US Patent

Basics

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US Patent Basics

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1. US PATENT BASICS

The US legal system provides certain rights and protections for owners of property, including real property (houses and real estate) and tangible property (the things we own, like cars and washing machines). The kind of property that results from mental labor is called “Intellectual Property” and certain legal rights are also provided for Intellectual Property under US law.

One important kind of Intellectual Property is the “patent,” which has been around in one form or another since 500 BC when certain Greek cities awarded all who discovered “any new refinement in luxury” a patent for one year. The first known patent law was from Italy with the Venetian Statute of 1474.

Patent grants were also awarded by Kings in England and were used to raise money for the Crown. The power to grant patents was abused, because the Crown granted patents for all sorts of common goods (e.g., salt). After public outcry, James I of England was forced to revoke all existing monopolies and declare that they were only to be used for "projects of **new** invention". This was incorporated into the Statute of Monopolies in which Parliament restricted the Crown's power explicitly so that the King could only issue letters patent to the inventors or introducers of original inventions for a fixed number of years.

In the reign of Queen Anne, the law further developed so that a written description of the invention must be submitted before the patent could be awarded. These developments were in place during the colonial period before independence of the U.S., and were the foundation for our patent laws in the United States, as well as for New Zealand and Australia.

Thus, the US Constitution in Article 1, Section 8, expressly gave Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

The first Congress adopted a Patent Act in 1790, and the first patent was issued under this Act in 1790 to Samuel Hopkins of Vermont for a potash production technique.

This introduction to patent law is written for the University inventor considering patenting one or more aspects of his or her research and who may ultimately branch out from basic research into the entrepreneurial world and start a new company.

Welcome to patent law!

What is a Patent?

A patent gives a right to **prevent others** from making, using, or selling what is covered by the claims of the patent. It is **not** a right to practice what is covered by the patent. You may—or may not—be able to practice your own patent depending on whether "dominant" patents exist.

For example, if you have a patent to an improved electric toothbrush that cleans much better because the bristles move side-to-side, instead of in a circle, you cannot make or use your patented toothbrush without licensing a "dominant" patent that includes all electric toothbrushes.

Kinds of Patents

There are three kinds of US patents:

Utility Patents: This is the most common type of patent. It is for machines, articles of manufacture, compositions of matter, and methods of making and doing things. Certain animal, microbial and sexually reproduced plant inventions also fall within this category.

Design Patents: This patent protects only the ornamental appearance of a device, such as a ceiling fan.

Plant Patent: Any plant produced by budding or grafting, e.g., asexually reproduced. When you buy a rose plant, for example, it is most probably patented.

There may be other types of patents in other countries, such as the petty patent that is not examined and has a shorter lifespan.

Patent Term

Generally, the "term" or lifespan of a utility patent is 20 years from the US or international filing date. Provisional patent applications and foreign priority applications do **not** count against patent term. Design patents last 14 years.

After a patent expires, anyone may use the invention without the inventor's permission. However, patent term can be extended under certain circumstances. For example, drug patents can be restored where market term was lost during the FDA approval period, and term may be extended if there were delays by the US Patent and Trademark Office (PTO).

Geographic Scope

Patents have geographic limits—that is a US patent only gives rights within the US. If foreign rights are desired, a patent must be filed in each country where protection is needed. Foreign filing can be expensive because local counsel must be hired in each country and the patent application must usually be translated into the language of that country.

Parts of an Application

A US patent application requires five things:

1) **Declaration:** An "Oath" that you are the true and first inventor, and that you understand the "Duty of Candor." See below for additional discussion of these issues.
2) **Fee:** About $500[1] in the US, but can be more if there are too many pages or claims.
3) **Drawings:** Are only required where needed to help explain the invention.
4) **Specification:** The body of the patent that references the drawings and describes the invention so that someone skilled in the art can understand what it is, how to make it, and how to use it.
5) **Claims**: At the end of the specification are a series of numbered claims precisely defining what the patent covers. This is the most important part of the patent! The claims are the basis for an infringement lawsuit if you ever need to enforce your patent.

What is Patentable?

To be eligible for a utility patent, an invention must belong to one of these classes:

1) a machine (e.g., a mechanism with moving parts);

[1] All prices are approximate and are for individuals, Universities, and small companies. Large companies (>500 employees) will pay twice as much, as will a small company that has licensed the patented technology to a large company.

2) an article of manufacture (e.g., a hand tool or a diagnostic kit);
3) a composition of matter (e.g., a drug or a mixture of compounds);
4) a process (e.g., a method of making nanotubes);
5) a new use of or improvement to an existing invention;
6) a modified living organism (e.g., transgenic mice or plants); and
7) isolated or purified natural materials (e.g., purified soil bacteria or purified proteins).

Intangible ideas, mathematical formulae, laws of nature, chemical elements, and the like are not patentable.

What is Required for Patentability?

Useful: An invention must be "useful," e.g., have utility, actually work, and not be frivolous or immoral.

Novelty: An invention must also be "novel" or "new," e.g., it was not previously known or used by others or described in a printed publication.

Non-obvious: The invention must also be "non-obvious" to a person having ordinary skill in the relevant art. Thus, merely changing the size or material of a known article does not make a new patentable invention.

Best Mode, Duty of Candor, Oath

Best Mode: In addition to utility, novelty, and non-obviousness, you **must** disclose the "best mode" of practicing an invention—that is your preferred materials, methods, or suppliers. Failure to comply used to result in patents being declared unenforceable, but the law recently changed in that regard.

Duty of Candor: Each individual associated with the prosecution of a patent application **must** comply with the "duty of candor and good faith." The duty includes the requirement that you disclose to the PTO all information known to be "material" to patentability throughout the entire pendency of the application. Failure to comply may result in your patent being declared **unenforceable**.

Oath: The inventor must swear that he or she has reviewed and understood the patent application, that the named inventor is the original and first inventor of the subject matter claimed, and that he or she acknowledges the "duty to disclose" to the PTO all information known to be "material" to patentability.

The oath is a serious matter and is sworn to under penalties of **fine, imprisonment, or both**. Further, willful false statements may result in your patent being declared **unenforceable**.

Inventorship

Inventorship has a strict legal meaning in US law and it is **critical** that the **true inventors** be named on an application. It is **not** the same as authorship, **nor** is it the same as leadership. Although determining inventorship is quite complicated, it is based on contributing to the "conception" of the invention (see also Chapter 3). Remember: the invention is defined by the claims!

Ownership

The US rule is that a patent is owned by the "inventors," although most employees have a contractual duty to assign any inventions to their employer. **Each owner may use or license an invention without permission or payment to any other owner**. Thus, where any collaboration or contract research may result in an invention being made, it is a good idea to spell out each party's rights and obligations in a written contract before beginning the collaboration or contract research.

Patent Counsel

Although it is possible to obtain a patent by yourself, typically a patent lawyer or patent agent is hired to assist with the process of drafting a patent application and getting it allowed by the PTO. One generally hires counsel with technical expertise in the field of the invention.

Drafting Costs

You should expect to spend between $6,000-15,000 dollars in order to draft and file a good patent application. There are additional PTO fees of about $500, and this can be higher if the pages and claims each exceed 20. Further, figures must be prepared by professional draftsman (unless you can prepare your own professional quality drawings), and these cost between $100-200 each. It is possible to include photographs,

but these can also be expensive. You can minimize expense by reducing the number of figures, for example by converting data to tabular format.

What Counsel Needs

Generally, you can minimize costs and get a better product by providing counsel with the following:

1) An electronic copy of a good description of the invention;
2) Electronic and editable copies of any figures;
3) Copies of the best "prior art" e.g., published papers or patents that are the closest to the invention; and
4) Describe ways that you can distinguish your invention from the closest prior art. For example, are **comparative experiments** available? Are there **failed experiments** that can be used to show non-obviousness? Are there any special advantages or **unexpected results** demonstrated by your invention?

A sample invention disclosure form is provided at Exhibit 1, and cost control is discussed in additional detail in Chapter 5.

What is an IDS?

Within three months of filing a patent application, you must submit known "prior art" and "material" information to the PTO in a form called an "IDS" or "Information Disclosure Statement." This is part of complying with the "Duty of Candor." "Prior art" and "material" information includes grant proposals, publications, web page postings, abstracts, posters, pending litigation, sales or offers for sales, and the like.

What is Material Information?

"Material" information is defined as information that is not cumulative and either establishes that a claim is not patentable or is inconsistent with any position the applicant takes in arguments made to the PTO.

What is Restriction?

If the patent application covers more than one type of invention, e.g., a drug and a method of making that drug, the applicant will be required to select one group of claims to pursue in the application. This is

called “restriction” to a single invention. The rest of the claims may be pursued in a “divisional” application, for which a new filing fee will be required.

What Happens After Filing?

About one to two years after filing (or longer if a restriction requirement was made first), the claims are usually “rejected” in an “Office Action” (“OA”) prepared by the Examiner.

Rejections are often made because the claims are not considered new or non-obvious over the prior art. Rejections can also be based on section 112, because the claims lack clarity or because the invention does have sufficient written description or is not fully enabled for the broad scope for the claims. Such written description and enablement claims are common in biochemistry where the art is young and not as predictable as other arts, such as engineering.

“Amendments” are often submitted by patent attorney or agent in a “Response to Office Action” (“ROA”) in order to overcome the rejections. It usually requires more than one round of these communications, but the claims may eventually be allowed after about three years.

These back and forth communications between the lawyer and the PTO are called the “prosecution history” but can also be called a “file wrapper.”

In some areas, especially biotechnology, it can require more than one round of prosecution to gain allowance. Therefore, although the PTO tries for an average of 3 years pendency, it is often 5-6 years in biotechnology before a patent is allowed, and it can be longer.

Each ROA costs between $2,000-4,000 to prepare and file, although the expense is typically higher where a substantive Declaration is also provided with the response.

Time for Reply

The usual period for reply to an Office Action is three months, but can be as short as 30 days, and in many cases can be extended up to six months on payment of extension fees. If no reply is received within 6 months, the application is considered abandoned.

Abandoned applications can be revived on petition, payment of fees, and submission of any required Response, if one can show that the abandonment was unavoidable or unintentional. However, this procedure

is expensive and should be avoided. Further, the standards for revival are quite strict and revivals are not always allowed.

Publication of Patent Applications

Most US plant and utility patent applications are published at 18 months after the earliest effective filing date (the "priority date"). An applicant may request that the application not be published, but only if the invention will not be filed in a foreign country that requires publication. Following publication, the application for patent is no longer held in confidence by the PTO and any member of the public may request access to the entire file history of the application.

As a result of publication, an applicant may assert "provisional rights." These rights provide a patentee with the opportunity to obtain a reasonable royalty from a third party that infringes a published application claim, **if** "actual notice" is given to the third party by applicant, **and** a patent issues from the application with a "substantially identical" claim. Thus, damage awards for pre-patent grant infringement are now available, but only after the patent issues.

Continuation

If after the final Office Action the claims are still not allowed (which is typical, especially in the life sciences), the applicant can continue to prosecute the claims in a "continuation" application or an "Request for Continued Examination" ("RCE"). Additional fees are paid, for which the applicant gains a additional opportunity to argue the patentability of the invention. It **must** be filed **while** the prior application is still pending. Continuation or RCE filings are common in the life sciences, where it often takes more than one round of prosecution to gain allowance.

Continuation-in-Part

A "Continuation-in-part" or "CIP" is a new application that is based on an old application, but has new material added to it. It is used where the invention has been improved and the inventor wants to patent the improvements. It **must** be filed **while** the prior application is still pending.

CIP applications are usually **not** available outside the US, and an entirely new application must be filed. Therefore, the original application can be applied prior art against the new application outside the US.

Divisional

A “Divisional” (“DIV”) application is a duplicate application that is filed because some of the claims were “restricted” as described above. Those claims that were not pursued in the parent application are pursued in the “divisional.” It **must** be filed **while** the prior application is still pending. Many clients wait until the first application is allowed before filing a DIV application, but these can be prosecuted at the same time as the original application.

Appeal

If the examiner persists in the rejection of the claims, or if the rejection has been made “final,” the applicant may appeal to the Board of Patent Appeals and Interferences. A notice of appeal and appeal fee are required and the applicant must file a formal brief within 3 months to support his/her position. An oral hearing can be held if requested and on payment of the required fee.

A five page “pre-appeal brief” can be filed together with the notice of appeal, and if so, three Examiners will review the case and decide if it should go to a full formal appeal, or if the Examiner was incorrect and the case should either be allowed or prosecution re-opened.

A full formal appeal brief typically costs about $5000, and as mentioned above, an oral hearing can be held which will add to the cost. If the decision of the Board of Patent Appeals and Interferences is still adverse to the applicant, another appeal may be taken to the Court of Appeals for the Federal Circuit or a civil action may be filed against the Director in the United States District Court for the District of Columbia. Alternatively, a continuation application can be filed and prosecution attempted again.

Interference

Occasionally two or more applications are filed by different inventors claiming substantially the same invention. A US patent can only be granted to one of them, and a proceeding known as an “interference” is initiated to determine **who** was the first inventor and thus entitled to the patent. Each party to the interference must submit evidence proving when the invention was made, and the party who establishes the earliest invention date is entitled to a patent.

Notice of Allowability

If the patent application is found to be allowable, a Notice of Allowability and Fee(s) Due will be sent to the applicant. The issue fee is due within three months from the date of the notice and this date is **not extendable**. The patent will issue as soon as possible after the date of payment, dependent upon the volume of printing on hand, and the patent is then mailed to the applicant.

Patent Marking

A patentee who makes or sells patented articles is **required** to mark the articles with the word “Patent” and the number of the patent. The penalty for failure to mark is that the patentee may not recover damages from an infringer unless the infringer was duly notified of the infringement and continued to infringe after the notice. The false marking of an article as “patented” when it is not patented is prohibited and subjects the offender to penalties.

Maintenance Fees

In addition to drafting and prosecution costs, there is a fee due on issuance of the patent. Maintenance fees are also due at 3 years, 6 years and 12 years, and the amount due increases with time. Many countries have patent maintenance fees, and some are due yearly even during prosecution.

Certificate of Correction

Minor typographical errors can be corrected by Certificate of Correction. The PTO will correct its own typographical errors without fee, but errors by the Applicant require a fee. The patentee may also “disclaim” one or more claims of his/her patent by filing a disclaimer with the PTO.

Reissue and Reexamination

When patent errors are significant and cannot be corrected by Certificate of Correction, either a “reissue” or “reexamination” proceeding may be held. Reissue may be employed, for example, where the "scope" of the patent (as defined by the claims) is too broad or too narrow, or where the specification or drawings are incorrect. It should be noted that a request for a broadening of the claims must be filed within two years of the

issuance of the original patent, and in no case may new matter be added to the patent.

