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PATENTING:

A Guidebook For Patenting in a Post-America Invents Act World

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Patenting generally offers a superior means for legally protecting most inventions, particularly since:

- copyright, when available, does not provide a broad scope of protection; and
- the ability to effectively protect an invention as a trade secret is in constant jeopardy, due to publication or oral disclosure.

Unfortunately, the patenting process can be complicated, time-intensive and costly. However, costs can often be minimized and opportunities to establish value in products and technology maximized if professionals with an understanding of the patenting process are actively involved throughout. This book is intended to provide that understanding.

Chapter 1

What Is a Patent?

A patent is a government-issued document that provides its owner with rights to prevent competitors from profiting from the invention defined by the patent claims, for the duration of the patent term. In the U.S., any of three different kinds of patents may be applied for, depending on the nature of the subject matter to be protected:

1) The most popular utility patent protects a variety of products and processes, and is the focus of this publication.

2) The design patent protects any new, original, or ornamental design.

3) The plant patent is useful only for protecting new and distinctive asexually reproduced plant varieties. (Sexually reproduced varieties are also entitled to certain legal protection upon certification, pursuant to the Plant Variety Protection Act of 1970.)

The rights conferred by a patent can be enforced in court by the patent owner against competitor infringers to protect or increase the patent owner's market share. For example, the patent owner can seek an injunction against and/or damages from any party infringing a valid claim of the patent. Alternatively, all or some of the rights can be contracted to a commercial partner (via an assignment or license agreement). A patent is an intangible asset and, depending on what it covers, may be very valuable.

The Origin of Patents and Trademarks

Intellectual property protection originated in medieval Europe. Members of medieval guilds would share their knowledge with each other, but guard it from disclosure to outsiders. Their closely guarded techniques and skills are precursors of today's trade secrets.

Partly in response to the closed societies arising from the guilds, governments passed laws to encourage dissemination of inventions and ideas by granting exclusive rights – a patent or copyright – for a limited period of time to anyone who disclosed a new and useful item, process, or creative work into the public domain.

The early guilds also used symbols and pictures to identify services performed or products made by guild members. Those guild symbols are the precursors of today's trademarks.

What a Patent Is Not

A U.S. patent does not give its owner an affirmative right to make, use, or sell the invention defined by the patent claims. Instead, it confers the right to prevent others from making, using, or selling – or even offering to sell – the invention within the United States or importing it into the United States, unless the owner's permission is obtained. This is a subtle but important distinction.

Blocking Patents

Because even a patented product may infringe another's patent, it is advisable to conduct a freedom to operate search to detect potential blocking patents, as early as possible in development, but at any rate, prior to putting a new product on the market, implementing a new manufacturing process, or offering a new service. Each component of a product or process, as well as the

process used to make a product and methods for using a product, should be searched separately, manually (by searching the stacks of issued patents in the U.S. Patent and Trademark Office) and/or in appropriate computer databases.

Because claim construction is a matter of law, a patent attorney should construe the claims of potential blocking patents to determine if any claim is actually infringed, either literally or under the Doctrine of Equivalents and/or whether the relevant patent claims should be held invalid and/or unenforceable.

If a blocking patent is identified early, it may be possible for a potential infringer to design around (i.e., develop an alternative product or process that is not covered by the patent claim) or negotiate a more favorable license than would otherwise be available when the product or process is actually sold.

Chapter 2

What Is Potentially Patentable?

The definition of what constitutes potentially patentable subject matter in the U.S. is defined in Section 101 of Title 35 of the United States Code:

> *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 therefor, subject to the conditions and requirements of this title. (35 U.S.C. 101)*

Eligible Subject Matter

In 1980, the Supreme Court held that a genetically engineered bacterium is patentable subject matter and in so doing, broadly interpreted 35 U.S.C. 101 to cover "everything under the sun made by man." (Diamond v. Chakrabarty, S. Ct. 1980) In 1981, the Supreme Court held that section 101 contains an important implicit exception, "[L]aws of nature, natural phenomena and abstract ideas" are not patentable. (*Diamond v. Diehr*, S.Ct. 1981)

More recently, the Supreme Court has ruled on three cases dealing with subject matter eligibility: *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.* (2014); *Association for Molecular Pathology v. Myriad Genetics Inc.* (2013) and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012). In addition, the U.S. Patent and Trademark Office has issued Eligibility Guidances intended to provide the Office's view of

subject matter eligibility based on the case law. The Guidances acknowledge that implementation "will be an iterative process continuing with periodic supplements based on developments in patent subject matter eligibility jurisprudence and public feedback."

