanding of the invention, NDSUTTO will often request the following information from the inventor(s):

- Background of invention;
- Other “art” in the field;
- Dates of invention, persons involved in the discovery;

- A review of research materials, such as lab journals with dates and signatures noted, to better understand the invention;
- Unique characteristics of invention.

A special reminder for anyone who has collaborated on an invention: be sure to obtain all the inventors' signatures on the disclosure. Your licensing associate will assist you with the assignment forms used to assign the invention to NDSU. The inventors will also need to determine the inventors' distribution of any royalties, should the invention be commercially licensed. Without these signed documents, the NDSUTTO cannot proceed with the protection of the invention. Again, if you have questions, please contact the office.

Intellectual Property "Landscape" Analysis

Once the inventor has completed the disclosure to NDSUTTO, the office evaluates the disclosed discovery and decides whether to recommend it for patenting and licensing. This process often involves in-depth discussions with the inventor(s), to determine the "IP landscape" and commercial market potential. The NDSUTTO will also assess whether the expected return from licensing justifies the time and cost involved in protection and commercialization.

Review of any Disclosures

One of the key issues in developing protection of an invention is whether the enabling information about the invention was disclosed before applying for patent protection. By patent law, even presenting a paper at a small seminar, poster session or a thesis defense that is open to the public, may be considered "public disclosure," and therefore disqualify the invention from being patented.

Conversations with other researchers or individuals outside your research team, unless there's a confidentiality agreement in place, could also be deemed as making the invention "public information." So, included in the review are also any disclosures that have been covered under a confidentiality agreement.

Patent rights may still be obtained for the United States if a disclosure is made within one year prior to the patent application. However, any non-US patent rights are usually lost if disclosure is made before patent protection is secured. The inventor must file on or before the date of public disclosure in order to preserve patent rights in many foreign countries.

Imbedded IP Sponsor Rights

Sponsors of research may have priority to the intellectual property discovered, such as first option to license. The sponsored research agreement (as well as material transfer agreements or confidentiality agreements) outlines the research sponsor or other third party involvement and potential rights to the invention. There is usually information on how the sponsor's confidential information is to be used within any agreement.

If federal funds were used in the development of the invention, the university is charged with filing progress and compliance reports with any federal sponsor. Plus, the government has certain rights to the invention:

> "With respect to any invention in which the contractor (i.e. university) elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world….In addition, the patent must "include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention…." www.uspto.gov

In 1980 Congress passed the Bayh-Dole Act to allow universities to own inventions developed from federally sponsored projects. Prior to that time, the U.S. government legally owned all rights to the research products that were produced from federally funded research.

Today, under the Bayh-Dole Act, NDSU (as do other institutions of higher learning), may claim ownership of the intellectual property generated by its faculty, staff or students from federally funded research. The government still retains the rights to any invention they have sponsored if they choose to exercise that right.

If other organizations have sponsored the research, they often have negotiated a sponsored research agreement spelling out certain rights to any intellectual property through the Sponsored Programs Administration office. In some cases, materials from another organization or university were used in the invention, and those rights should be covered under a material transfer agreement or an inter-institutional agreement. Confidentiality agreements may govern the use of a third party's confidential information in a research project as well. These shared interests must be documented in any patent application.

Review of Prior Literature or Art

Most researchers have completed some type of review regarding the current state of the art, prior to beginning their research. The NDSUTTO will request the information found regarding prior published information or "art" that may already exist. Inventors typically will provide technical evaluations of previous patents and publications to the Tech Transfer Office. In addition, the NDSUTTO may conduct a search to see if there is other relevant literature regarding the proposed invention.

Commercial Market Analysis

When looking at patenting an invention, part of the due diligence process is looking at similar products that may already be in the marketplace. If there are similar products, answers need to be provided regarding the unique characteristics of the invention that distinguish it from the products already in the marketplace.

Included in the review is the potential significance of the product, perceived market value and industry trends for future use.

The marketing analysis helps determine whether to patent an invention:

- Is the perceived market need a major or minor one?
- What size market are you attempting to reach (general public, a large market segment or a tiny niche market)?
- How is the market need being fulfilled now? What makes your invention better, different, or more appealing to the market?
- Is anyone investing in this market now? Is it an established area where your invention might spark interest, in a declining market, or in an area that is just being developed?
- Are there other patents in this field that will limit the usefulness of your invention?
- Are the claims for your patent enforceable, or are they so broad/narrow that detecting infringers would be impossible?
- Is the invention so early that patents might expire before products come to market?
- Is the field changing so quickly that by the time your invention is patented, the technology will be obsolete?
- What trends does the invention follow? Societal barriers?