Reexamination is more limited in its application than reissue. It may not be used to broaden claims or correct errors, but allows newly discovered publications to be brought before the PTO and the claims reexamined in light of that new material. Reexamination thus serves to defuse the potential argument of an accused infringer that the PTO "missed the best reference." Reexamination requests may be made by the patent owner, third parties, or even the PTO.

What about Foreign Protection?

A "PCT" ("Paris Cooperation Treaty") application is an application that covers about 140 countries in the world and allows you to **defer** foreign filing decisions for about 30 months. The PCT application filing fee is about $4000-5000.

The PCT application will **NEVER** mature in to a patent—it only holds your place for 30 months while you decide whether you need to and can afford to file in foreign countries. At the 30 month deadline, you must **still** hire local counsel and pay to have the application translated into the appropriate language and pay foreign filing fees.

Each foreign country application can be expected to cost about $5000-10,000 to file. Japan and Europe tend to be more expensive places to file in.

There are similar place holding applications in Europe, the Middle East, and Africa, although some of these applications may eventually mature into a patent. Also, one can always proceed direct to foreign filing without utilizing a place holding application.

What is a Provisional Application?

The "provisional" application is another place holder application that will never mature into a patent. It will, however, hold your place for one year while you develop the invention or raise funds to continue. At the end of that year it becomes abandoned and a real application must be filed **before** abandonment.

The provisional application is inexpensive and it is possible to file a draft paper as is with only a cover sheet. However, most of the time your Patent Counsel will draft the best application he or she can, or at least add a few patent claims to the paper.

One benefit of using the provisional application is that it holds your place for one year, while you refine and develop the invention, yet that year does **not** count against your patent term. Thus, it's like having a free year!

What about Publications?

In the US there is a "one year grace period" to file a patent application after making a public disclosure of an invention. Thus, any public disclosure will start the one year US clock ticking.

Most of the world does **not** offer a grace period.[2] Therefore, if foreign patent protection is desired, a patent application **must** be filed before **any** public disclosure. For this reason, it is wise to check with the Technology Transfer Office **before** disclosing any material.

How about Grant Proposals?

Because Grant Proposals are publicly available under the Freedom of Information Act, sensitive parts of grant proposals should be labeled "confidential" upon submission. When submitting a proposal to an agency or a private/corporate foundation, notification of proprietary content should be included in the transmittal letter and all pages containing proprietary material should be stamped with the words "Confidential, Proprietary Information."

Don't forget that grant proposals, dissertations, abstracts, posters, and offers for sale, all **start** the one year US clock ticking!

Invention Records

If someone else invents the same invention or if there is an inventorship dispute (such as an interference), having good records mean the difference between winning or losing the case. It is **critical** to keep good records, as follows:

1. Inventors should keep good research notes in indelible ink in a bound notebook with numbered pages. The notebook is a

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[2] Japan (six months), Canada (one year) and Russia (sixth months) include a grace period in their patent laws. China has a sixth-month grace period for inventions which have been disclosed in an obviously abusive way or disclosed at a "prescribed academic or technological meeting" or at an international exhibition, if it is "sponsored or recognized by the Chinese Government". Europe offers a six month grace period if the disclosure was abusive, or when the disclosure was at an official international exhibition falling within the terms of the Convention on international exhibitions.

record of progress, what was done and when, what parts were bought, what was thought of when, and includes sketches.

2. Leave no blank pages or large blank spaces in the notebook.
3. Date and initial every page.
4. Courts always want corroborating witnesses. They want to see dated signatures on the research notes by a colleague (not a close relative or someone you supervise). The corroborating witness must be someone that can read and understand what you've accomplished. Ideally, **each** page of the invention notebook will be witnessed.
5. Identify and cross-reference non-notebook material, i.e., tapes, biological materials, x-rays, scans, etc.

What is the Inventor's Commitment in the Process?

Although most of the marketing and patenting functions will be **managed** by the Technology Transfer Office, considerable input is usually required from the inventor, especially during application drafting and drafting a Response to Office Action.

In addition, the inventor is usually in the best position to "market" the invention by speaking at conferences and in communications with colleagues. Thus, in a University environment, inventors typically make the initial connections with a potential licensee and then confer with the Technology Transfer Office when someone expresses interest in the invention.

Can Marketing Begin Before Filing?

A patent is not required in order to sell an invention in the US. BUT, don't forget that the one year clock begins ticking on the first public disclosure or offer for sale and that there is **no** grace period in most foreign countries!

A "Confidential Non-disclosure Agreement" or MTA ("Material Transfer Agreement") should always be signed **before** you discuss your invention with anyone. **Consult your Technology Transfer Office before communicating with anyone outside your institution!**

2. BEST MODE, OATH, CANDOR

The Patent Basics discussion above does provide a basic description of the best mode, the oath and the duty of candor. However, these issues are so important, it is worth reviewing them again in more detail.

Best Mode

A patent application must describe the "best mode" of practicing the claimed invention as of the time of filing the application. The statute states:

> The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the best way for practicing the claimed invention. It is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves.

Since the patent reform of September 2011, it is no longer possible to invalidate a patent based on a failure to disclose the best mode (see Chapter 4). Thus, best mode failures are not as critical as they used to be.

Oath or Declaration

Another important part of filing a patent application is the execution of the oath or declaration on filing or shortly thereafter. An oath must be sworn to by the inventor before a notary public, but a declaration may be used in lieu of an oath and does not require any witness or person to administer or verify its signing. Thus, declarations are preferred.

The oath or declaration requires you to read the application immediately before signing it. You must then swear under penalty of perjury the following:

1. That you have reviewed and understand the contents of the specification, including the claims;

2. That you believe the named inventor or inventors to be the original and first inventor or inventors of the subject matter claimed; and

3. That you acknowledge the "duty to disclose" to the PTO all information known to the person to be material to patentability.

This oath or declaration is a serious matter and is sworn to under penalties of **fine, imprisonment, or both**. Further, willful false statements may jeopardize the enforceability of any patent issuing thereon.

Duty Of Candor

A duty of candor and good faith in dealing with the PTO exists for **each** individual associated with the filing and prosecution of a patent application. Subsumed within the duty of candor is a duty to disclose to the PTO all information known to the individual to be “material to patentability.”

Only “known” information needed be submitted—the duty does not include a duty to “search” for additional information. However, you do have to review the articles already in your possession and disclose them if material.

The duty of candor exists during the entire pendency of the application, i.e., from the date of filing to the date of issuance. Further, the duty to disclose material information exists with respect to each pending claim in the application, i.e., until the claim is either canceled or withdrawn from consideration, or the application becomes abandoned.

Please note that no patent will be granted on an application in which fraud on the PTO was practiced or attempted, or wherein the duty of disclosure was violated through bad faith or intentional misconduct. Moreover, even if a patent has issued, intentional failure to comply with the duty of candor may cause the patent to be unenforceable if “inequitable conduct” toward the PTO is found to have occurred. Related patents may also be rendered unenforceable.

Persons Owing A Duty Of Candor

Individuals associated with the filing or prosecution of a patent application, and therefore owing a duty of candor, include:

1. Each inventor named in the application;

2. Each attorney or agent who prepares or prosecutes the application; and

3. Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application.

Individuals other than the attorney, agent, or an inventor may comply with the duty of disclosure by disclosing the material information to the attorney or agent or an inventor.

Materiality Of Information

Information is “material to patentability” when it is not cumulative to information already of record or being made of record in the application, and

1. It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

2. It refutes, or is inconsistent with, a position the applicant takes in:

i) opposing an argument of unpatentability relied on by the PTO, or

ii) asserting an argument of patentability.

A “prima facie case of unpatentability” is established when the information compels a conclusion that a claim is unpatentable under the standard of a preponderance of evidence when each term in the claim is given its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Thus, any information that on its face would lead to a conclusion that one or more claims in the application are unpatentable, either alone or in combination with other information, must be brought to the attention of the PTO.

Please remember that "material" information may be found in non-traditional sources of information, such as web sites, brochures, offers for sale, pending litigation, and the like.

A helpful Duty of Candor Checklist is provided at Exhibit 2.

3. INVENTORSHIP

Under US law, a patent application **must** be made in the name of the original and first inventor(s). Naming incorrect inventor(s) on a patent may invalidate the patent or make it unenforceable. Inventorship is also important because ownership generally follows from inventorship, and each owner of a patent has the right to license the patent **without** accounting to the other.

Joint Inventors

The statute provides that: When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath . . . Inventors may apply for a patent jointly even though:

(1) they did not physically work together or at the same time,

(2) each did not make the same type or amount of contribution, or

(3) each did not make a contribution to the subject matter of every claim of the patent. 35 U.S.C. § 116.

Claims

Inventorship is determined with respect to the claims—that is one must review the claims and determine which person(s) contributed each element of the claims.

Not Authorship

Inventorship is **not** the same as authorship. Although authorship may be granted several individuals in recognition of their valuable contributions to research, inventorship is a legal determination based on principles of law.

Invention

It has long been established that there are two stages to the making of an invention: “conception” and “reduction to practice.”

Conception

Conception is the key to determining inventorship—only those individuals who participate in the conception of an invention may be named as true inventors. Conception must include every feature or limitation of the claimed invention.

The inventor must form a definite and permanent idea of the complete and operable invention to establish conception.

“An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity.”

“Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”

Reduction To Practice

Reduction to practice requires a showing of the invention in a physical or tangible form. Reduction to practice may be an actual reduction to practice or a “constructive” reduction to practice, which occurs when a patent application on the claimed invention is filed.

Reduction to practice does not have to be carried out by the inventor—all that is required for one to be an inventor is to have conceived a definite and permanent idea of the complete and operative invention. However, under certain circumstances, those who offered suggestions and ideas leading to the operative invention may be inventors because they contributed to the conception.

The following contributions are generally **not** inventive:

- Contributing an obvious element or general knowledge.
- Merely suggesting a desired result or outcome without providing the means to accomplish the same.
- Following the instructions of the conceivers.
- Explaining how or why the invention works.
- Adopting information derived from another.
- Providing additional research or testing that is not related to the claimed invention.

- Merely supplying a known component or starting material.
- Merely refining or perfecting another's design or making only superficial changes.
- Providing well-known principles.
- Explaining the state of the art.

Correction Of Inventorship

Errors in inventorship can be corrected if the error was made without deceptive intent.

Inventorship determinations can be both complicated and contentious and its myriad permutations cannot be adequately described in a short summary such as this. If you have any questions concerning inventorship, please consult your Patent Counsel.

4. PATENT REFORM 2011

The most significant changes to the U.S. patent law in more than 50 years were signed into law on September 16, 2011. The Leahy-Smith America Invents Act (the Act) presents a major overhaul of many provisions of U.S. patent law.

The Act fundamentally changes how patent applications will be prosecuted in the USPTO by changing from the current first-to-invent system to a first-to-file system, redefining what is prior art, and modifying various procedures in significant ways. We have summarized the changes below, but note that patents governed by the prior law will be in existence for many years to come, and many provisions do not take effect until September 2013. Thus the old patent law will control many issues for a long time.

First-to-File System

One of the most significant changes in the Act is replacing the current first-to-invent system with a modified first-to-file system. Under the current first-to-invent system, if two independent inventors file for a patent on the same invention, the inventor with the earlier invention date gets the patent. On the other hand, with a first-to-file system in most of the world, the inventor with the earlier filing date gets the patent. The provisions relating to the switch will not take effect until 18 months after enactment (March 2013).

The move from first-to-invent to first-to-file comes with corresponding changes to 35 U.S.C. § 102, which defines "prior art in relation to the effective filing date of the application under examination, rather than the invention date. Thus, under the Act, it would no longer be possible to "swear behind" prior art by establishing an earlier invention date.

The Act also changes § 102 in other notable ways. The overall effect of these changes appears to increase what is available as prior art.

Removing Geographic Limits on Prior Art

The Act eliminates any geographic limitations on prior art, providing that an invention is not patentable if it was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." Thus,

public use, sales, and knowledge by others anywhere in the world will be prior art.

Grace Period Limited

Current US law provides a one year grace period, allowing inventors to swear behind any prior art that is less than a year old if they can prove their invention predate the art. The Act eliminates this one-year grace period except in limited circumstances. In particular, the grace period only applies to disclosures made by the inventor, a joint inventor, or "another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor."

Post-Grant Proceedings

The post-grant proceedings currently available include reissue, ex parte reexamination, and inter partes reexamination. The Act keeps reissue and ex parte reexamination substantially the same, but significantly revises inter partes reexamination, which is renamed "inter partes review," and introduces new "post-grant review," "supplemental examination," "transitional post-grant validity review of certain covered business method patents," and "derivation proceedings."

Inter Partes Review

The inter partes review provisions in the Act are similar to the current inter partes reexamination provisions provided in 35 U.S.C. §§ 311–318 in that a petitioner may request review only for novelty and obviousness, and only on the basis of patents or printed publications. Similarly, inter partes review in the Act includes estoppel provisions as provided in inter partes reexamination and does not allow for broadening of the claims. Inter partes review includes a number of new features that will significantly change post-grant inter partes practice:

Time Limits: A request can be filed to the later of nine months after the grant of a patent or after a post-grant review (discussed below) is terminated.

Preliminary Response by Patentee: A preliminary response can be filed by the patent owner to explain why the inter partes review should not go forward, in contrast to the present system, which allows a patent owner response only after the patent office determines that there is a substantial new question of patentability.

Threshold: A higher threshold to determine whether a review should go forward is imposed, based on whether there is a "reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition," as compared to the "substantial new question of patentability" threshold in current reexamination proceedings.

Civil Action Prevents Use: An inter partes review cannot be maintained if a civil action was filed challenging the validity of the patent or if more than one year has passed since the petitioner was served with a complaint alleging infringement. This change makes prevents patent challengers from having two opportunities to invalidate a patent, one at the patent office and one in a parallel litigation.

Authority: The Act gives the patent office the authority to stay, transfer, consolidate, or terminate a related interference, reissue, or ex parte reexamination. This provision will allow the patent office to focus on one submission at a time, not multiple post-grant filings involving the same patent. In a further attempt to streamline the proceedings, the Act gives to a new Patent Trial and Appeal Board ("PTAB"), not the patent office's Central Reexamination Unit ("CRU"), the authority to conduct inter partes reviews, and provides for appeal directly to the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). Currently, inter partes reexaminations are heard by the CRU with appeals to the Board of Patent Appeals and Interferences ("BPAI"), and appeals from BPAI to the Federal Circuit.