The America Invents Act specifically bars the patenting of any claim directed to or encompassing a human organism or tax strategy.

Further, although methods of performing a medical or surgical procedure on a human body may be patent eligible subject matter, medical practitioners are exempted from infringement (35 U.S.C. 287(c)).

Product claims (i.e. claims to a "machine, manufacture or composition of matter") cover an item and may be infringed even if the product is made differently or is used for a different purpose than that described in the patent. Therefore, generally speaking, claims that are directed to and cover an actual product provide optimal patent protection.

However, process claims – including processes for making or using a product or affecting a certain result – can also provide useful protection (when available as patentable subject matter):

- if claims on the product cannot be obtained;
- if only product claims of narrow scope are obtainable; or
- as an extra layer of protection, even if broad product claims are obtainable.

In addition, 35 U.S.C. Section 271(g) makes unauthorized importation, sale, or use of a product made abroad by a process

patented in the U.S. (a process of making claim) an infringing activity, as long as that product has not been materially changed by a subsequent process or does not become a trivial and nonessential component of another product.

Generally speaking, the greater the number and types of patent claims protecting a product or process, the greater the chance that a potential infringer will be deterred from infringing or ultimately be held liable for patent infringement.

Chapter 3

What Is Not Patentable?

Utility

In addition to being directed to patentable subject matter (discussed in Chapter 2), an invention must also be useful and actually work, in order to be considered patentable (35 U.S.C. 101).

Novelty

The invention must also be new. In addition to the requirements of section 101, much of 35 U.S.C. 102 is devoted to defining what is not novel.

35 U.S.C. 102 (a)-(d) of the America Invents Act, substantially changed the U.S. law for determining novelty and is now being applied for all patent applications having a first effective filing date on or after March 16, 2013.

Section 102(a) provides a bar under which any information available to the public prior to the application filing date will be considered prior art. Section 102(a)(1) significantly broadens the scope of prior art from that specified by the prior law to encompass any information that is available to the public prior to the filing date of the application. Printed publications, patents, public use and sale are expressly defined as prior art. However, prior art under the new law also encompasses any other form of disclosure that was otherwise available to the public before the effective filing date of a claimed invention (e.g. experimental uses and oral presentations).

Section 102(a)(2), like prior section 102(e)(1), provides that a patent or published application invented by another is prior art as of its effective filing date. However, unlike prior section 102(e)(1), an applicant cannot antedate a 102(a)(2) reference by showing a date of invention earlier than its earliest effective U.S. filing date. The effective filing date of a 102(a)(2) reference is the earliest priority date, if priority is claimed from a prior application (e.g. under 35 U.S.C. 119 or 120) (See section 102(d)).

Section 102(b) provides exceptions to the prior art of section 102(a)(1) and 102(a)(2). With respect to 102(a)(1), a limited one year grace period is provided with respect to disclosures made by an inventor or a person who derived the disclosure from the inventor (102(b)(1)). In addition, any subsequent public disclosure resulting from such disclosure is also excluded.

In addition, if the claimed invention and the 102(a)(2) disclosure were owned by the same person or subject to an obligation of assignment to the same person as of the effective filing date of the

claimed invention, the disclosed subject matter is excluded from being applied as prior art under 102(a)(2).

Section 102(c) defines common ownership to include joint research agreements that are in effect as of the filing date of a claimed invention. However, the patent application or patent must clearly identify the names of the parties to the joint research agreement and the invention must be a result of activities under the joint research agreement.

Accordingly, to avoid the creation of prior art by a research collaborator, research agreements must be in writing and in effect before the research begins. In addition, research agreements should broadly describe the scope of work, so that resulting inventions are clearly covered. Also, research collaborators should maintain good written records, not only of the research, but also of public and confidential disclosures to collaborators. The names of all parties involved in the research should be documented, preferably in the actual research agreement, so that potential prior art resulting from a collaborator may be identified. Finally, when appropriate, resulting patents or patent applications should be amended to disclose the names of all parties involved with the collaborative research.