Evaluation Results

Although all inventions are to be disclosed, not all invention disclosures will result in a patent. In fact, only about half of the inventions disclosed are finally patented or copyrighted. Many times, the research may be fascinating, but not of a patentable nature. Or there may be prior art, which would block the possibility of obtaining a patent, or the market potential may be so small that the estimated commercial return will not even support the cost of the patent process. There are many reasons involved in a decision to not pursue additional protection of a discovery.

Even for those inventions that are evaluated and protected, only about 30 percent are licensed, due to the early stage of the technology, market trends or other factors.

Protecting the Intellectual Property

Once the NDSUTTO has determined the patent potential of the invention, they will begin to arrange the protection of the intellectual property. A first step is assigning the ownership rights, as per NDSU policy, to NDSU. NDSU will then assign ownership of the invention to the NDSU Research Foundation (NDSU/RF). The NDSU/RF then handles the rest of the steps in the process.

Working with Attorneys

A thorough analysis by the inventor, with help from a licensing associate, is beneficial for everyone in the patenting process. With a clear understanding of the scope of the invention, the marketing potential and the benefits that can be derived from the invention, contacts are made with qualified and available attorneys who specialize in the invention's particular area of patent law. The selected attorney can then prepare the most appropriate patent application. Expertise is necessary in the scientific specialty area to provide the best possible protection from infringement and to ensure that the patent claims are appropriate to the invention.

Often misunderstood as a simple element, the language used in the claims section of the patent must be carefully crafted to include a variety of benefits:

- Provide adequate protection in the event of litigation;
- Develop the "broadest" reasonable claim basis to establish a field that can be commercialized;
- Create a strategy to protect against infringement;
- Protect against "copy-cat" art;
- If appropriate, construct the framework for a long-term, multi-patent group of related inventions.

One of the best resources for any patent attorney is a helpful inventor. A friendly collaboration between the patent attorney, inventor and licensing associate ensures that the patent language will be appropriate for the invention, provide appropriate protection and open the door to commercialization possibilities.

About Patentability

Patentability is determined by the US Patent and Trademark Office (USPTO). A patent is a grant by the federal government to new and useful machines, processes or methods, articles of manufacture, compositions of matter, or improvements thereof that exclude others from making, using, selling (or offering for sale), or importing that protected entity.

Any invention needs to comply with three key characteristics to be patented: novel, non-obvious and useful. Here's how the USPTO defines what can be patented in 35 U.S.C.:

- Must be new and useful (section 101);
- Must be novel and not anticipated by someone who understands the art (section 102);
- Must be non-obvious (section 103);
- Written description (section 112) must be full, clear, concise and exact; enabling to one skilled in the art; and provide the best techniques or best mode of making the patented entity;

Some examples of what ***can't*** be patented, according to the USPTO, include:

- Things that don't have utility (like pet rocks);
- Naturally occurring products, in the form they exist in nature;
- Scientific principles, including algorithms and mathematical equations;
- Products that already exist;
- Illegal, immoral or dangerous activities;
- Inoperable devices or processes;
- Inventions that have national security issues;

For more information about patents, please consult the US Patent Office website at http://www.uspto.gov/main/aboutuspto.htm.

Types of IP Protection

The NDSU/RF, in cooperation with the patent attorney and inventor, will pursue one of several forms of protection for the IP:

- Patents: either a utility or design patent protects novel, non-obvious useful inventive matter;
- Copyrights: protects authorship, computer programs;
- Trademarks: protects identifying symbols, words or designs of goods or services;
- Plant patent and plant variety protection: protects unique plant varieties.

Provisional Patent

The NDSU/RF or patent attorney may recommend a provisional patent application as the most appropriate vehicle for an initial step in the process. A provisional patent provides protection for up to one year; then it must either be abandoned or converted into a conventional utility patent application.

Although the basic claims are included in the provisional, there may be "adjustments" to the patent to reflect updated information when filing the conventional patent. The provisional patent can be useful in a variety of situations, including when:

- Publication/presentations/dissertation or other public disclosure is about to happen within a short time and there's not time to complete a full patent application.
- The research is progressing nicely, but not completed, and the IP needs initial protection. In some cases, the "utility" data is not ready at the time of discovery, but the idea looks promising and the inventor can complete the necessary data analysis/invention construct/model within several months to allow the patent attorney to convert to a conventional application within the 12-month deadline.
- Added time is necessary to assess the commercial potential of an invention.