Discovery: Limited discovery will be allowed, including depositions of witnesses who have submitted affidavits or declarations, and what is otherwise necessary in the interests of justice. The "interests of justice" standard is the same standard used for discovery under the present interference proceedings.

Settlement: The Act allows the parties to settle and therefore terminate an inter partes review based on a joint request by the petitioner and patent owner. Currently, inter partes reexaminations cannot be settled by the parties.

One Year Limit: The Act requires the final determination in an inter partes review be issued not later than one year after the institution of the review, except that, for good cause shown, the period may be extended by not more than six months. For inter partes reexamination, it currently takes approximately 38 months from filing a request to obtain an inter partes reexamination certificate.

The above provisions take effect upon the expiration of the one-year period beginning on the date of enactment of the Act (September 2012) and apply to any patent issued before, on, or after that effective date. However, the higher standard for determining whether an inter

partes reexamination should be granted became effective upon enactment.

Post-Grant Review

Post-grant review provides another way for a third party to challenge a patent. Post-grant review is similar to inter partes review in many ways. For example, it provides a similar estoppel provision and allows a preliminary response by the patent owner to explain why post-grant review should not go forward. In addition, a post-grant review cannot be initiated if the petitioner filed a civil action that challenges the validity of the patent. Post-grant reviews will also be handled by the PTAB with decisions appealable to the Federal Circuit and may be settled by the petitioner and patent owner. Post-grant reviews also are to be completed within one year after institution, with certain exceptions.

Post-grant review and inter partes review differ, however, in several significant aspects:

Timing: A petition for post-grant review must be filed within nine months of patent issuance, whereas a petition for inter partes review cannot be filed until after the later of nine months from issuance or the termination of any post-grant review.

Available arguments: A petitioner in a post-grant review can request that the patent be invalidated on the basis of any provision of the patent statute, whereas a petitioner in an inter partes review can rely only on prior art patents and printed publications. This brings post-grant review more in line with European opposition proceedings.

Threshold for institution: A post-grant review may be instituted only if "information presented in the petition, if not rebutted, would demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable."

Discovery: Discovery in a post-grant review proceeding is limited to evidence directly related to factual assertions advanced by either party in the proceeding. This appears to permit more discovery than inter partes review, where discovery consists only of depositions of witnesses who have submitted affidavits or declarations, and what is otherwise necessary in the interests of justice.

Staying of Preliminary Injunction: If an action alleging infringement is filed within three months of the granting of a patent, a court cannot stay consideration of a patent owner's motion for preliminary injunction against infringement solely on the basis of the filing of a post-grant review or the institution of such a proceeding.

The above provisions take effect one year after enactment of the Act (September 2012) but apply only to patents issuing from applications filed pursuant to the first-to-file provisions, i.e., for applications filed on or after March 16, 2013.

Supplemental Examination

The Act attempts to minimize the effects of inequitable conduct allegations in patent litigation by allowing a patent owner to obtain supplemental examination of a patent. For example, a patent owner may use supplemental examination to have the USPTO consider prior art not previously reviewed by the Examiner before initiating a patent infringement action.

Review of Business Method Patents

The Act provides for an eight year transitional post-grant review proceeding to determine the validity of business method patents. Like post-grant review, the subject patent can be invalidated on the basis of any provision of the patent statute including Section 101/Bilski matters, not just patents and printed publications as required by current reexamination proceedings. The only eligible petitioners are individuals who have been sued for or charged with infringement of a covered business method patent.

The Act does not include any time frame on when this post-grant request can be filed. In addition, the Act includes provisions that allow a petitioner to request a stay of any corresponding litigation and to file an interlocutory appeal to the Federal Circuit if the district court renders an adverse decision in response to the Petitioner's request for the stay. Moreover, the estoppel provisions in this section of the Act are less restrictive, as they prohibit a petitioner only from asserting in a corresponding civil action that the claim is invalid on any ground that the petitioner raised during the proceeding, not "raised or reasonably could have raised" as provided in the Act's post-grant and inter partes review estoppel provisions. This provision becomes effective one year after enactment (September 2012) and applies to any patent issued before, on, or after that effective date, but lasts only eight years.

Derivation Proceedings

For issued patents, the Act replaces interferences with new "derivation" proceedings to determine if the inventor of an earlier-filed patent "derived" the invention from the inventor of a later-filed patent. A

civil action can be filed only within one year of the issuance of the earlier-filed patent containing a claim to the allegedly derived invention and naming an individual alleged to have derived such invention as an inventor.

For pending patent applications, the Act also provides that an applicant may file a petition in the patent office to request the PTAB to institute a derivation proceeding on grounds that the inventor of an earlier-filed patent application derived the invention from an inventor named in the later-filed patent application. Any petition for such derivation proceedings must be filed within one year of publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention.

Prioritized Examination

The Act authorizes the USPTO to provide for priority examination of "applications for products, processes, or technologies that are important to the national economy or national competitiveness." This provision goes into effect 10 days after enactment and requires an additional $4,800 be paid on top of an application's filing fees to obtain prioritized examination. The Act sets a limit of 10,000 applications that can use this procedure in the first year.

Third-Party Submissions of Prior Art

The Act permits any third party to submit any patent, published patent application, or other printed publication as part of the pre-issuance examination of an application if such submission is made within a specified timeframe, generally the earlier of the issuance of a notice of allowance or six months after publication of an application. The Act also allows any person at any time (pre- or post-issuance) to submit to the USPTO prior art consisting of patents or printed publications, or statements of the patent owner filed in a proceeding before a federal court or USPTO in which the owner takes a position on the scope of any claim. Such prior art or statements become part of the official file if the requisite conditions are met.

Best Mode

The Act eliminates failure to disclose the best mode from the other litigation defenses, precluding the use of the best mode violation as a basis for invalidating a patent. The Act does not eliminate the best mode requirement for patent applications, but instead eliminates the

enforcement mechanism that ensured that applicants complied with this requirement. This provision takes effect on the date of enactment of the Act, and applies to all proceedings that commence on or after this effective date.

Commercial Use

The Act expands the defense based on prior commercial use beyond business methods, to include machines, manufactures, or compositions of matter. The Act also permits more parties to claim the defense, although there are exceptions for university owned patents.

Marking

The Act now allows for virtual marking, where the customer is referred to a website that provides patent numbers. The Act provides that only the United States has standing to sue for the statutory penalty for failure to mark. This provision was effective upon enactment.

Advice of Counsel

The Act provides that the failure of an infringer to obtain advice of counsel with respect to any allegedly infringed patent, or the failure of an infringer to present such evidence to the court or jury, "may not be used" to prove willfulness or induced infringement. This provision governed by the catch-all effective date provision and thus is one year after enactment. It applies to any patent issued on or after this effective date.

This is by no means a full explanation of the changes that have been or will be made to patent law, but the text is available online at http://www.aipla.org/advocacy/congress/112C/Documents/S.%2023%20intro.pdf. The following chart provides effective dates for the various sections.

Issue (§ of the Act)	Effective as of...
Transition from first to invent to first to file (§3)	The expiration of the 18-month period starting September 16, 2011. Applies to any patent application that has an effective filing date on or after this effective date.
Assignee of invention may file a patent application (§4)	The expiration of the one-year period starting September 16, 2011. Applies to any patent application filed on or after this effective date.

Defense to infringement based on prior commercial use (§5)	Available as a defense to all patents issued on or after September 16, 2011.
Post-grant review (§6)	The expiration of the one-year period starting September 16, 2011. Applies to any patent issued before, on, or after the effective date. Within one year of enactment the Patent Office must establish a system for post-grant review.
Pre-issuance submissions by third parties (§8)	The expiration of the one-year period starting September 16, 2011. Applies to any patent application filed before, on, or after the effective date.
PTO's fee setting authority (§10)	September 16, 2011, except for the electronic filing incentive provision, which goes into effect upon the expiration of the 60-day period beginning September 16, 2011.
New Fees (§11)	A 15% surcharge will be added to all patent-related fees as of September 26, 2011.
Supplemental examination (§12)	The expiration of the one-year period starting September 16, 2011. Applies to any patent issued before, on, or after the effective date.
Elimination of tax-strategy patents (§14)	September 16, 2011. Applies to any patent application pending on, or filed after September 16, 2011 and to any patent that is issued on or after September 16, 2011.
Elimination of best mode defense (§15)	September 16, 2011. Applies to any proceedings commenced on or after September 16, 2011.
Virtual marking and Elimination of qui tam false marking cases (§16)	September 16, 2011. Applies to all cases that are pending on, or commenced on or after September 16, 2011.
Transitional program for business method patents relating to financial products (§18)	The expiration of the one-year period starting September 16, 2011. Applies to any covered business method patent issued before, on, or after the effective date (with limited exceptions). Within one year of enactment, the Patent Office must establish a system for post-grant review.
Joinder of parties (§19)	Applies to any civil action commenced on or after September 16, 2011.
End of fee diversion: USPTO's fees directed to reserve account (§22)	October 1, 2011
Prohibition against patents "directed to or encompassing a human organism" (§33)	Applies to any patent application pending on, or filed on or after September 16, 2011.

5. COST CONTROL

Patent applications can be expensive to draft and prosecute, but the following provide some practical tips for reducing costs:

Public Use

Provide your Patent Counsel any information about the first use or offer for sale or public disclosure of the invention. Tell your Patent Counsel about any future disclosures. This information allows the Patent Counsel to determine when the patent application must be filed, because protection in most foreign countries is lost after a public disclosure of the invention, and a year after such disclosure in the US.

Inventor Information

Prepare a list of inventors for your Patent Counsel, giving all contact information, home and work addresses, county of residence and citizenship. Your Patent Counsel will need this information to prepare formal papers.

Invention Disclosure

Provide a substantial written description of the invention in electronic form. A draft paper containing at least the “Materials and Methods” and “Results” sections would be appropriate.

Length

Many countries have page and claim limits over which additional fees must be paid. Plan on keeping the length to about 20 pages and 20 claims or less. Your Patent Counsel will make additional adjustments where required.

Protocols

Don’t provide detailed lab protocols—it takes a long time to convert these to text. Instead provide the kind of experimental summary you would find in a paper. Put all reagents and recipes in a table; they take less room that way and in many countries the extra pages cost more.

Figures

Figures are expensive and should be minimized. Convert data to tables wherever possible. Avoid the use of photographs or color. For those figures that are necessary, make sure you provide an editable electronic copy. Your Patent Counsel must be able to adjust font size and margins to the PTO requirements.

Best Mode

Don't forget to include your preferred materials, methods, suppliers and the like in your written description.

Description of Figures

Provide a description of each figure in simple language explaining the experimental goal, design, and results.

Prior Art

Provide copies of the closest prior art, especially your own publications. Don't forget non-traditional sources such as web pages, brochures, abstracts, and grant proposals.

Comparisons with Prior Art

In your invention disclosure, point out the difference between the closest prior art and your invention. Do side-by-side comparisons where possible.

Failed Experiments

Don't hesitate to bring failed experiments to the attention of your Patent Counsel. They may help to show why your invention is not "obvious."

Citations

Minimize citations to the literature and provide only those needed to practice the invention. Your Patent Counsel will typically provide a copy of every article you cite to the PTO to meet the Duty of Candor, and so be prepared to provide copies of every paper cited. While your Patent

Counsel can obtain his or her own copies, the costs are typically about $30 per article.

Time

Delays in responding to your Patent Counsel will often increase costs because reminder costs, overtime costs, and late fees may be incurred as the deadlines approach and are not met. Be prompt in all responses.

6. PATENT STRATEGY

It's impossible to provide an adequate discussion of patent strategies in an introduction to patent law—indeed an entire book could be written on the topic and there still would be much room for discussion. However, this brief introduction to the topic should at least jumpstart your thinking in this critical area.

Patent Purpose

One of the first questions to ask in considering an appropriate patent strategy is what is the purpose of your patents? Is it to **block** all entry to the market, as in the pharmaceutical and biotechnology industries? Or is it to generate licensing income, as with IBM's portfolio of more than 40,000 patents and more than 1 billion in licensing revenue. In addition to licensing income, a large portfolio can be a good defensive tool, providing the company with assets to cross license in the event that another company turns up with claims of patent infringement. Or are you trying to build a portfolio as a technology start up in order to increase your value to potential investors and buyers? Once you have decided what the purpose of your patent portfolio is, you will be better equipped to decide on a suitable strategy.

Core Technology versus Enabling Technology

The above discussion assumes that there is only one type of patent, but even a drug company will have different patents for different purposes. For a drug company, any patent covering a drug would be considered "core" technology and they would ordinarily seek to maximize patent protection and patent term for such patents. However, even large pharmaceutical companies have limited research dollars and cannot pursue every drug to market. Thus, they may consider licensing on an exclusive basis or even selling a patent that covers a drug with a smaller market or a drug outside their key business areas.

In addition to core technology, drug companies also invest in non-core or "enabling" technology that allows them to better make or deliver a drug, and these enabling technologies are often available for license on a non-exclusive basis. Since the technology is not "core" to their business, which is selling drugs, there may be a benefit to obtaining licensing revenue from these patents, and licensing on a non-exclusive basis ensures the maximum number of users.

Thus, it is possible to have more than one patent strategy for different types of patents in your portfolio.

Product Lifecycle

Patent strategy can also vary with the lifecycle of the invention. In the drug industry, a product will not get to market for 6-10 years after patent filing, and it is highly likely that the ultimate product will have evolved since the initial patent application. In this instance, it is important to ensure that a patent is issued that covers the ultimate product, and this may require secondary filings if the product has changed significantly since the initial filing. Further, since drugs have such a long lifecycle, managing patent term is a critical consideration in any patent strategy. Therefore, it is usually important to begin the patent lifecycle with a **provisional** patent application, which saves the priority date but does **not** count against patent term. Other ways of managing patent term are discussed below.

In the electronics industry, by contrast, the product lifecycle is typically in the 2-3 year range and it may be more important to get patents issued quickly. In this instance, one might start with a utility application and pursue fairly narrow, easily issued claims first. The broader claims can then be pursued in a divisional or continuation application.[3] It is also possible to file a "Petition to Make Special" in certain circumstances to speed the process up.

Be aware that even in the quickly evolving electronics industry, there is core technology that can be expected to long outlast a particular model of an electronic device. Thus, there may be different strategies for core technology versus patents directed to particular embodiments of that technology due to the different lifecycles of the various inventions.

Patent Term

As mentioned above, managing patent term is very important in the pharmaceutical industry, where the patent term is the most valuable in its last days. However, any product with a long market life should consider managing patent term as part of its strategy.