Non-obviousness

> *A patent may not be obtained though the invention is not identically disclosed or described…if the difference 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 the subject matter pertains…(35 U.S.C. 103(a)).*

The invention must be an unobvious advance over the prior art. Determination that an invention is non-obvious is typically based on four factual inquiries:

1) Scope and content of the prior art at the time of the invention

2) Differences between the prior art and the claimed invention

3) Level of skill in the art to which the invention pertains

4) Evidence of secondary considerations, such as a long-felt need, commercial success, failure of others, and unexpected results.

The U.S. Supreme Court's 2007 decision in *KSR International v. Teleflex Inc.*, rejected the Federal Circuit's "rigid approach" to obviousness challenges to patents claiming combinations of known elements. In particular, the Court rejected the Federal Circuit's limitation of the "problem" that could give rise to the motivation to combine references, to the problem the inventor was trying to solve. KSR held that "any need or problem known in the field of endeavor at the time of invention" can provide a motivation for the claimed combination.

In KSR, the Court also said that when appropriate (e.g. for more basic technologies), common sense and ordinary creativity can be used to provide motivation to combine references to deal with a known problem, even when neither that problem nor its solution can be found in a prior art publication or the subject of expert testimony. The Court further pointed out that the problem should not be defined based on the use of hindsight bias, but simply affixing the label "hindsight" does not justify a rigid approach that defeats an obviousness challenge.

Since 2004, U.S. law has excluded from consideration for obviousness purposes, prior art made by a non-inventor collaborator, if the prior art and the claimed invention were, at the time the claimed invention was made, commonly owned or subject to an obligation of assignment to the same entity. A claimed invention and subject matter developed by a collaborator, which qualifies as prior art are deemed to be owned by the same entity or subject to an obligation of assignment to the same entity, if:

1. The claimed invention is 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;

2. The claimed invention is the result of activities undertaken within the scope of the joint research agreement; and

3. The application for patent on the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. (35 USC §103(c))

Enablement

The examiner also studies the patent application itself to determine whether the invention has been adequately described and enabled (35 U.S.C. 112). The body of the patent application (the specification), must contain a written description of the invention and of the manner and process of making and using it…to enable one of ordinary skill in the art to which it pertains…to make and use the same (35 U.S.C. 112), without undue experimentation.

The enablement requirement is at the root of all patent systems. In exchange for teaching the public how to practice an invention, the

inventor is provided exclusive rights to prevent others from exploiting that invention for a limited term. The scope of enablement must be commensurate with the breadth of the claims. In other words, broad claims must be broadly enabled.

Written Description

Only that which has been specifically described by sufficient and relevant identifying characteristics (as opposed to just functionally) in the patent specification may be claimed. The specification, therefore, should describe all possible parameters and components of an invention, preferably in very specific as well as in more general terms. The written description must be detailed enough to convey "possession" of the claimed invention, as of the filing date.

The specification must include a sequence listing for any disclosed (not merely claimed) protein (or peptide) consisting of four or more amino acids, and any disclosed nucleic acid of ten or more nucleotides. In addition to appearing in the written patent application, sequences must also be submitted to the USPTO on computer disk.

Best Mode

In addition to appropriately describing and enabling an invention, the patent specification must disclose the best mode known by the inventor(s) for carrying out the invention at the time the patent application was filed. This requirement prevents inventors from retaining critical elements of the invention as trade secrets. Under the America Invents Act, best mode is still required, but can no longer be used as a defense in any action involving the validity or infringement of a patent. In other words, the failure of an inventor to disclose their best mode is no longer a basis for invalidating, canceling or making a claim unenforceable, even if it is later shown

that the inventor knew of a best mode and did not disclose it in its patent application.

Definite Claims

35 U.S.C. Section 112 also requires that the patent specification conclude with one or more claims specifically pointing out and distinctly claiming the invention (35 U.S.C. §112, para. 2). For years the Federal Circuit held that a claim is indefinite when it is not "amenable to construction" or it is "insolubly ambiguous." In *Nautilus v. Biosig Instruments, S.Ct. 2014*, the Supreme Court held that the Federal Circuit's standard does not satisfy the definiteness requirement of Section 112, because it "tolerates some ambiguous claims, but not others." The Supreme Court then held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention."