Conventional Patent

A conventional patent outlines the claims or the areas that will be protected in the patent, confirmation of the inventors, and the details of the invention. Protection, if the patent is granted, is 20 years from the date of application (if the application was filed after June 8, 1995. Filing before that date means the term is for 17 years from the date of issuance of the patent). For example, if the application approval by the USPTO takes two years, the patent will be in force for an additional 18 years.

Patents are usually obtained in one of three general areas:

- Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new useful improvement,
- Design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture; and
- Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plants.

Trademark/Copyright

Copyright and trademarks provide protection for a different type of invention. According to the US Patent Office:

> "A trademark is a word, name, symbol, or device that is used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others. A servicemark is the same as a trademark except that it identifies and distinguishes the source of a service rather than a product."
>
> "Copyright is a form of protection provided to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished…. The copyright protects the form of expression rather than the subject matter of the writing. For example, a description of a machine could be copyrighted, but this would only prevent others from copying the description; it would not prevent others from writing a description of their own or from making and using the machine."

Plant Patent

The Plant Patent law provides for the granting of a patent to anyone who has invented or discovered and asexually reproduced any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state. The plant patent consists of the same parts as other applications with the addition of a plant color coding sheet. The

term of a plant patent shall be 20 years from the date on which the application for the patent was filed in the United States.

For additional information on plant patents, see www.uspto.gov for more details.

Plant Variety Protection

The Plant Variety Protection Act (PVPA), enacted in December of 1970, and amended in 1994, provides legal intellectual property rights protection to developers of new varieties of plants that are sexually reproduced (by seed) or are tuber-propagated. Bacteria and fungi are excluded. The PVPA is administered by the United States Department of Agriculture.

A Certificate of Protection is awarded to an owner of a variety after an examination shows that it is new, distinct from other varieties, and genetically uniform and stable through successive generations. The term of protection is 20 years for most crops and 25 years for trees, shrubs, and vines. The owner of a U.S. protected variety has exclusive rights to multiply and market the seed of that variety.

For additional information on PVP protection, see http://www.ams.usda.gov/science/PVPO/PVPO_Act/PVPA.htm for details.

Patent Considerations

Geographic Scope

The geographic coverage of your patent/copyright depends, in part, on what information has been publicly shared, and when the information was disclosed:

- If there has been no public disclosure of the IP before filing a U.S. patent, there may be opportunities, through the NDSU/RF office, to protect the invention in foreign countries. The decision to pursue foreign rights, since it is a very expensive process, would also need to include a discussion of the commercial potential of the invention in those foreign markets.
- If there has been a public disclosure prior to filing a patent application, the foreign rights have been forfeited in nearly all countries.
- If there has been a public disclosure within 12 months prior to the U.S. patent filing, the U.S. rights may be retained.

If the discovery is deemed to be of commercial value overseas, there may be need to file for foreign patent protection as well as in the United States. (Remember, if you file a patent with the USPTO, the only protection you have is in the US. Foreign countries do not recognize our patents, just as the US does not recognize their patents.) There are a couple options for filing in foreign countries:

- File with central offices, like the European Patent Office, which covers several European countries. Countries must be specified at time of filing.
- File a PCT patent application, which are administered by the World Intellectual Property Organization. The Patent Cooperation Treaty permits an inventor to file a PCT patent application, providing some streamlining of patent applications across some 115 countries at once. Then the inventor has up to 30 months to decide if the invention warrants filing in each individual country.
- File a patent application in each country.

Inventorship

Although outwardly straightforward, determining who should be named as inventors of an invention can be a complex process. Because “invention” and “inventors” are terms integral to patent law, the determination of inventorship is a legal process requiring the participation of competent patent legal counsel.

Patent law dictates the specific factors that make an individual an inventor or co-inventor of an invention. Applying these legal principles to a particular invention may be especially complex when the invention involves several people from the principal inventor’s laboratory; when collaborators from other institutions have contributed; when an invention has been reduced to practice over an extended period; when several claims are needed to obtain the broadest patent protection; or when certain claims of a patent application are not allowed by the USPTO, and an inventor no longer has claims that are included in the issuing patent.