There are many methods of managing patent term, ranging from term adjustments to FDA restoration to follow-on filings. Patent term

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[3] Patent rules were scheduled to take effect on November 1, 2007 that allow limit the number of additional filings that can be made. However, implementation of the rules has been permanently enjoined as of April 1, 2008.

adjustments are awarded by the patent office to account for any lost term due to patent office delays. It is also good practice to petition for a longer patent term adjustment where warranted. Your Patent Counsel can elaborate on how to qualify for additional term adjustments.

FDA restorations are available for any product for which market term was lost while awaiting FDA approval before marketing. Thus, drugs, biologics, medical devices and combination products can all obtain an FDA restoration. Applications are made to the FDA very shortly after the product is approved, and about half of the lost time can be awarded. Only a single patent can be extended, and the extension only applies to the actual FDA approved product.

In addition to FDA term restoration, drug companies often plan ahead and make judicious use of **follow-on**, but un-related patent filings to manage their patent term. “Un-related” in this context means that the follow-on application does **not** claim priority to the original filing.

For example, a generic class of drug molecules might be claimed in an initial patent application, but specific members can be claimed in later un-related applications as the pharmaceutical data for such members becomes available. Because the follow-on patent does not claim priority to the original application, its term will run from the new filing date.

Follow-on patents can claim the ultimate product in a variety of ways. For example, different (and perhaps more efficacious) forms of a drug may be patented. As one example, the hemi-hydrate form of Paxil for treating depression is much more stable than the prior art anhydrate form, providing a significant commercial advantage. Similarly, a more convenient dosage form, such as once a day versus three times daily, can provide significant commercial advantage and is worth patenting. Another useful follow-on patent may be the process by which a patented molecule is made. This is particularly useful for biological products that are difficult to make by non-recombinant methods.

A variety of techniques are used to address the possibility of the first application being prior art to the second. First, the follow-on application may be filed **before** publication of the first application—that is within 18 months of the first filing date. This removes the reference as prior art from most countries, and a statutory exemption can remove it as prior art in the US.

Alternatively, researchers may plan ahead to collect comparative data, showing that the new species has **unexpected advantages** over the species disclosed in the original application. Thus, a particular species with a particular activity level might be patentable, even though the genus was disclosed earlier.

Consider planning your research program from the beginning to accommodate your patent strategy, and draft each patent application with follow-on filings in mind.

Patent Scope

In the past, it was common practice to draft patent applications very broadly, trying to capture all possible applications of a technology in the first application. Even if certain applications of the invention were inadequately described or enabled, one could always file a continuation-in-part application with additional data to support the less well described and enabled applications.

Claims were also drafted very broadly, and then narrowed only when necessary to overcome the Examiner's rejections. In a sense, patent practitioners tried for the broadest claim scope possible, and let the search results determine the ultimate scope of the claims.

However, two changes in the law have made these strategies less effective. First, in 1995 patent term was changed to twenty years from filing, rather than 17 years from issue. Thus, although patent applications can still be supplemented with continuation-in-part applications, patent term is all the while ticking away, and the continuation-in-part or "CIP" patent will issue with less patent term. This is particularly detrimental in the pharmaceutical industry, where the last days of patent term can be worth a 1 million dollars a day for a blockbuster drug.

Secondly, the law underwent a change in 2002 when the Supreme Court changed the Doctrine of Equivalents in *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 US 722 (2002). The Doctrine of Equivalents imposes liability for patent infringement when the difference between the claims as written and the accused product is so slight that it would be unfair not to impose liability. Thus, liability is found even though the claims are not literally infringed (see also Chapter 9 below).

Since the *Festo* case, patent practitioners are reluctant to make narrowing changes to patent claims because the patentee is **presumed to have surrendered** all equivalents between the claims as originally presented to the PTO and the claims as finally allowed. Thus, it is common post-*Festo* practice to draft an application with knowledge of the closest prior art and to draft the claims sufficiently narrowly so as to distinguish the invention over this art. In this way, the patent practitioner hopes the claims will be allowed as is, avoiding the detrimental application of any presumptions in later patent litigation.

Because of these changes in the law, and because biotechnology patents often have problems with enablement and written description, it is

may be wiser to draft a patent application tailored to what is enabled and well described. A somewhat narrower application can also make it easier to draft and obtain a follow-on or second generation patent, as discussed above.

Breakthrough versus Improvement Patents

Some companies patent only the most important technological breakthroughs, but do not patent all of the incremental improvements that follow the breakthrough invention. Often, this is due to budgetary constraints, but it can also indicate that patent protection is less critical in that industry than other market considerations, such as good design, or providing cutting edge features ahead of the competition.

In other cases, companies may file a great number of improvement patents, building a "patent thicket" covering essentially all aspects and ways of practicing an invention. This strategy is designed to create very dense patent protection in order to encourage competitors to take a license, either because they cannot navigate a clear path through the entire patent thicket or because the legal costs of analyzing the entire portfolio would be prohibitive. This is true for certain biotechnology and electronics companies that have invested heavily in their patent portfolios.

In certain industries there are companies that are known to **follow** a breakthrough technology and patent many improvements of that technology, thus **surrounding** the breakthrough patent with numerous improvement patents and forcing the breakthrough patentee to cross license its technology if it wants to practice any of these improvements.

Thus, the importance of patents and budgetary constraints determine how many improvement patent applications are filed.

The recent Supreme Court decision in *KSR Int'l Co. v. Teleflex*, 550 US 398 (2007), indicates that it may be more difficult to patent incremental improvements in the future. In that case, the Supreme Court indicated that to patent improvements it is probably necessary to show "unexpected advantages" for the improvement. Thus, comparative studies, unexpected advantages or failed experiments will become even more important in the future.

Patents versus Trade Secrets

Not every innovation needs be patented—some can be protected by trade secret. Trade secret protection is only useful for technology that cannot be easily be reversed engineered, and there is no cost beyond the cost of security measures to keep the trade secret a secret. Other kinds

of intellectual property protection are also available that can be used to complement patent protection (see Chapter 10).

7. INTERNATIONAL PROTECTION

Patents are Geographic

Patents generally **only** provide protection in the country that issued the patent. To obtain protection outside of the US, you must file a patent application in each country where protection is desired.

Costs of Foreign Patents

Applications must be translated into the local language, foreign filing fees paid, and a foreign associate hired to prosecute the application. Thus, the costs can be significant and are in addition to the initial drafting costs and regular annuity payments. Europe and Japan tend to be more expensive, but some other countries cost less, especially English speaking countries. As a rough estimate, set aside $10,000 US dollars for every country for the filing costs and another $10,000 for obtaining and maintaining the patents.

Absolute Novelty

Many foreign countries have an absolute novelty requirement—that is, **any** public use or disclosure of the invention before filing an application will bar the granting of a patent. In contrast, the US has a **one-year grace** period, and a patent may still be granted as long as an application is made within one year of the public use or disclosure.

Priority Date

Many countries will recognize a foreign priority date if an application is filed in that country within one year of the first filing (i.e., the priority date), thus allowing delay of the foreign filing decision. A list of countries allowing a one year priority claim is found at: http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2.

PCT Application

A Patent Cooperation Treaty (PCT) application is a centralized application for more than 170 countries. In other words, a single application can serve as the entry point for each PCT member country, thus allow a patentee to avoid 170 sets of conflicting format requirements.

More information, including a list of PCT contracting states, is available at http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=6

PCT Benefits

A PCT application delays the time that patent applications must be filed in individual countries until 30 months from the priority date. Thus, the foreign filing costs are delayed, allowing more time to explore potential markets, obtain licensees and choose countries in which to pursue patents. Another benefit of filing a PCT application is that a search and examination can be made during the PCT phase. The examination report, while not controlling, is often followed by foreign patent offices. Thus, to the extent that the report is favorable, it can be a benefit.

PCT Disadvantages

The PCT application will **never** mature into a patent. The applicant must eventually pay costs in each country where a patent is pursued. Therefore, the PCT filing approach is more expensive in the long run.

PCT Costs

A PCT application filing fee is about $4-5,000. Costs increase for applications that have more than 20 pages or more than 20 claims.

If you are either a resident or a national of a country which is a member of the PCT (more than 170 are), you can file a PCT application, either as your first filing or based on a national or regional patent application. If are neither a resident nor a national of a PCT member country, you cannot file through the PCT.

EP Application

The European Patent Office (EPO) also has a centralized application, similar to the PCT system. Unlike a PCT application, an EP application will mature into a patent, although translations of the claims for each country where protection is desired are still required. More information is available at http://www.european-patent-office.org/.

Certain African, Eurasian and Middle Eastern countries also have centralized application systems.

Foreign Filing Options

Many foreign filing options are available. However, one common filing strategy is to file in the US and within one year file a PCT application designating all countries. If the first US filing is a provisional application, then it is typical to file **both** the US utility application and the PCT application at the one year deadline. Others file only a PCT application, and then file the US case with other foreign cases at the 30 month deadline.

If the inventors are certain that no competitors are working in the field of the invention, it is possible to abandon the provisional filing date for non-US countries, and file the PCT application one year after the utility application (e.g., 2 years after the provisional date). With this approach, however, there is always the risk that an overlapping patent application was filed within the year that the provisional application was pending. If so, this might prevent or limit what protection can be obtained outside of the US. However, this approach might be reasonable for a company with a very limited budget and in a very new area of technological development.

If world-wide patent protection is essential, a company will also consider filing in non-PCT countries at the one year deadline. This is useful where world-wide markets are already well established. Important non-PCT countries include Argentina and Taiwan.

If there are no existing foreign markets and little realistic possibility of signing up a paying licensee or otherwise obtaining additional capital within 30 months of the priority date, you should consider filing only in the US. PCT applications on improvement inventions may still be filed at a later date when foreign markets or paying licensees are closer to being realized, or when additional capital has been raised.

National Phase

If the PCT filing option is used, you must choose those foreign countries in which to file by the 30 month deadline. Translations take time, so you should plan ahead and give foreign associates at least two months to prepare for this deadline. Otherwise, additional last minute filing costs will be incurred.

A full discussion of foreign filing strategy is too complicated for a short summary such as this. Consult with your Patent Counsel for additional details.

8. RECEIPT OF A US PATENT

Safekeeping

Original US patents should be kept in a safe place. If original patents are lost, certified copies may be obtained from the US Patent and Trademark Office ("PTO") for a nominal fee.

Correction of Printing Errors in the Patent

Applicants are encouraged to proofread their patents for accuracy. Printing errors in a patent can be corrected by preparing and filing in the PTO a request for issuance of a "certificate of correction."

Term of Patent

If the United States utility patent application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the utility or international filing date of the application, subject to any statutory extension.

If the application was filed on or after June 8, 1995, the term of this patent is twenty years from the US or international filing date, subject to any statutory extension.

The term of a design patent grant is fourteen years from issuance.

Required Maintenance Fees

Periodic maintenance fees must be paid to the PTO for most patents, including reissue patents. Payment can be made at any time during the six month period preceding the deadline date set forth below (or within a grace period ending six months after the deadline if a surcharge is paid).

Failure to pay a required maintenance fee results in automatic cancellation of the patent and reinstatement may be difficult or impossible. Maintenance fees can be found in 37 C.F.R. 1.20 or at http://www.PTO.gov/web/offices/ac/qs/ope/fee2005oct01.htm. As of April 1, 2011 the fees were as follows (with a 50% discount for "small entities" such as universities and small businesses); all amounts are subject to change:

Payment Deadline	Amount
3.5 years after issuance	$ 980.00
7.5 years after issuance	$ 2,480.00
11.5 years after issuance	$ 4,110.00

Address Changes

A patent owner should keep the PTO apprised of its current correspondence address and fee address. Note that recordation in the PTO of an assignment of a patent does **not** change the correspondence address nor the fee address for the patent in question.

Marking of Certain Patented Items

All articles covered by a US patent and made or sold in the US by the patent owner (or a licensee thereof) should be marked "Patent" or "Pat." and the patent number. EXAMPLE: "US Pat. No. 5,432,123." All patents that cover any such product should be marked on the product in this way. By statute, in the absence of such marking an infringer might be liable for damages only for acts of infringement committed after receiving formal notice of infringement from the patent owner.

Other Marking and Display of the Patent Number

It is usually advisable to refer to the patent number (whether the patent covers a product or a process) in promotional and instructional materials, publications, and brochures dealing with the patented invention. Mention of the patent in this manner may help demonstrate that an infringer's conduct was willful, which in turn can help in obtaining certain types of judicial relief such as recovery of attorneys' fees and/or increased damages.

Do **not** mark products with patent numbers that do not cover the product, as this can subject you to penalties.

Broadening Patent Claim Coverage Through Reissue

A "reissue" application may be filed to correct a patent that, through error without deceptive intent, is defective. Notably, a reissue application that is filed within two years of issuance may include broadened claims if, through error, the original patent's claims are too narrow. Additional information on this point is available from your Patent Counsel.

9. PATENT ENFORCEMENT

The whole point of obtaining a patent is to exclude others from making, using or selling the claimed invention. Assuming that you have not sold or licensed the patent to someone else, you may find yourself with a need to enforce this right.

Generally, one begins the process by sending notice of a patent to an alleged infringer. Care should be taken in drafting this letter, because you may inadvertently give the recipient a right to bring a suit in an undesirable location. Therefore, typically the initial letter does little more than bring a patent to an alleged infringer's attention, and perhaps suggest that the owner might be amenable to licensing discussions.

If licensing attempts fail, or the patent owner has no desire to license others, the patent owner may proceed to bring a patent infringement lawsuit. This suit must be brought in a Federal court, since patents are a creation of the federal laws.

Patent litigation is very expensive, averaging about 3 million dollars in 2009, and thus is not undertaken lightly. Further, in addition to the financial costs, litigation is stressful and time consuming for both the managers of a company and the inventors and can go on for years. Nonetheless, sometimes it is critical to the life of the company to assert a patent forcefully and litigation is initiated.

When a patent infringement lawsuit is filed, the opposing side will counterattack. Typically, they will assert that the patent is invalid because it is not new (e.g., the patent is "anticipated"). Alternatively, they may argue that the invention is "obvious." They may also attack the patent based on a failure to comply with the duty of candor and such failure is called "inequitable conduct." Additionally, patents can be attacked for failure of "written description" or "enablement" or as being "indefinite." Defendants may also assert that their own patents are infringed.

There are many creative attacks that can be launched by opposing counsel, and you can be sure that they will discover all of the embarrassing e-mail, and damaging documents in the bottoms of drawers and on hard drives.

Litigation begins with a lengthy phase called "discovery" whereby both sides exchange documents. This can take a long time—sometimes years—and the parties may decide to settle the case when they see the other side's documents.