The claims are the most important part of an issued patent: They define the extent of protection that the patent provides. Clearly, the patent applicant should devote a great deal of thought to the claims when drafting and prosecuting an application.

Words and terms used in the claims that are not generally known or that may have a specific or different meaning in relation to the

"The claims are the most important part of a patent: they define the extent of protection."

invention must be defined in the patent specification. One of the challenges of drafting a patent application is to provide language that is specific, but of a broad enough scope to provide useful protection. Another challenge, particularly in biotechnology, is in disclosing and claiming commercial embodiments (the ultimate products or processes to be marketed). The patent application should not only describe what the inventor discloses, but everything that could reasonably be developed based on the inventor's actual work.

Claims in a patent application are not typically allowed upon initial examination. Almost inevitably, the examiner issues an office action rejecting the claims and/or objecting to the specification on one or more grounds. The patent applicant can then respond by pointing out errors in the examiner's reasoning and/or amending the claims or specification. Although a patent applicant may introduce evidence (such as declarations or affidavits) to support arguments, no "new matter" (i.e. additions to the specification) may be introduced to the patent application during prosecution.

On the other hand, additional information or data developed after a patent application was filed that broadens the scope of the original claims may be filed in the U.S. via a Continuation-In-Part (CIP) patent application, which adds new disclosure to the original, parent application. In determining patentability in light of prior art disclosures, any claim in a CIP that is supported by the parent patent application will be entitled to the parent's filing date, while claims supported only by the new disclosure will only be entitled to the CIP's filing date for priority purposes. The GATT-implemented change in patent term from 17 years after issuance to 20 years after the

original patent application filing date (see Chapter 10) places a premium on filing well-considered patent applications at the outset, rather than relying on filing CIPs.

"One of the challenges of drafting a patent application is to provide language that is specific, but of a broad enough scope to provide meaningful protection."

Chapter 4

How Is a Patent Obtained?

To be granted a patent on an invention in the U.S., a patent application must be prepared, filed, and prosecuted in the U.S. Patent and Trademark Office. Because of the many legal and technical requirements, a patent application is generally best drafted by a patent attorney (a scientist or engineer who is registered to practice before the U.S. Patent and Trademark Office (USPTO) and the courts of at least one state) or a patent agent (a scientist or engineer who is registered to practice before the USPTO, but is not a member of a state bar).

Provisional Patent Application

Since June 8, 1995 - the day the U.S. implemented the General Agreement on Tariffs and Trade (GATT) - the USPTO has accepted provisional patent applications (patent applications containing a disclosure of the invention, but not necessarily claims). As long as a comparable, complete patent application (including claims) is filed within one year after the provisional patent application's filing date, the date on which the provisional application was filed serves as the priority date for determining patentability, with the utility patent application's filing date used to calculate the patent term. As a result, the publication, public use, or sale of the invention occurring after the filing date of the provisional application, but before the filing date of the complete application will not be considered prior art for determining the novelty and/or non-obviousness of the invention (see Chapter 3).

Utility Patent Application

When a utility (as opposed to a provisional) patent application is filed, a PTO official will briefly review the application to make sure it is complete and, if so, grant a filing date and direct the application to an examiner in an appropriate examining group. Depending on the backlog of applications in the group, it may take anywhere from a few months to a few years for an application to actually be examined.

Accelerated Examination

The USPTO now accepts requests for prioritized examination of patent applications through the Track One prioritized patent examination program. Track one allows applicants of utility or plant patent applications filed after September 26, 2011 to have their applications examined within 12 months, if they file an appropriate request and a complete application including all drawings electronically and pay a fee of $4,800 (or $2,400 if the applicant qualifies as a small entity). The application must also contain no more than thirty claims of which no more than four are independent.

"Provisional patent applications may be useful for securing an early filing date, but only if they fully describe what is ultimately claimed."