Despite the potential difficulties, inventorship must be very precisely determined because only the inventor or co-inventors may apply for a patent. Including individuals who aren’t actually inventors, or excluding those who really are, can result in invalidation of the patent. Inventorship may also be different than authorship of a journal article or scientific paper. For more information about inventorship, consult legal counsel or your NDSU/RF licensing associate.

Equity

After an invention disclosure is received, an equity review is conducted to determine ownership of the invention. The equity review process establishes clear title to the intellectual property in much the same way that a title search establishes clear title to real estate. Ownership of an invention must be clearly determined before a patent application can be filed or a license agreement signed.

Assignment

As required by university policy and federal law, any invention arising from university research must be assigned to NDSU. NDSU then assigns the invention to

NDSU/RF for commercialization. If NDSU or NDSU/RF decides not to pursue commercialization of an invention, ownership may revert to the sponsoring entity (such as the federal government) or to the inventor, according to NDSU policy.

Filing the Patent

Process and Costs

Keep in mind that once a patent application has been filed, it may be from one to three years before it is granted. An inventor should be prepared for a lengthy, ongoing relationship with the NDSU/RF and the filing attorney.

NDSU/RF works with the inventors and files any patent application(s), initially paying all the associated attorney fees and costs of discovery. They also handle all the filing details with the attorneys, and monitor the application process. When the invention is licensed, all or a portion of the direct costs associated with the patent process are recouped before royalties are paid out.

Although the actual filing fee in the US is relatively inexpensive, the cost of having a patent attorney prepare a thorough, legally sound patent application can often cost $5,000 to $20,000 or more, depending on the scope of the application and the breadth of the claims. Filing in foreign countries for patent protection can easily run over $100,000 for protection in several countries, plus the cost of attorney fees.

Oversight of Application

Once a patent application has been filed, the NDSU/RF will continue to monitor progress and keep the inventor informed. Typical examinations may take up to three years to process.

Examination

The US Patent Office examination of the application involves searches for compliance with the legal requirements and a search through U.S. patents, patent applications, foreign patent documents, and available literature, to see if the claimed invention is new, useful and non-obvious and if the application meets the requirements of the patent statute and rules of practice. A decision is reached by the examiner once they complete their study and review results of the searches.

Rejection

Many times an initial patent application will have claims that may be rejected by the US Patent Office because they need an additional piece of information or clarification. A rejection does not necessarily mean there is not merit in the application! Instead, the

NDSU/RF will work with the inventor and attorney to answer the specific objections within the necessary timeframes.

Patent Issued

On the date of the grant, the patent file becomes open to the public. Printed copies of the specification and drawing are available on the same date. Applications can be published after 18 months unless elected otherwise (for U.S. applications only).

Ready for the Next Stage

There are usually four final development options available when new technology has been disclosed and/or protected:

1. The invention is licensed, through the NDSU Research Foundation, to an outside commercial entity;
2. Inventors may be requested to complete added research before pursuing patent or licensing;
3. The invention is released or returned to the inventor, per NDSU policy, and subject to any federal government, and/or any applicable third party contractual obligations;
4. The invention is licensed to a faculty member's start-up company; (See ***A Guide for New Business Ventures at NDSU*** for further details at www.ndsu.edu/techtransfer.)

License to Commercial Entity

The goal of the NDSUTTO and NDSU/RF is to find commercial outlets for the inventions discovered by NDSU faculty, staff and students. Although listed as the "last step" in the process, often the NDSU/RF licensing associate is searching and contacting companies much earlier in the process regarding the possibility of licensing the technology. Both exclusive and non-exclusive license agreements are available, depending on the invention and ownership of the patent rights.

The licensing strategy may include:

- Inquiries sent to a variety of companies in the targeted industry, using a non-confidential marketing piece; following up with confidential discussions with selected companies.
- Targeted contact, with a specific company, analyzing business information, developing approach strategies, and considering sponsored-research opportunities.
- Pre-licensing may include a letter of intent, term sheet, material transfers and seeking opportunities for further sponsored research.
- Once a company is interested in a specific patent or group of patents, NDSU/RF will work with the company to construct and negotiate an appropriate license

agreement. Included in the license would be options/methods for using the invention, field of use, length of license, milestones, licensing and royalty payments, exclusivity factors and many other details. In addition, if the company is interested in other opportunities for sponsored research, NDSU/RF will direct them to the Sponsored Programs Administration at NDSU.