If the case proceeds beyond discovery, the court will first have to "construe the claims" or tell us what the claims mean. This "claim construction" is reviewable *de novo* (from scratch) by the appeals court, known as the Federal Circuit. If an appeal is required, it will further delay the time to fully resolve the lawsuit.

After claim construction, the accused product or method is compared against the construed claims to determine if they infringe. In other words, do the construed claims "read on" the accused product or method. If they do, then there is "literal infringement" and the infringer will have to pay at least a reasonable royalty.

Further, if their actions were "willful" and they acted badly or in wanton disregard of patent rights, the court may apply a multiplier as high as three times (3X) to the damages award. This is called "treble damages." The infringer might even be required to pay attorney fees. Often, this part of the case is only addressed after infringement is found.

Sometimes the infringer changed a very minor component of the accused product only very slightly, and it is felt that allowing them to avoid infringement with such a minor deviation outside the claim scope would not be fair, thus infringement is found under the "doctrine of equivalents." The doctrine of equivalents allows minor variations from the literal claim language to still be included in the scope of the claim. There are legal limitations on the scope of the doctrine of equivalents that are too complex to be discussed herein, and it is always better to have literal infringement than infringement under the Doctrine of Equivalents.

Assuming that the court found infringement and awarded the patent owner a reasonable royalty, the owner must still collect that money and that can be difficult. If the infringer lacks assets, he may simply declare bankruptcy and disappear. However, a substantial company will usually initiate settlement discussions at this point (if not sooner). If the company declines to settle or pay the judgment, yet another legal action might be required to collect the damage award.

This discussion of patent litigation is greatly simplified to give you a general understanding of what to expect in a patent infringement case. Consult your Patent Counsel for additional information.

10. OTHER TYPES OF PROTECTION

There are several different types of intellectual property protection that are available, including patents as discussed above, trade secrets. copyrights, and trademarks or service marks. Although there may be some similarities among these kinds of intellectual property protection, they are different and serve different purposes.

Patents

Patents provide the right to exclude others from making using or selling a claimed invention and the right is generally good for 20 years from filing. However, the process of obtaining a patent is quite rigorous, requiring examination where the applicant must show utility, novelty and non-obviousness. Further, the process can be quite expensive, requiring tens of thousands of dollars.

Trade Secrets

A trade secret includes any secret information that a company deems of value. It could range from secret formula (for example the Coke® recipe) to customer lists to design drawings. A trade secret can be protected forever, so long as the information does not become publicly available. Further, there is no cost to obtaining a trade secret, beyond the costs of the security measures needed to keep the information secret. Trade secrets are only useful where a product cannot easily be reverse engineered.

Trademark

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. The terms “trademark” and “mark” are commonly used to refer to both trademarks and servicemarks.

Trademark rights may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same goods or services under a clearly different mark.

Trademarks that are used in interstate or foreign commerce may be registered with the PTO, as well as with state offices, and the process is much less expensive than obtaining a patent. However, trademark rights exist even if the mark is not registered with the PTO. The registration is useful however, because it confers additional procedural rights and puts the world on notice of your trademark claims. General information concerning trademarks can be found at:

http://www.PTO.gov/web/offices/tac/doc/basic/.

The procedure for obtaining a trademark is much easier than that of obtaining a patent. All that need be shown is actual use in commerce, and that the trademark is not confusingly similar to another mark, and not descriptive or generic.

A trademark can last forever, as long as the owner takes steps to control the quality of the goods associated with the trademark, and to prevent the use of the mark from becoming generic. For example, aspirin used to be a brand name for a acetylsalicylic acid (ASA), but it is now used generically in the US to describe any ASA containing product.

Copyright

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.

Copyright generally gives the owner the exclusive right to reproduce the copyrighted work, to prepare derivative works, to distribute copies or phonorecords of the copyrighted work, or to perform or display the copyrighted work publicly.

Copyright is generally available for the life of the author plus 70 years. For an anonymous work, or a work made for hire, the copyright endures for a term of 95 years from the year of its first publication or a term of 120 years from the year of its creation, whichever expires first. General information about copyrights is available at http://www.copyright.gov/.

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 actual description; it would not prevent others from writing a description of their own or from making and using the machine.

Copyrights are registered by the Copyright Office of the Library of Congress. However, the copyright exist independently of registration, and the registration only provides certain procedural rights and provides notice

to third parties of your copyright claims. Registration is very inexpensive, although there is a mandatory deposit requirement, and there is no examination of the registration.

All forms of Intellectual Property can be used to protect different aspects of the same products. For example, a drug may have a patent on the actual chemical compound in the drug, but certain special formulation techniques may be kept a trade secret. The brand name of the drug would be protected by trademark, and the advertisements may be protected by copyright. The unique shape of the pill may even be protected by design patent. Consult your Intellectual Property Counsel for a complete discussion of how you can use these various forms of Intellectual Property protection to protect your products.

Comparison of Types of Intellectual Property Protection

Type of Intellectual Property	**Ease of Ownership or Registration**	**Length of Protection**	**Scope of Protection**	**App. Fees (Legal Fees)**
Utility Patent	Difficult	20 years	Right to exclude others from making, using & selling invention	**~ $1000 ($10-20,000)**
Design Patent	Medium	14 years	Right to exclude others from making, using & selling design	**~ $200 ($1-2000)**
Copyright Registration	Easy	Individual: life + 70 years Business: 95 years from publication or 120 years from creation, whichever is shorter.	Exclusive right to reproduce, display & create derivative works	**~ $30 ($2-400)**
Federal Trademark Registration	Medium	Perpetual as long as in commercial use, quality maintained, and not allowed use as a generic term	Exclusive use of mark and "confusingly similar" marks	**~ $375 ($2-4000)**
Trade secret	**Only requires reasonable precautions to keep secret**	**Perpetual as long as it is kept a secret**	**Right to stop others from using trade secret only if improperly taken**	**Only cost to keep secret**

11. FDA BASICS

Although this booklet is mainly about patent law, many products in the life sciences will also be subject to food and drug laws. Therefore, it is worth learning the Food and Drug Administration ("FDA") basics.

The FDA provides significant barriers to market entry because drugs, biologics and certain medical devices cannot be placed on the market without prior FDA approval. Before approval, one must generally show that the product is safe and effective, and this is generally proven in clinical trials with human patients.

Before a company can even begin clinical trials for a new drug or biologic, permission from the FDA is required, and is applied for in a investigational new drug application or "IND," which is usually supported by animal testing results. When the clinical trials are completed, a new drug application or "NDA" is filed for a new small molecule drug, and the equivalent application for most biologics is the biologic license application or "BLA".

NDA and BLA applications are very large, containing all of the manufacturing and stability testing data, proposed labeling, as well as all of the clinical and animal data establishing that the drug or biologic is both safe and efficacious for its proposed use.

Medical devices, in contrast, present a wide range of risk for patients, ranging from little or no risk posed by bandages to a high degree of risk posed by pacemakers. Therefore, there are three levels of medical device regulation—Class I to III—and the regulations generally increase with the classification.

The premarket notification application or PMA is roughly analogous to the NDA or BLA and requires complete manufacturing information, proposed labeling, and all animal testing and clinical trial results. Further, an investigational device exception or "IDE" is required before clinical trials can begin, and is analogous to the IND.

The 501(k) application is for less risky devices and the application need only establish that the device is "substantially equivalent" to a predicate device. Clinical data may or may not be required to support a 510(k), depending on the device.

It is important to remember that PMA products are said to be "approved," whereas 501(k) products are "cleared." The FDA takes these distinctions seriously, and more than one company has received warning letters for using incorrect terminology.

Generally speaking, class III devices are subject to PMA approval, Class II are subject to 510(k) clearance and Class I devices are exempt from the approval requirements, although they are still regulated. However, there are many instances where the classification and the type of approval process do not coincide because many class III devices were already on the market when the law was enacted and thus are cleared under a 510(k) application.

In addition to the premarket approval requirements for many healthcare products, there are certain instances when the FDA will **withhold** approval of certain drugs and biologics for a period of time, and to understand why, we must first understand 1984 amendments to the food and drug laws.

In 1984 Congress enacted "The Drug Price Competition and Patent Term Restoration Act," more commonly known as the "Hatch-Waxman Act." The purpose of Hatch-Waxman was to strike a balance between brand-name and generic drug manufacturers by providing incentives to produce new drugs, while offering quick FDA approval for low cost generic drugs.

Prior to the Act, generic drugs had to undergo the **same** rigorous safety and effectiveness testing that new drugs underwent. Hatch-Waxman created a faster approval process for generic drugs, allowing generic manufacturers to file an "Abbreviated New Drug Application" or "ANDA" that is supported only by showing that the generic drug is "the same" as or "bioequivalent" to an already approved drug. This process is somewhat analogous to the 510(k) approval process, which was already in existence when the Hatch-Waxman Act was passed into law.

Hatch-Waxman also provided a "safe harbor" against patent infringement, expressly overruling the 1984 *Roche v. Bolar* decision holding that clinical tests conducted by generic manufacturers before patent expiration were infringing. As a result of *Roche v. Bolar,* market exclusivity was extended beyond the patent term, because the generic manufacturer could not even **begin** FDA testing until the patent expired. Hatch-Waxman changed this, allowing bioequivalence testing to be performed **prior** to patent expiration. As a consequence, the FDA can now approve generic drug applications immediately on patent expiration, and generics can reach the market more quickly.

In exchange for allowing easier and faster generic drug approvals, the Act established patent term restorations for innovator drugs. Because new drug patents usually issue long before the drug receives FDA approval, part of the patent term is spent performing clinical trials and that portion of exclusive market time is lost. Patent term restorations were intended to offset the term used up during the approval process.

There are some limits to the restoration—it cannot exceed five years, nor can the period between product approval and patent expiration exceed 14 years. The patentee must also act with "due diligence" throughout the regulatory period. That is they must not delay FDA review and anyone can challenge a restoration on that basis.

The Act also provides a dispute resolution procedure. The ANDA rules offer four routes for marketing of generic drugs. Three routes–called Paragraph I, Paragraph II, and Paragraph III certifications–apply to ANDA filings that do not involve challenges to patents. Through these routes, multiple generics can enter the market at the same time, creating a very competitive market.

The fourth route is called a Paragraph IV certification. It applies when patent protection has not expired, and the generic drug maker claims that **either** that the patent is invalid **or** that its product does not infringe the patent.

Paragraph IV certifications are desirable, because the **first** to file one becomes eligible for 6 months of market exclusivity, during which time the FDA will not approve any other generic drug application. In this way, the Act encourages challenges to patents, thus bringing cheaper generic drugs to the market more quickly.

However, the rules also provide that a Paragraph IV certification is an infringing act, allowing the patentee to sue the generic manufacturer for patent infringement and obtaining an **automatic** 30-month stay on FDA approval.

In addition to the abbreviated generic drug approval procedures and Paragraph IV certification scheme, the FDA also provides 5 years of data exclusivity when a new drug application is filed on a new chemical entity. During the five year period, the FDA will not approve a second application covering the same chemical entity unless the Applicant provides its **own** safety and efficacy data. Since generating safety and efficacy data is so expensive, this has the practical effect of excluding generic applicants for the five years, even if there are no blocking patents.

There are also FDA exclusivities applicable for new uses for a drug, pediatric studies, orphan drugs, and biologics, but there is no equivalent exclusivity period for medical devices. Table 1 lists these exclusivities.

Table 1: Summary of FDA exclusivity periods

Type	Requirements	Period	Cumulative
New Chemical Entity	Chemical entities never previously approved by FDA either alone or in combination with other drugs. Bars 505(b)(2) and ANDA	5 years 12 years for biologics	No

	applications for five years where applicant has not provided its own data or authorized data. Can be reduced to 4 years if ANDA application contains a ¶ IV certification. 12 years data exclusivity and four year submission exclusivity for biologics.		
New or Modified Indication	Changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the application containing those changes. Bars 505(b)(2) or ANDA applications where applicant has not provided own data or authorized data. Not available for biologics	3 years	No
Pediatric	FDA must request pediatric data, can be two pediatric term extensions, scope of protection same as that to which the 6 months is appended.	6 months	Yes
Orphan Drug	For a rare disease affecting fewer than 200,000, bars any other FDA applications for that disease for 7 years, unless the holder cannot manufacture sufficient quantities to meet the needs or the holder gives consent.	7 years	no
First ANDA	First to file ANDA for generic drug with ¶ IV certification challenging a patent Bars subsequent ANDA applications until 6 months after first marketing or favorable patent decision. If patentee files infringement suit, first ANDA is stayed for 30 months.	6 months for ANDA applicant 30 months for patentee	no
Animal Product	Includes both new animal drugs and new uses. Can be reduced to 4 years if ANDA application contains a ¶ IV certification	5 years for new animal drug 3 years for new use	no

The final piece of the FDA puzzle is the generic drug therapeutic equivalence ratings. Basically, any rating that starts with an "A" is either bioequivalent or the FDA considers bioequivalence to be irrelevant. Thus, "AB" means bioequivalence has been studied and demonstrated, and it is **not** a lower rating than "AA". The ratings AA, AN, AO, and AP do not require bioequivalence studies, because the FDA believes them to be unnecessary.

In contrast, drug products for which actual or potential bioequivalence problems have not been resolved begin with "B". Usually, the problem is with specific dosage forms or formulations, rather than with the active ingredients. These are designated BC, BD, BE, BN, BP, BR, BS, BT, BX, or B*. For example, an ointment would probably get a B rating if the name brand drug was formulated as a cream.

In order for a pharmacist to exchange a name brand drug with a generic, it must have an A rating—the pharmacists cannot automatically switch to a B rated drug in most states. Therefore, A ratings are highly desirable, and indeed, an A rated generic drug can take 50-80% of a name brand drug market within a year of market entry, whereas B rated generics usually gain much less market share.

12. TEN ISSUES FOR THE START-UP

A successful life science start-up company needs more than a good idea backed by good science to be successful. It also needs to fund its research, obtain patent protection, negotiate good deals, obtain FDA authorization, develop good manufacturing practices, sell the product with sufficient margin to cover all of these early expenditures, and to comply with all post-market FDA requirements.

Clearly these very different tasks require people with different expertise, and no single person could do it all. Yet at the beginning, a new company may be on a shoe string budget—often financed with an inventors own savings—so that one or a very few people DO have to do it all. This chapter describes 10 tips to help the entrepreneurial scientist make the transition from the lab bench to the marketplace. Hopefully, with these tips you can avoid some of the potholes along the way and make your start-up a success.