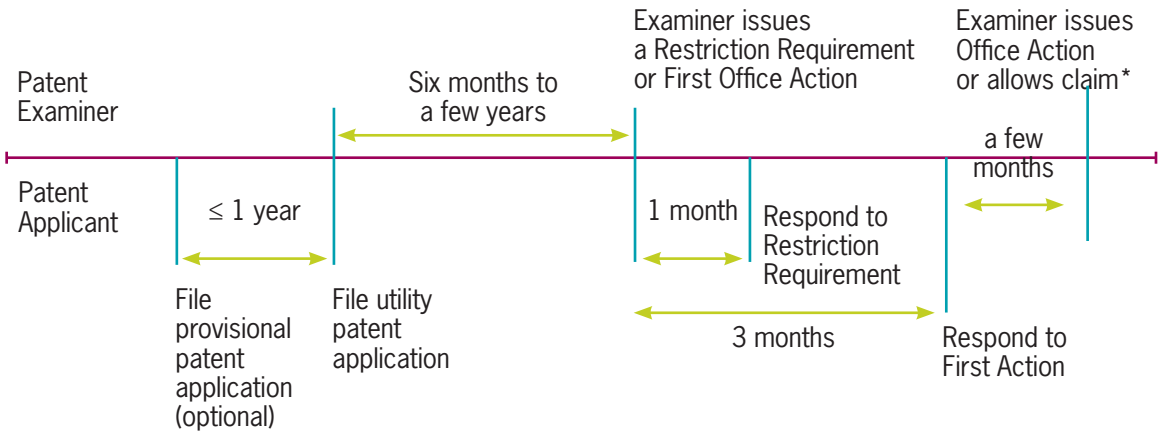
Restriction Requirement

A patent examiner initially looks at the claims to determine whether they are directed to two or more independent and distinct inventions. For example, a patent application for a new recombinant protein may include claims to any or all of the following:

1) the protein itself;
2) antibodies to the protein;
3) nucleic acid sequences encoding the protein;
4) nucleic acid sequences antisense to the coding sequence;
5) processes for making the protein;
6) therapeutic uses of the protein;
7) diagnostic uses of the antibodies; and
8) diagnostic use of the antisense nucleic acids.

The patent examiner may consider each of these to be independent and distinct inventions, in which case the examiner may issue a restriction requirement.

U.S. Patent Application Timeline



*The Examiner can continue to issue Office Actions, which the Patent Applicant must respond to, but if the Office Action is made final, the Patent Applicant must either:

- appeal to the Board of Patent Appeal and Interferences;
- file a continuation application; or
- abandon the application.

A patent applicant is typically given one month in which to elect one invention (i.e., one of the groupings of claims) for further examination on the merits or to dispute the restriction. If the restriction stands, nonelected claims will remain pending and may be pursued separately by filing a divisional patent application any time before the elected claims issue as a patent. The GATT-implemented change in patent term – from 17 years after issuance to 20 years after the original patent application filing date (see Chapter 10) – provides incentive for filing divisional applications on commercially important claims sooner rather than later.

Although restriction of a patent application inevitably results in increased effort and expense for obtaining the issuance of various claims, the restriction is a USPTO acknowledgment that each group of claims is separately patentable. A subsequent ruling of invalidity on claims directed to one invention, therefore, would not necessarily invalidate restricted claims directed to another invention.

Following restriction, or if no restriction is required, the patent examiner conducts a search of the prior art and substantively "examines" the patent application to determine whether the invention:

- is directed to appropriate subject matter (35 U.S.C. 101);
- has at least one utility (35 U.S.C. 101);
- is novel (35 U.S.C. 101 and 102);
- was not obvious at the time it was made (35 U.S.C. 103); and
- appropriately enables, describes and claims the invention

Pre-Grant Prior Art Submission

The America Invents Act adds a subsection "e" to 35 U.S.C. 122. This provision expands the two month window in which a third party could submit prior art to the USPTO from when an application has been published (as provided by 37 C.F.R. 1.99) to a six month window or first office action, whichever is later (assuming no intervening notice of allowability). Also, whereas third parties were previously prohibited from offering any explanation of the patent or publications, 122(e) requires an explanation of the relevance. This provision took effect on September 16, 2012 and will be applicable to any applications then pending.