After a company has expressed interest in commercially developing a technology, a "license agreement" is signed that provides that company with the legal right to use NDSU/RF intellectual property rights (such as patents). Licenses are negotiated to ensure that the company has the resources and commitment to adequately develop the technology. License agreements also spell out the details of the compensation back to NDSU/RF as products based on the technology are commercialized.

There are three basic types of license: exclusive, semi-exclusive and nonexclusive. Nonexclusive licenses are used when many licensees are sought to all use, make, or sell the technology; this works well for technologies that are close to final form (e.g. software) or that present foundational or enabling technology.

In the event that some development work is still needed or there are only a few major players in the marketplace, then a semi-exclusive license may be granted to a limited number of companies. Semi-exclusive licenses may also be given to a number of companies where each is licensed to sell in a given territory (e.g. Europe vs. USA). Semi-exclusive licenses can also be given by field of use. This might entail licensing a technology to different companies for veterinary or human medical use.

If a technology requires considerable time/risk/resources to develop, then an exclusive license is often used. Exclusivity encourages companies to invest in the further development of technologies.

Companies may seek a period of time to evaluate a technology before licensing it. To insure that another company can't license it during this evaluation period, a "license option" may be negotiated. The company pays NDSU/RF a fee in exchange for being able to evaluate the technology for a given time period before beginning the process of licensing the technology.

Added Research

Sometimes a technology is in such early phases that it must be further developed before applying for a patent or seeking a licensing agreement. In these cases, the inventor is asked to continue doing research to confirm, modify or redirect the technology. It may provide another opportunity for a Sponsored Research Agreement with an outside company (who may be interested in licensing the invention if it proves viable) or be the subject of further academic study.

Returned to Inventor

For a variety of reasons, sometimes NDSU/RF is not interested in pursing the commercialization of an invention, and will transfer the ownership (barring other interests from companies or government agencies who sponsored the research) to the inventor, according to NDSU policy. The inventors can then take the lead in commercializing the invention if they choose, and the only requirement from the NDSU/RF is the reimbursement of costs associated with initially researching/patenting the invention, and a portion of the net licensing revenue and/or royalties if the inventors start a business. These reimbursed funds are used to partially repay NDSU/RF for costs incurred and potentially provide additional research support to contributing departments. University facilities and resources cannot be used for further development, unless there is a sponsored research project and compliance with conflict of interest policies.

Licensed to Faculty Start-up

Occasionally, a faculty member will want to use their invention and start a business. NDSU/RF may license the technology to the start-up company if they can create a viable company. For more details on this option, please see the Technology Transfer website at www.ndsu.edu.techtransfer, and look for ***A Guide for New Business Ventures at NDSU.***

Appendix 1: NDSU Intellectual Property Policies and Procedures

This section provides a brief overview of the NDSU policies and procedures concerning intellectual property created by NDSU researchers. Note that the following **policies and procedures apply to all inventions created at NDSU**.

For more detailed information on the NDSU intellectual property policies, faculty activities and policy governance, view the NDSU web site at http://www.ndsu.edu/policy/al_index.htm. Here is a list of policies you should review:

- NDSU 151: Conflict of Interest
- NDSU 152: External Professional Activities
- NDSU 190: Intellectual Property
- NDSU 343: Confidential Proprietary Information
- NDSU 700: Services & Facilities Usage
- NDSU 700.2: Taking Equipment Home
- NDSU 700.3: Personal Use of State Property

Invention Disclosure Reporting and Equity Reviews

The patent process begins while the inventor is conducting the research. Make sure that the research process is well-documented and protected as appropriate. When a discovery is made, as a university employee, the first step in protecting a discovery or invention is the filing of an Invention Disclosure with NDSUTTO. *All inventions must be disclosed to NDSUTTO, regardless of their funding source* (e.g., federal grant, ongoing department research or sponsored research dollars from a company).

Researchers must disclose to NDSU/TTO so that the university can conduct an equity review of the invention in compliance with federal law. Forms are available for download on the NDSUTTO web site at http://www.ndsu.edu/techtransfer/.

Questions on Protecting Intellectual Property?

For more information about protecting your research process or invention, please contact:

NDSU Technology Transfer Office
701-231-6659
www.ndsu.edu/techtransfer

Questions on Commercialization of Inventions?

For more information regarding the patenting process or commercialization of inventions, please contact:

NDSU Research Foundation
701-231-8931
http://www.ndsuresearchfoundation.org