1. Get it in Writing

Research scientists often start companies backed only with a good idea, some basic research, personal savings and a few colleagues. Sometimes in the excitement of the moment and with a dearth of funds, the founders don't prepare the proper written contracts at the beginning. This is a BIG mistake! You can be sure that AFTER a technology generates commercial interest that everyone involved will have a different recollection of what they were supposed to do and what their ownership stake was. Even if you have to draft the contracts yourself, get everything in writing before taking any further steps. At the minimum, the agreements should address the scope of employment, confidentiality obligations, and ownership of both the resulting intellectual property (IP) and the company.

Be extra careful where inventions might be made with collaborators or contractors outside the company. The default rule in the US is that the employer owns all inventions made by its employees and that co-owners of a patent can each use or license the patent WITHOUT paying the other. Therefore, it is essential to have written contracts addressing the ownership of Intellectual Property before beginning any work with a non-employee.

2. Cultivate A Culture of Invention

Scientists in the life sciences may not be in the habit of thinking about invention and commercialization, and sometimes they don't even believe that patents should be awarded for life science research. But to be successful, a company must cultivate a culture of invention. After all, without commercialization, even the best science will never benefit the public and without patents, basic research often can't get funded.

Start down the right road by having monthly patent meetings where employees can brainstorm about product ideas and new methodologies. Reward each employee for filing a patent disclosure and then again on patent issuance. It doesn't have to be a large amount of money—a small honorarium coupled with recognition and a plaque go a long way towards making scientists take the time away from their research and write up a good patent disclosure. Having donuts or pizza at all meetings helps too!

3. Getting Inventorship Right

Inventorship has a strict legal meaning in US law and it is critical that the correct inventors be named on a patent application. Falsifying the inventors can result in that patent being unenforceable and therefore worthless! Further, inventorship is NOT the same as authorship, NOR is it the same as leadership.

Determining inventorship is quite tricky, but simply explained it is based on contributing to the "conception" of the invention. In other words, the inventor is the person or persons who had a "definite and firm idea" of the invention, and the "invention" is defined with reference to the actual patent claims. Occasionally, in less predictable fields (like biology and medicine), it isn't possible to have a sufficient conception until the invention is reduced to practice, and thus the inventors would also include the person who actually "made" the product. This might be true, for example, in cloning a new gene.

To ensure that a company gets the inventorship correct, the inventorship of each claim can be discussed at the monthly patent meeting once the application is drafted. Each person who believes they invented a claim, or a part thereof, should circle that part of the claim and present their proof of conception—ideally a witnessed notebook or meeting notes. With this information, Patent Counsel can ensure that the correct inventors are named on the application.

4. Using Hardbound Notebooks

In any court dispute over inventorship, the QUALITY of the evidence is critical to win the case. Thus, lab notebooks should be hard bound with numbered pages and each employee should keep track of his or her ideas and all data. It should be witnessed and signed each week, taking care to cross off any unused portions of the pages. If possible, it would be best if someone with no interest in the company witnessed the book, but this may not be practical given the confidential information it contains. This notebook will be critical to the company's survival if an inventorship dispute ever arises with a third party and management must be rigorous about enforcing the notebook rules.

5. Planning a Patent Strategy

Obtaining patents can mean the difference between getting funding or outright failure of the company. Additionally, companies should file patent applications as early as possible to beat possible competitors. Yet, patents are expensive—expect to spend $10-20 thousand dollars per country to obtain patent protection. Therefore, it's important to decide early on a patent strategy the company can afford.

First, ALWAYS start with a provisional application. This should be as well drafted as possible, but in pinch you can file it yourself for minimal cost and gain a year to generate the funds needed to convert the provisional application to a regular patent application within the one year deadline. Consider various types of claims that might cover various aspects of the invention and try to describe reasonable variations of each. Claims can recite new features, entire devices housing those features, computer or web-based systems using the device or data, compounds, as well as method of manufacture and use of those compounds, devices or systems. The provisional application doesn't count against term, so this approach will also result in an additional year of patent term—an important consideration for any FDA regulated product.

Second, know the prior art and provide Patent Counsel both an excellent disclosure and copies of the best prior art. Educate Patent Counsel about the invention, and explain the differences between invention and the closest prior art. Employees should retain and include failed experiments in the invention disclosures as well. In the current legal environment, it can be difficult to obtain patent protection, and sometime failed experiments provide the best evidence that a patent should be granted.

Third, realistically consider when the company can anticipate financing and how many countries it can afford to file in at each stage of the financing. A PCT application is a patent application that covers more

than a hundred countries, but it costs about $4-5000 just in filing fees and it will NEVER mature into a patent. Instead, it holds the Applicant's place for 30 months from the initial filing date while the Applicant decides which countries to file in and arranges the needed funds. Thus, if a company can only afford to file patent applications in Europe and/or the US, it will probably be cheaper to file at the one year conversion deadline in both places, than to file a PCT, followed by filing in Europe and the US.

Consider also what useful foreign patent protection might be obtained in a second generation patent. Second generation or "follow-on" patents can be filed in more countries, and with a new initial filing date, the follow-on patent will have a longer patent term too. Remember to plan your research program and draft patent applications with these follow-on patents in mind.

6. Planning an FDA Strategy

Obtaining FDA approval for drugs and certain medical devices is an expensive process. Founders will have to learn enough about the FDA rules to be conversant about the requirements and to decide on the most cost effective, least risky, approval strategy. It is too complicated a subject to address adequately in this short chapter, but realize that the FDA is in one sense an advertising agency, and their goal is to ensure that product labels are not misleading to the public. Thus, a company can influence the difficulty of the FDA process by choosing WHICH medical claims to include on a label.

For example, proving safety and efficacy in breast cancer may be a significant endeavor, involving very large clinical trials. It might be easier to prove safety and efficacy in pancreatic cancer, which has no suitable treatment available, and thus expedited approval procedures may be available. Similarly, one could pursue an orphan drug designation, resulting in smaller study size and possibly faster approval. In the device arena, a more modest claim may mean that a filing can be based on a existing similar device and avoid the need for clinical trials, whereas claiming more innovative uses may necessitate a full approval application with clinical trials being required.

In each case, broader approvals can still be obtained after the more narrow use is approved, and this approach can decrease your time to market and make it much easier to obtain financing along the way. At the same time, be cautious of choosing an indication that will be difficult or impossible to enroll patients, and also an indication that has so little market potential as to discourage investors. A careful understanding of the FDA process, medical realities AND market considerations are all required to choose an optimal FDA strategy.

Remember to consider how FDA barriers to market entry combine with patents to protect your market. Therefore, even a very narrow patent directed to a drug formulation can be very valuable, because generic drug competitors must either risk infringing that patent, or get a "B" rating because they avoided the patent by re-formulating their generic drug.

As an example, a cream name brand drug is protected by a narrow formulation patent. Although easily designed around by formulating the generic as an ointment, this is less desirable because ointments are greasy and because the changed formulation will likely give the ointment a B rating. Thus, the formulation patent is very valuable, even though of narrow scope.

7. Loosening the Reins

It is clear that good marketing and business savvy are required to convince investors to part with their funds. Effective communication and direction from the helm is therefore critical to a company's success, and if the founders cannot fulfill this role, it may be necessary to hire someone to meet this need fairly early on.

Founders should be prepare to realize their limitations, and not hesitate to hire a Chief Executive Officer (CEO) when ability or time limitations mean that the marketing, managerial and business needs cannot be met by the founders. Founders should also be prepared to listen to—and take—the advice of the CEO. Business realities sometimes dictate different directions or priorities than might be suggested by purely scientific considerations.

8. Stirring Public Interest

Public interest in your company can be very valuable. If an investors have **heard** of the company, they will be more receptive to a pitch and possible investment. One way to generate public interest is to publish early and often in many different venues, ranging from peer reviewed journals to magazines and newspapers to shameless advertising. Since most foreign countries don't allow patent protection once an invention is disclosed, all publications should be cleared at the monthly patent meeting BEFORE being shared with anyone outside the company. This includes grant proposals, which become publicly available on grant unless "Confidential Proprietary Information" is marked on each page.

Once published, post copies of every publication on the company website so that colleagues and investors can easily refer to and cite the work (make sure your copyright agreement with the publisher allows for this).

Good public speakers inside the company should accept every public speaking opportunity that arises at a variety of venues including scientific, technology incubator and investor meetings. Founders and the CEO should prepare and hone an "elevator pitch"—a 90 second speech that tells a potential investor what the technology is, what the market potential is, what the current status of the company is and how much investment is needed for the next step. The founders and CEO will give this pitch hundreds of times as they seek investors.

9. Financing the Company

Not all money is the same, and some types of financings trade control for money. Therefore, the founders need a basic education in finance and to understand the different types of financing available in order to make wise decisions. If a company is trading control for money, get to know the financer and make sure that company management can effectively work with that person (or persons), and that it is someone with sufficient experience in the technology to make good decisions.

Be careful about encumbering the company too heavily up front. If you promise inventors or early investors a significant royalty percentage, what will be left for later investors that finance the bulk of the research? Similarly, employment agreements with significant termination packages may deter future investors, as might onerous share ownership packages.

The company will also need an excellent business plan that addresses its FDA, patent and market strategies. Local technology incubators can help with this and there are several good books on writing a winning business plan for the technology start-up. Consider the advice of serial entrepreneurs and investors when they critique your business plan, and update the plan as needed.

The company should apply for every available grant, award or prize, including scientific grants, small business or technology grants, state grants and awards or prizes. Good writing skills are needed to be successful at application writing, and it's not necessarily the same as writing scientific papers. Consider using or consulting with a professional grant writer if company grant proposals seem to be failing.

10. Preparing for Due Diligence

We have discussed the path to commercialization as though that was every start-up company's ultimate goal. But there are many different exit strategies, ranging from obtaining private investment to selling the company outright to partnering with a bigger company to going public with an Initial Public Offering (IPO) of shares. Regardless of what the company's strategy is, be prepared and have all of the company

documents well organized and available for the inevitable due diligence that will occur.

PDF all documents and label each in a meaningful way. Organize the PDF files in a sensible way in well-labeled folders, and keep copies of all e-files in an offsite location too, preferably in another city—something Katrina taught us all. Due diligence files should include at least the following categories:

1. Organizational: including all incorporation documents, bylaws and the like.

2. Financial: include copies of all financing documents, lists of shareholders, tax filings, business plan, market analyses and the like.

3. Employment: including copies of all employment contracts and any related employee benefit information, including a summary of all employees and their significant rights.

4. Confidentiality Agreements: including copies of each, and ensure that everyone with access to confidential information, including third party vendors, executes a confidentiality agreement.

5. Intellectual Property: Including copies of all patent applications and assignments, and include an up-to-date summary of patents, their ownership, the scope of claims, freedom to operate, status, maintenance and expiry information. Include additional files for trademarks, trade secrets, copyrights and domain names as needed.

6. Licenses: Including copies of all in-and out-licensed technology, and include a summary describing the general scope of each and significant terms, such as royalty obligations, and restrictions on transfer, field of use, or geography.

7. Contracts: including copies of all non-employee contracts such as with laboratory or computer service providers, landlords, and the like.

8. Publicity: including copies of all publications, press releases and brochures.

9. FDA: Including copies of all communications with the FDA and all supporting data.

10. Other: including such material as lists of assets, real estate, a description of any disputes or litigation and supporting documents, environmental documents including permits, audits and lists of hazardous materials, etc.

We hope that these ten tips give you the courage needed to start a technology company and give your company a better chance at success.

The risks are great, but the rewards can also be great and what better way to express a passion for research and commitment to the betterment of humanity.

13. PATENT STATUTES

The prior description of basic patent law principles was greatly simplified for ease of comprehension, but in fact there is considerable complexity in the details. Therefore, we have also included the most important statutory provisions from 35 United States Code (35 U.S.C.) and 37 Code of Federal Regulations (37 C.F.R.) for your reference. Please note that the new patent reform provisions have **not** yet been included in these statutes, but are expected to become available over the next year. This booklet will be updated at that time.

§101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

§102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international

application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(g)(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

§103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if--

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(b)(2) A patent issued on a process under paragraph (1)--

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(b)(3) For purposes of paragraph (1), the term "biotechnological process" means

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to--

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(c)(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if--

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(c)(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement

entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

35 U.S.C. 112 Specification.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

§271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(e)(2) It shall be an act of infringement to submit -

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151— 158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a

patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(e)(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(e)(4) For an act of infringement described in paragraph (2)-

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product. The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(e)(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components

of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(f)(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after -

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee or any assignee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

37 C.F.R. § 1.56 Duty to Disclose Information Material to Patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination

occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the

specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

14. ADDITIONAL RESOURCES

Additional educational material is available at the following links:

The patent statue can be found in 35 U.S.C. at http://www.law.cornell.edu/uscode/ and http://uscode.house.gov/search/criteria.shtml. A complete copy of the statute is available in the Manual for Patent Examining Procedure (MPEP) at Appendix L.

The patent regulations are in 37 C.F.R. at http://www4.law.cornell.edu/cfr/ and http://www.gpoaccess.gov/cfr/index.html. A copy of the regulations are available in the MPEP at Appendix R.

A searchable MPEP is at http://patents.ame.nd.edu/mpep/search.html. A PDF can also be downloaded at http://www.PTO.gov/web/offices/pac/mpep/mpep.htm. However, you should be warned that the MPEP is **very** large.

Considerable basic patent information by the PTO is available at http://www.PTO.gov/main/patents.htm.

The PTO fee information is at http://www.PTO.gov/go/fees/index.html

Free patent searching can be done at http://www.PTO.gov/patft/index.html or http://ep.espacenet.com/ and free patent PDF files can be downloaded from http://www.pat2pdf.org/ or http://www.freepatentsonline.com/

Other important patents sites include WIPO at http://www.wipo.int/portal/index.html.en and EPO at http://www.epo.org/

An FDA glossary can be found at http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm and a large list of acronyms can be downloaded at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/ucm116266.pdf.

FDA regulations can be searched at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

The Food Drug and Cosmetic Act or FDCA is codified at 21 USC and can be found at http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/default.htm. There are additional related laws at 42 USC

as well as other places, but most of the drug and medical device laws can be found here. Searchable USC sites are also provided above.

The Orange Book is the place where patents relating to approved drugs are listed. It can be searched at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. The equivalent for animal drugs is the Green Book, which is found at http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm and is searchable at http://www.accessdata.fda.gov/scripts/animaldrugsatfda/.

510(k) cleared medical devices can be searched at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm and PMA approved devices can be searched at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

15. PATENT GLOSSARY

Abstract—A brief (150 word or less) summary of a patent, usually printed on the first page.

Actual Reduction to Practice—See Reduction to Practice.

All Elements Rule—An accused device only infringes a claim if it includes all elements of the claim, either literally or under the Doctrine of Equivalents.