Information Disclosure Statement

Each individual associated with filing and prosecuting a patent application has a duty to act with candor and good faith. In other words, patent attorneys/agents, inventors and others involved in the patenting are obliged to disclose all prior art relevant to the patentability of an invention that is known before the patent application is filed or that becomes known during prosecution. This obligation is fulfilled with the filing of an Information Disclosure Statement (IDS) listing relevant prior art. Relevant prior art not known at the time an initial IDS is filed can be supplied later in a Supplemental IDS.

A violation of the duty of candor and good faith can be raised by an accused infringer as an affirmative defense to render the patent permanently unenforceable based on inequitable conduct. In any case, a patent is stronger if all relevant prior art was cited during prosecution, since the patent is presumed to be novel and non-obvious over the prior art cited during prosecution.

If all the above requirements of the patent application are met and the patentability hurdles surpassed, claims will be allowed and a patent will be issued on the application.

To be eligible for the provisional or utility patent application's filing date for priority purposes, divisional or continuation patent applications (e.g., for pursuing nonelected claims, or claims different from the allowed claims, but supported by the application), must be filed before the allowed claims issue as a patent. It is therefore generally a good idea to keep a patent application pending to preserve the option of pursuing additional claims.

Ex Parte Reexamination

In 1981, Congress amended the patent laws to provide for reexamination of patents. Anyone including the patentee or a third party could request *ex parte* reexam, but it could only be used to reconsider the validity of claims based on prior art patents or printed publications.

Ex parte reexamination favors the patentee. If initiated by the patentee, the public can not participate in the actual proceedings. The AIA made minor changes to this procedure.

"A patent is stronger if all relevant prior art was cited during prosecution, since the patent is presumed to be a novel and nonobvious over cited prior art."

A petition for *ex parte* reexamination will be granted if a "significant new question of patentability" has been raised, which is considered a fairly easy standard to meet.

Inter Partes Review

Laws establishing *Inter Partes* Reexamination were enacted by Congress in 1999 to provide third parties with limited rights to participate in the proceedings. These laws include an estoppel provision, so that anything that a challenger raises or could have raised in the Inter Partes Reexamination, could not be raised again as a defense in a subsequent patent infringement suit in federal court.

On September 16, 2012 *Inter Partes* Reexamination was replaced by *Inter Partes* Review. The IPR proceeding is conducted before a panel of three administrative patent judges. Many of the rules for *inter partes* exam remain in the IPR.

For example, the real party of interest must be identified and there is still an estoppel. Also, the requestor can only raise novelty and obviousness arguments based on prior art patents or printed publications. The patentee has only one opportunity to amend the claims.

There are also a lot of differences from the old *inter partes* reexam. Rather than the significant new question of patentability standard, IPRs are initiated if there is a reasonable likelihood that the requester will prevail with respect to at least one of the claims challenged in the request. In addition IPR proceedings include limited discovery (e.g. depositions of those who submit a factual or expert opinion). The fee for filing an IPR petition of up to 20 claims is $23,000, $14,000 of which is refunded if the petition is not granted.

A patent must have been in existence for at least 9 months for an IPR challenge to be granted. Under most circumstances, a final opinion is issued within a year. Parties can settle anytime before the written opinion is issued. If there is a settlement, there is no estoppel and the substance of the proceeding will remain confidential.

Post-Grant Review

For patents having a priority date on or after March 16, 2013, the America Invents Act, like European Opposition Proceedings, allows anyone but the patent owner to petition for cancellation of one or more claims on any ground of invalidity. The petition must be filed within 9 months of patent issuance or broadened reissuance. The USPTO will grant the petition and proceed with a post-grant review if it determines that more likely than not at least one challenged claim is unpatentable. The office can also grant a petition if it raises "a novel or unsettled legal question."

The review is conducted by the Patent Trial and Appeal Board and must be completed within 12 months, although there may be a 6 month extension for good cause. The decision can be appealed to the Federal Circuit. Once the petition is filed, a patentee may file a preliminary response before the USPTO considers the petition. The fee for filing a PGR petition of up to 20 claims is $30,000, $18,000 of which is refunded if the petition is not granted. Like IPR, PGR includes limited discovery, motion practice and the right to an oral hearing before a final written decision is issued. Also, as with IPR if a PGR is settled prior to a decision, the proceeding will be terminated without any finding and no estoppel will attach.

Covered Business Method Review

The America Invents Act also provides a special post-grant review for certain business method patents (those that claim a method or

corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except patents for "technological inventions," as defined by the USPTO). A petition for this type of review can only be filed by a party sued or charged with infringement and the filing must occur within the 8 year window beginning one year after the Act's enactment (9/16/12). This review, which can be used to stay a civil action, can be retroactively applied to existing patents.

A patent owner can also request further examination on any grounds that raises a substantial question of patentability. This allows a patent owner to initiate *ex parte* reexamination for any information believed to be relevant to the patent, including non-publication prior art, such as public use or sale.

Like PGR, the filing fee for up to 20 claims is $30,000, $18,000 of which is refunded if the petition is not granted.

Supplemental Examination

Under the AIA, as of September 12, 2012, a patentee may request supplemental examination of a patent to "consider, reconsider or correct information believed to be relevant to the patent," presumably to prevent an inequitable conduct claim, in an action challenging the validity of one or more claims of the patent.

Any issue may be revised and an examination will occur if the petition presents a significant new question of patentability. Amendments may be made during the examination, but not as part of the petition. The fee is $16,500 (large entity) with the majority refunded if the examination is not needed. The petition can identify up to 10 items and provide an explanation of the issues raised by each item.

Chapter 5

What Should You Do Before Filing a Patent Application?

Before filing a patent application, you should document the invention and communications with collaborators relating to the invention.

Documenting the Invention and Derivation Proceedings

Although the American Invents Act does away with interference proceedings for determining who among multiple applicants was the first to invent, appropriate notebook records documenting the conception of an invention are still important, for example, to provide a defense in a derivation proceeding, which seeks to determine whether a named inventor in an earlier filed application "derived" the claimed subject matter from an inventor of a later filed patent application. A third party may initiate a derivation proceeding by filing a petition within one year after the first publication of a claim to an invention that is the same or substantially the same as a claim filed in an earlier filed patent application. Such a proceeding is only available for patent applications having a priority claim after March 16, 2013.

In view of the expanded definition of prior art under the America Invents Act, research collaborators should keep good written records not only of laboratory research, but also public and confidential disclosures to, from and by collaborators for use as evidence, if prior art generated by a collaborator ever becomes an issue.

Determining Whether Patenting Is Appropriate

If an invention is potentially patentable (See Chapters 2 and 3) a decision should be made as to whether pursuing a patent makes sense. This determination often involves business, scientific, and patent law considerations.

A patent should only be pursued if the invention has sufficient commercial potential to merit the costs and effort involved. Although the commercial potential may be difficult to assess at the outset, factors to consider include:

- size of the potential market
- whether noninfringing alternatives are available
- ease and cost of production and use
- whether there is a recognized need for the invention
- expected useful life of the product
- whether trade secret protection is preferable

Trade Secret Protection

A "trade secret" is defined by most states as *anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences or records a secret scientific, technical, merchandising, production, invention or improvement.* It may make sense to protect certain inventions as trade secrets rather than patent particularly since trade secrets are not limited to a particular term. For example, pharmaceutical companies have traditionally protected manufacturing technologies as trade secrets. Similarly, software companies often guard the basic algorithm supporting a computer program as a trade secret.

This strategy can be effective when the invention itself provides no indication of how the invention was actually made, particularly since it may be difficult to obtain sufficiently broad process claims to effectively guard against a design around.

However, if trade secret protection is to be pursued, appropriate safeguards must be in place, so that the invention will in fact be considered a trade secret if the issue ever arises in a court. To ensure consideration as a trade secret, access to laboratory or manufacturing facilities containing trade secrets should be limited to "authorized personnel only." Also, the few employees knowing the trade secret should be contractually obliged to keep the information or materials confidential.

Chapter 6

What Shouldn't You Do Before Filing a Patent Application?

Any action by an inventor that could prevent issuance of a patent should not occur before a patent application (provisional or utility) has been filed. In other words, prior art should not be created by an inventor.

For example, before a patent application has been filed on an invention, the inventor(s) should not:

- submit a document disclosing the invention for publication or funding approval;
- talk about the invention to others;
- demonstrate the invention;
- offer the invention for sale (advertise); or
- sell the invention.

Chapter 7

How Are Foreign Patents Obtained?