Allowed, Allowance—When the Examiner decides that a claim in an application is patentable, it is "allowed." If all of the claims in the application are allowed, the Examiner will issue a "Notice of Allowability and Issue Fee Due," indicating that examination of the application is now over, and setting a deadline (three months, typically) for paying the issue fee. Often, this is accompanied by a document entitled "Reasons for Allowance," in which the Examiner explains why he or she thinks the claims are patentable. Once the issue fee is paid, the PTO will issue the patent.

Antecedent Basis—Any term you refer to in a patent claim as "the …" must have been named previously in that claim, or one upon which it depends. That is, if a claim reads, "2. The widget of claim 1, in which the fringe is bidirectional," the word "fringe" must appear in claim 1 in a way that would permit the reader of the claim to determine what "the fringe" is. If "a fringe" does not appear in claim 1, then claim 2 would be rejected as "lacking antecedent basis."

Annuity—Annual payment to keep patent or patent application alive in some countries. In the US, fees are due 3.5, 7.5 and 11.5 years after issue, and are called "Maintenance Fees" (see below).

Appeal—Asking a higher authority to review a decision. Some decisions of Examiners (i.e. final rejections) may be reviewed by appeal to the Board of Patent Appeals and Interferences (BPAI). Some BPAI decisions may be appealed to the Court of Appeals for the Federal Circuit (CAFC) and Federal Circuit decisions are appealable to the Supreme Court. Some decisions that are not appealable may be overturned by petitioning the Commissioner of Patents.

Applicant—The person filing the patent application. In the US, patent applications are always filed in the name of the actual inventors,

who may then assign their rights to, for example, their employer. In other countries, the “assignee” and the “applicant” are the same.

Apparatus Claim—A claim that describes a device or product. For example, “A widget comprising a handle and a spiral arm set at right angles to the handle.”

Art Unit—The Examiners in the Patent Office are organized into “Technology Centers,” which cover broad ranges of technologies, and the Technology Centers are further divided into “Art Units.”

Assignee—Person who buys and thus owns the rights to a patent.

Assignment—As a verb it is “selling” a patent or application, and as a noun it is the actual document evidencing the sale. See also “license.”

Assignor—Seller of the rights to a patent.

BPAI—Board of Patent Appeals and Interferences. A part of the PTO that is staffed by senior Examiners and hears appeals from decisions of Examiners and interferences between competing inventors.

Best Mode—A condition for the grant of a patent. An inventor must describe the best materials and methods he or she knows for carrying out the invention.

CAFC—Court of Appeals for the Federal Circuit. The Federal Appellate Court that hears primarily appeals from District Courts or the PTO in patent and trademark cases.

CIP—See Continuation-In-Part.

Claim—That part of the patent that defines the limits of the grant of rights. A claim may be “independent” or “dependent” (e.g., refer to another claim). Claims are written in a very odd legalistic form, in which every claim starts with a capital letter (the only capital letter permitted in the claim) and ends with a period (the only one permitted in the claim), and each element in the claim must be named before it is used (it must have “antecedent basis”).

Class—The PTO uses its own US Patent Classification System, in which all inventions are first put in a class having a three-digit number, then in a numbered subclass under the class. The subclasses are arranged in a hierarchical form, but not necessarily in numerical order.

Conception—When an inventor has a "definite and firm idea" of an invention. Must be followed by "reduction to practice" to complete the act of invention.

Confirmation Number—A four-digit number which the PTO uses to make sure that any papers filed in the case are assigned to the right file.

Co-inventor—One of two or more people who contributed to the conception of an invention. Note that mere reduction to practice does not make one a co-inventor, it is contributing to the "conception" that is key.

Constructive Reduction to Practice—Building the invention is "actual reduction to practice" but one can complete the act of invention by filing a patent application and this is known as "constructive" reduction to practice. Since the invention has not been built, it is not "actually" reduced to practice, but only "constructively" (e.g. by a legal fiction).

Continuation—A patent application filed to continue prosecution on an earlier-filed application, perhaps to present new arguments or evidence (but not to add new matter— see "Continuation-In-Part," below). The difference between a "continuation" and an RCE (see below) is that a continuation is a new application and will receive a new application number, whereas under an RCE, the old application continues on. A continuation may be filed at any time during the pendency of an application (i.e. before it is abandoned or issues as a patent).

Continuation-in-Part (CIP)—A patent application filed to add new material to an earlier filed application, or to claim a new embodiment of an invention disclosed in an earlier application. Anything that was in the original application is given the benefit of the filing date of the original application. Any new matter added in the CIP receives the actual filing date of the CIP. A CIP may be filed at any time during the pendency of an application (i.e. before it is abandoned or issues as a patent).

Continuing Prosecution Application—The CPA was a predecessor to the "Request for Continued Examination" (RCE) and is now obsolete. A CPA was filed to continue prosecution on the parent application without having to file a completely new application.

Contributory Infringement—Manufacture, use or sale of a part of a patented combination, or manufacture or sale of a device that is used by others in a way to infringe a method claim. Note that (1) there cannot be contributory infringement by a supplier without direct infringement by the customer; and (2) there is no contributory infringement by a part that has a substantial noninfringing use.

CPA—See Continuing Prosecution Application.

Date of Invention—The date the invention is completed—that is, both conceived and reduced to practice.

Design Patent—A special kind of patent that covers the ornamental appearance of a useful object and has a 14 year term.

Dependent Claim—A claim that is based upon and narrows another claim by adding another claimed feature or limitation. For example, "3. The widget of claim 2, wherein the handle is removably attached to the spiral arm."

Divisional—A second patent, identical to a first, but having different claims, that was created by restriction of the invention into separate patents.

Doctrine of Equivalents—The rule that an element in a claim also includes equivalent structures, if they do the same thing in the same way to accomplish the same result.

Election of Species—Similar to a restriction requirement, in that the applicant is required to choose one member of a number of species within a single claim to be examined.

Embodiments—Versions or variations on the invention.

EPO—European Patent Office, the office that administers applications under the European Patent Convention (EPC).

esp@cenet—Patent search database, operated by European Patent Office at http://ep.espacenet.com.

Examiner—PTO employee that reviews patent applications. Each Examiner is assigned to an Art Unit and handles applications in one particular area of technology.

Examination—The review of a patent application by an Examiner. The Examiner will review the application for conformity with regulations ("formality"), and will do a search of the prior art to see if there are any earlier patents or publications that might make the invention unpatentable. The results of the examination are reported to the applicant in an Office Action, in which the Examiner objects to parts of the application, and/or rejects claims. The applicant is given a time within which to respond to the Office Action by arguing or amending the application, after which the Examiner may allow the application or reject it again.

Figure—An individual drawing in a patent or application.

File History—See “prosecution history.”

File Wrapper—See “prosecution history.”

File Wrapper Estoppel—Also “prosecution history estoppel.” The legal principle that requires you to abide by whatever you say in the patent's prosecution history. For example, if you tell the Examiner that something is not part of your invention, you can't say it is part of the invention years later when you bring an infringement lawsuit—in other words you are “estopped” from making the later inconsistent argument.

Filing Date—The date on which the application is filed in the PTO. If the application is filed by Express Mail, the filing date is the date that the application was accepted by the Post Office, otherwise it's the date the application was actually received in the PTO mail room.

Filing Receipt—Document returned by the PTO to acknowledge the filing of an application.

Final Office Action—Normally, the Examiner will declare the second rejection in a given case “final.” The declaration of finality just restricts your options in how you can respond to the rejections. Usually an appeal or an RCE is filed “after final.”

Foreign Filing License—For purposes of national security screening, US law requires that US applicants get a “Foreign Filing License” before filing applications in other countries. This is routinely granted when an application is filed (even a provisional application), unless the application deals with defense-related technologies (nuclear weapons, encryption, etc.).

Freedom to Operate—A term of art that means you are clear of any dominant patents. If you have Freedom to Operate or “FTO” you are free to sell your own product without risk of infringing a third party patent.

IDS—See “Information Disclosure Statement.”

Independent Claim—A claim that does not depend on another claim. For example, “1. A widget comprising a handle...”

Industrial Design—A term used in some countries for something similar to “Design Patents” in the US.

Information Disclosure Statement—A form filed in the PTO in order to satisfy the legal requirement to inform the Examiner of all prior art known to the inventor that is material to the patentability of the invention. The IDS is usually filed with, or soon after, the filing of the application. "Supplemental IDS's" are filed with references the inventor discovered after filing—usually in connection with the examination of related (or foreign) applications.

Infringe, Infringement—An accused device or method infringes a patent if it is within the scope of at least one claim of the patent. A patentee has the right to stop an infringer from making, using or selling an infringing device or method.

Interference—Under US law, a patent goes to the first person to invent an invention (as opposed to "first to file" systems in most other countries, where the first person to file an application gets the patent). If two people file applications at nearly the same time claiming the same invention, the PTO declares an "Interference" to decide who is the first to invent. An interference proceeding is basically a lawsuit before the BPAI, in which each side gets to present evidence and take testimony about the priority of invention.

Invention—As a noun "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," 35 U.S.C. 101. As a verb the act of making an invention, which consists of two steps: conception and reduction to practice.

Invention Date—See "date of invention."

Issue Date—The date on which a patent becomes enforceable. All US patents are issued by the PTO on Tuesdays.

Jeppson Claim—A special claim form which starts "An improved widget of the kind having..." followed by the prior art elements of the claim, and then says "in which the improvement comprises," followed by the novel or new part of the invention.

Large Entity—A company with more than 500 employees.

Literal Infringement—A device (or method) that literally contains every element of a claim (as opposed to infringement under the Doctrine of Equivalents).

License—A document or contract permitting a licensee to make, use or sell products or services that would otherwise infringe the claims of

a patent (or application). A license can be exclusive or non-exclusive. If an exclusive license is granted, the patentee may not issue any other licenses conflicting with the exclusive license. Licenses may be limited by geographical area or field of use. See also “assignment.”

Maintenance Fee—There are maintenance fees to be paid at 3.5 years, 7.5 years and 11.5 years from the date of issue. The fees must be paid within six months after the due date, and may be paid up to another six months after that with a surcharge. If the maintenance fees are not paid, the patent expires at the end of the surcharge period (4.5, 8.5 or 12.5 years after issue).

Markush Group—A special claim form in which a list of alternatives are provided. Markush groups are most often used in chemical practice, but may be proper in other kinds of technologies.

“Means Plus Function”—A way of describing an element in a claim by describing what it does, rather than what it is. For example, instead of claiming “a bolt,” one can claim “means for fastening.”

Method Claim—A claim that covers a way of doing something, usually expressed as a series of “steps.” For example, “A method of treating hypertension by administering to a patient in need thereof an effective amount of drug X.”

Multiple-Dependent Claim—A claim which depends on more than one preceding claim (“The widget of any of claims 1-6...”). Not favored in US practice due to additional costs.

MPEP—Manual of Patent Examining Procedure. Sets out instructions on virtually all phases in the examination of a US patent application.

Novelty—In order to be patentable, an invention must be new or “novel” as defined in 35 U.S.C. § 102. Briefly, something is “novel” if it was not patented, described in a publication, in public use or on sale by others before you invented it, or by anyone (including you) more than a year before you applied for a patent.

OA—See “Office Action.”

Objection—The Examiner may object to the specification, drawings or claims for various reasons. Typically, claim objections deal only with very obvious errors—misspellings, duplicated or missing words, or incorrect punctuation.

Obvious—In order to be patentable, an invention must not be "obvious" to a "person having ordinary skill in the art to which the invention pertains." Obviousness is defined in 35 U.S.C. § 103. Basically, "not obvious" is a way of saying "an invention must be more than just a simple development from what went before."

Office Action—Once a patent application is filed, it will be assigned to an Examiner, who will review it for format and wording, and do a search for prior art. The claims will nearly always be rejected. The document which the Examiner provides to explain why the claims are rejected is called an "Office Action."

OIPE—Office of Initial Patent Examination—branch of the PTO which does initial screening of newly filed patent applications. The OIPE determines if the application meets minimal standards, that the proper fee has been paid, and that the drawings are publishable. Then, the OIPE makes a preliminary decision as to what class the invention belongs in, and sends the application to the correct Technology Center for that class.

Opposition—Some countries have procedures whereby a someone may object to the issuance of a patent on an application, or ("post-grant opposition") may object to an issued patent. The US has no such procedure (yet). See also "protest."

PAIR—Patent Application Information Retrieval—PTO database with status information about patent applications and issued patents, including payment of maintenance fees. PAIR has two separate systems—"Public PAIR" allows anyone access to issued patents and published applications, "Private PAIR" allows access to unpublished applications, but only to the inventor or the attorney on the application. Although the system is not yet complete, in time images of all documents filed in the PTO will eventually be accessible through PAIR. See http://portal.PTO.gov/external/portal/pair.

Paris Convention—The international treaty that provides that if a national of a member country files a patent application in his own country, then follows up with an application in another member country within one year, he can claim priority to the original application for the later-filed application. Information about various Intellectual Property treaties is available from WIPO at http://www.wipo.int/treaties/en/.

Patent—The grant by the government of the right to stop others from making, using or selling an invention.

Patent Agent—Someone licensed to prosecute patent applications in the PTO. A Patent Agent must have a degree in

engineering or one of the “hard” sciences and pass an examination given by the PTO. A Patent Agent may not prepare or prosecute trademark applications, even though these, too, are in the PTO.

Patent Attorney—A Patent Agent who has been admitted to the Bar of at least one state. In other words, a Patent Attorney is a Patent Agent who is also a licensed attorney.

Patent Cooperation Treaty (PCT)—An International treaty allowing a national or resident of a member country to file a single application in his own country, that can later be converted into a national stage application in any member country. Information about various Intellectual Property treaties is available from WIPO at http://www.wipo.int/treaties/en/.

“Patent Pending”—A product may be marked “patent pending” if at least one patent application covering the product is on file, and is not abandoned. A provisional application will support a “patent pending” marking.

PCT—Patent Cooperation Treaty.

PCT Application—a global patent application that covers more than 170 countries and holds the filing options open for 30 months. It will never mature into a patent.

PE—See “Primary Examiner.”

Petition—A document asking the PTO to do something, usually accompanied by a fee. Some petitions are included in routine paperwork and routinely granted. For example, if a response to an office action is filed after the due date, the response is accepted if the applicant pays a fee with a “petition for extension of time.” Other petitions are more substantive, and are reviewed by the Office of Petitions in the PTO. For example, an applicant who gets a restriction requirement may file a petition to force the Examiner to retract the restriction, or an applicant might need to petition to get the PTO to waive its rules for one reason or another.

Petty Patent—A term used in some countries for patent-like protection for products. Details differ from country to country, but petty patents usually are not examined (or are examined only as to form, and not novelty), and have a shorter term than regular patents. In some systems, these must be examined before bringing suit against an infringer, in others they are examined in court during the suit. These are called “utility model” in Japan and China, “Gebrauchsmuster” in Germany, and other countries use other names.

"Person Having Ordinary Skill In The Art"—A mythical person who has all possible knowledge of the prior art, but only in a given field of technology. Yet, they do not need to be highly trained, ordinary skill will suffice.

Plant Patent—A special kind of patent, which covers asexually reproduced plants, "including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state." See 35 U.S.C. § 161.

Preferred Embodiment—One particular variation of the invention that may be better than the rest, e.g., preferred. See also "best mode."

Primary Examiner—An Examiner who has the authority to sign office actions and make other determinations without prior review (as opposed to an "Assistant Examiner," who must have office actions co-signed by a PE). A PE, in turn, works under a Supervisory Primary Examiner (SPE).

Prior Art—Publications, earlier patents, public use or sale that occurred before the filing date of the patent.

Priority Date—The earliest date to which a patent is entitled.

Product by Process—A type of claim that defines a product by the method of making it.

Prosecution—The applicant's side of the Examination process, convincing the Examiner to issue a patent.

Prosecution History—The written record of the Examination Process. Also known as the "File Wrapper," because all of the papers involved in a patent application were covered in a paper wrapper. Today, the "Image File Wrapper" contains much the same information in electronic form.

Protest—A procedure whereby someone may file a "protest" with an Examiner, bringing prior art references to the attention of the Examiner with respect to a pending patent application. This procedure is very seldom used because a protest may only be filed with reference to a specific application identified by serial number, but it must be filed before the application is published and thus before the serial number becomes publicly available.

Provisional Application—An application that reserves a filing date for the material in the application, but will never be examined or become a patent. Provisional applications are automatically abandoned one year after filing, and a utility application must be filed within that year claiming benefit of the provisional application to preserve the filing date.

Provisional Patent—There is no such thing. See "provisional application."

Provisional rights—While patents are only enforceable after they issue, a patentee may ask for a reasonable royalty for activities of an infringer which occur between the publication of the application on which the patent was based and the date of issue, if the claims in the published application and the issued patent are "substantially identical." The ability to ask for pre-issue damages is called "provisional rights."

RCE—See Request for Continued Examination.

Reduce to Practice—To complete the process of invention by actually building the device (or practicing the method), or filing a patent application ("constructive reduction to practice").

Re-examination—A patent may be subjected to the examination process again after it issues, if the PTO, or a patentee, or a third party thinks there was some prior art missed in the original examination.

Reference—A piece of prior art.

Rejection—In an Office Action, the Examiner may reject claims based on form (section 112), patentability of the subject matter (section 101), or as unpatentable in view of the prior art (sections 102 or 103).

Reissue—If there was an error in the examination that might result in some claims being invalid, or if the patentee failed to claim the invention as broadly as he was entitled to, he may ask for the patent to be reissued with amended claims. Reissue patents are distinguished by patent numbers starting with "RE."

Request for Continued Examination (RCE)—Basically, "buying another bite at the apple" during examination. If the Examiner issues a final office action, the applicant's options are limited, and the Examiner does not have to enter any claim amendments offered after the final rejection. By filing an RCE, the applicant can amend the application and make any arguments he would have made after final, and the Examiner must enter and consider them. An RCE is an alternative to filing

a Continuation, which is a new application—an RCE merely continues the same application in the examination process.

Restriction Requirement—The Examiner believes there is more than one patentably distinct invention in the application. Since the rule is "one invention to a patent," the claims will be "restricted" and the patentee will be required to "elect" one invention to proceed with. The claims directed to that invention will be examined, and the claims directed to the other invention(s) will be withdrawn from consideration. A "Divisional" application may be filed to pursue the withdrawn claims at any time until the application issues.

Serial Number—A number assigned by the PTO to identify a patent application. The number is usually a two digit series number, followed by a slash and a six digit application number— 10/123,456. The six-digit application numbers will repeat from series to series. Utility and plant patent applications are in series 02-12, design applications in series 29, and provisional applications in series 60.

Small Entity—Individuals, Universities, not-for-profits, or companies with less than 500 employees, provided that such party has not licensed any large entity. PTO fees are generally reduced 50% for Small Entities.

SPE—See "Supervisory Primary Examiner."

Specification—The patent or patent application document, excluding the abstract, drawing and claims.

Subclass—The PTO uses its own US Patent Classification System, in which all inventions are first put in a class having a three-digit number, then in a numbered subclass under the class. The subclasses are arranged in a hierarchical form, but not necessarily in numerical order. The US classification system is based more on structure than function.

Supervisory Primary Examiner—A higher-level Examiner, with more authority to decide certain matters.

Supplemental IDS—See Information Disclosure Statement.

Terminal Disclaimer—The terms of some patents are limited to coincide with the terms of earlier-issued patents as a result of filing two applications that claimed essentially the same invention. Terminal disclaimers will be marked on the later-issued patent.

Useful/utility—In order to be patentable, an invention must be "useful." That is, it must have some definable use, no matter how trivial.

Most rejections for lack of utility are for applications claiming perpetual motion or antigravity, or for chemical compounds, drugs or DNA sequences with no known (or stated) practical application.

Utility Model—See "petty patent."

Utility Patent—A "regular" patent, as opposed to Design Patents or Plant Patents.

USPTO or PTO—United States Patent and Trademark Office—a branch of the Department of Commerce that is in charge of patent and trademark matters. Often called simply "the Patent Office."

Withdrawn—Withdrawn claims are "alive," but the Examiner is not reviewing them because of an election in an earlier Restriction Requirement or Election of Species. These claims will usually have to be canceled prior to allowance if the Examiner does not allow them to be rejoined with allowed claims.

EXHIBIT 1

RECORD OF INVENTION AND INVENTION DISCLOSURE

We are required to disclose to the US Patent and Trademark Office all information that is material to the examination of a patent application. In addition, under US patent law, an application must be filed within one year of the earliest event which tends to publicize or commercialize the invention which is the subject of the application. Moreover, in order to preserve the right to obtain foreign patents, a US patent application must be filed before such event occurs.

Therefore, please carefully complete the following questionnaire to provide us with the information necessary to comply with these disclosure requirements. Also, please attach a complete description of the invention in the manner described below so that a patent search may be conducted and a patent application prepared and timely filed. It should be noted that errors and omissions in connection with this information can result in the invalidity or unenforceability of any resultant patent.

1. Title of Invention:

_____

2. Inventor(s): Include all persons associated with the making of the invention. Please note that only true inventors, as determined under the technical requirements of the patent law, can be named in a patent application, and that no such inventor should be omitted.

Full Name (Including middle initial):_____

City, State & Country of Residence:_____

Postal Address: _____

Citizenship:_____

Phone:_____

Cell Phone:_____

Fax: _____

Email: _____

3. Conception of the Invention: Briefly describe the contributions, suggestions, experiments, etc. of each inventor listed above, as well as any other pertinent circumstances surrounding the conception of the invention.

Inventor:_____

Date(s):_____

Place(s):_____

Inventive Contribution(s): _____

4. Data and Drawings: Attach copies, if available, or describe the present location of initial drawings, sketches, lab notebooks, descriptions, etc.

Date or Drawing:_____

Location(s):_____

5. Initial Disclosure of the Invention to Others:

Date(s):_____

Place(s):_____

Person(s) Receiving Disclosure: _____

Circumstances:_____

6. Initial Tests, Uses or Operations of the Invention: Describe any changes made as a result of these initial tests, uses or operations.

Date(s):_____

Place(s):_____

Person(s) Present:: _____

Circumstances:_____

7. Closest "prior art": What devices, technologies, structures, processes, information or materials that existed publicly or privately before the invention was made are considered to be most closely related to the invention? Each person identified in paragraph 2 should answer this question. Attach copies of prior publications, patents, etc. that are most closely related to the invention.

Inventor: _____

Date(s):_____

Citation or Description of Prior Art:_____

_____

8. Disclosures: Other than the initial disclosure described in paragraph 5, has the invention ever been disclosed orally or in writing to any person other than fellow employees? If so, provide the information below. Include any instances of private or public offers to sell the invention, as well as requests for financing, grant applications, demonstrations, theses, abstracts, oral presentations, trade shows, catalogs, etc. Identify all relevant publications, correspondence, etc. and, if possible, attach copies.

Date(s):_____

Place(s):_____

Person(s) Receiving Disclosure: _____

Circumstances:_____

9. Commercial Uses: Has the invention ever been used commercially for any purpose? If so, provide the information below. Include any commercial uses, even if details of the invention were kept secret and not disclosed to the public.

Date(s):_____

Place(s):_____

Person(s) Involved: _____

Circumstances:_____

10. Future Disclosures: Are any disclosures of the invention planned for the near future? Describe any imminent publication, oral presentation, trade show, offer of sale, or sale of the invention.

Date(s):_____

Place(s):_____

Planned Disclosure: _____

Circumstances:_____

11. Financial Support: Identify any entities who sponsored or paid, in whole or in part, for the work that led to the conception or reduction to practice of the invention. Describe the contribution of any funds, grants, salaries, materials, equipment or facilities provided by any governmental agency, academic or research institution, industrial sponsor, etc.

Entity:_____

Nature of Sponsorship:_____

Grant No.:_____

Circumstances:_____

12. Invention Disclosure: Describe the invention in the spaces provided below. If necessary to fully describe the invention, attach reports, drawings, written descriptions, shop and lab notebook records, etc. Please note that the patent application based on this invention must be sufficiently detailed so as to "enable" a person of ordinary skill in this technology to make and use the invention, and that it must disclose the "best mode" for carrying out the invention. Attach sheets as needed.

(1) BACKGROUND. Describe the field to which the invention relates and explain what is wrong with the prior art. Provide sufficient background information to enable the reader to clearly appreciate the problems that existed prior to the invention.

(2) DESCRIPTION. Write a detailed description of the invention, referencing sketches, drawings or photographs. Describe the best way to carry out the invention, including preferred materials, methods and suppliers. Describe possible uses.

(3) **ADVANTAGES**. List and explain the advantages of the invention in the order of their importance, and describe how the invention solves or overcomes the problems of the prior art. Include all possible uses and modifications for the invention. Speculate reasonably on any additional uses that the invention may have, either by itself or in combination with other known or as yet unknown technologies.

(4) **NON-OBVIOUSNESS**. Patent are often rejected as obvious over two or more articles or patents providing the various claimed elements. **Failed experiments**, **unexpected results**, and **direct comparisons** with the prior art can all be used to prove the invention is **not** obvious. Also, any suggestions in the prior art that disparage or **teach away** from the invention can be useful. If any of these exists, please provide same.

I (we) verify that the foregoing is true and correct. I hereby assign all rights in the above described invention to * and agree to execute and further documents that may be necessary to perfect ***'s ownership in the invention.**

Inventor (printed name):_____

Date:_____

Signature:_____

Witnessed and Understood: Two or more witnesses should sign.

Date:_____

Printed Name:_____

Signature:_____

Phone:_____

Date:_____

Printed Name:_____

Signature:_____

Phone:_____

Exhibit 2

DUTY OF CANDOR CHECKLIST

Re: Serial No.: ***
Title: ***
Priority Date: *** (Priority document no.)
Filing Date: ***
Assignee(s): ***
Inventor(s): ***
Client Ref'c: ***
Attorney Ref'c: ***
IDS DUE: ***

Please indicate yes or no upon considering of each item and provide details as appropriate. Return the completed checklist to Patent Counsel by facsimile at _____. Each inventor and other person(s) substantively involved in the making of the invention or the prosecution of its patent should complete the checklist. Update and return to Patent Counsel as needed throughout the prosecution of the patent application.

Yes/No	Item	Details
	Have you or your co-workers performed a prior art search?	
	Have you provided complete copies of closest known relevant patents?	
	What are the two closest competing products?	
	Do you have any related co-pending US applications? Do any of your co-workers have related applications in this field?	
	Are there any related foreign applications?	
	What are the two closest articles from the prior art?	
	Have you provided copies of articles from technical journals, magazines, web-sites, books, etc. with publication and copyright information?	
	Have you provided copies of all handouts, slides, posters, abstracts, blueprints, product specifications, etc.?	
	Have you provided copies of all advertising materials, including brochures, web-site materials, etc.?	
	Has the invention, blueprints, product specifications, or prototypes been shared with anyone not immediately employed by the company? When, Where, with Whom?	
	Was this invention made with government funds? What grant number applies. Have you provided copies of all grant proposals?	
	Have you provided copies of all relevant theses?	
	Has there been any sales or gifts of this product or similar products?	

	When, Where, to Whom?	
	What marketing efforts have been made to date?	
	Has there been any offers for sale? When, Where, to Whom?	
	Have there been any development contracts, distributorship contracts, purchase orders, joint development agreements, etc.?	
	Has there been any Web-site offers or advertisements?	
	Has a prototype or a detailed blueprint been made? When?	
	Was a prototype tested or demonstrated? When, Where and by Whom?	
	Have there been any product demonstrations? When, Where, to Whom?	
	Has a blueprint been shown to anyone? When, Where, to Whom?	
	Have there been any oral disclosures of products and related products? When, Where, to Whom?	
	What work of others was worked from or known of?	
	What prior work within the company relates to this invention?	
	Have you disclosed all preferred materials, suppliers, concentrations and details of preferred methods?	
	Have you disclosed all failed approaches?	
	Have you disclosed all contradictory data?	
	Have you ever asserted a position or argument contrary to one taken in the specification or during prosecution?	
	Is there pending litigation related to this technology?	

By: _____

Date: _____

FIRM INFORMATION

Two of the most recognizable names in patent, trademark and copyright law, Meg Boulware and Tamsen Valoir, have formed a firm to deliver state-of-the-art intellectual property (IP) legal services.

After only six months in service, Boulware & Valoir is already listed as a go to firm in Best Lawyers Annual Guide to Patent Law for both patent prosecution and litigation. The firm is also recognized in the International Who'sWhoLegal of Business Lawyers for Patents 2011. Meg Boulware has long been listed as a Texas Super Lawyer and both World Trademark Review and Chamber's rank Meg's trademark practice highly in Texas.

Boulware and Valoir have more than 50 years of combined IP experience. They represent Fortune 100 companies as well as new market entrants with cutting edge technologies. They represent leaders in industries such as pharmaceuticals, medical devices and petrochemicals and have obtained and enforced patents dealing with a spectrum of inventions involving nanotechnology, molecular biology, polymer chemistry and alternative energy. The firm supervises worldwide trademark and patent portfolios and provides strategic advice on clients' competitive IP positions.

www.boulwarevaloir.com