Patents are generally applied for and granted on a country-by-country basis. Fortunately, however, foreign filing decisions need not be made at the outset. Pursuant to the Paris Convention, which has been signed by virtually every industrialized country, a foreign patent application corresponding to a U.S. application may be filed any time within one year after the U.S. patent application filing date and still retain the U.S. application's filing date for priority purposes.

This means that a foreign patent application will be treated as if it were filed on the same day as the U.S. application for purposes of determining patentability, so that any publication, public use, or sale of the invention occurring after the filing of the U.S. application is not considered prior art with respect to the foreign patent application.

Any public disclosure occurring before the U.S. patent application filing date, however, is considered prior art in the foreign patent application. However, the patent laws in certain countries provide grace periods. For example, Canada provides a one-year grace period in which to file a patent application after the occurrence of certain prior art events. Japan and Australia provide a six-month grace period.

It is generally advisable to wait until close to the one-year anniversary of the U.S. filing date to file a corresponding foreign patent application to ensure that the foreign application is as complete as possible. This is particularly important for inventions which continue to be developed over the course of a year.

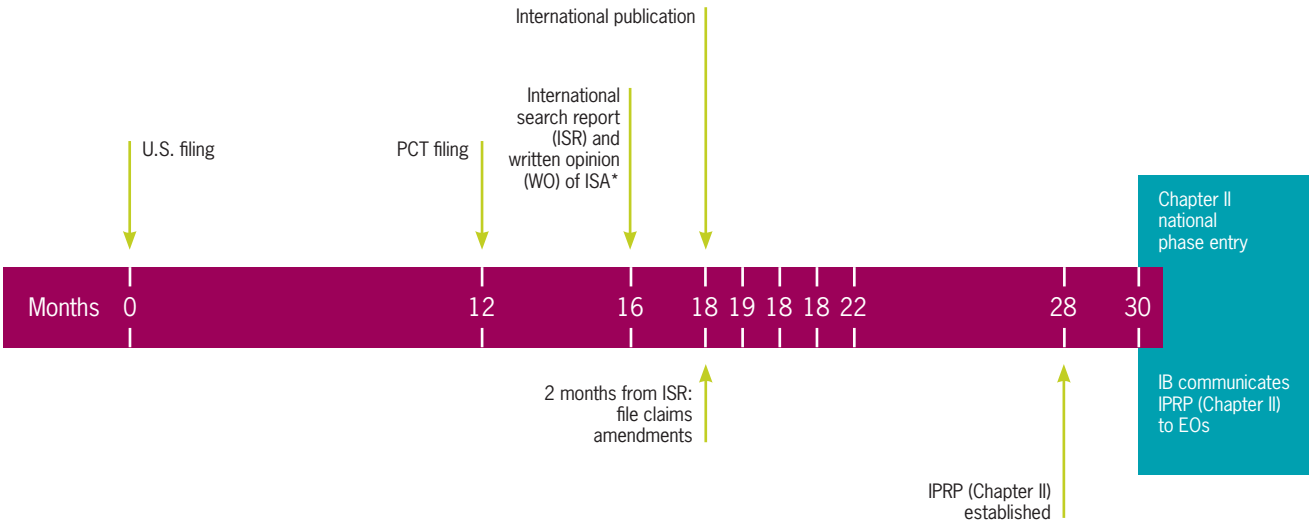
Direct National or Regional Foreign Filings

Although most foreign patents are obtained by filing a patent application with the patent office of the country in which protection is desired, several regional filing systems issue a single patent that is enforceable in any member country. For example, a patent issued from the European Patent Office (EPO) can be enforced in European Patent Convention (EPC) member counties (i.e., most European countries); two regional filing systems provide protection in certain African regions (OAPI and ARIPO); and the Eurasian Regional system provides protection in certain countries of the former Soviet Union.

The major advantage of pursuing a regional patent is that only one application (in English, for an EPO application) and one foreign associate (a patent attorney registered to practice before the relevant patent office) need be involved. Upon grant, the regional patent can be made effective in whichever of the designated

PCT Timeline: Chapter II

(for international applications filed on or after January 1, 2004)



* If PCT is a first filing, the ISA will establish the ISR and WO of the ISA before the expiration of 9 months from the priority date (Rule 42.1)

countries protection is still desired by meeting national formal requirements and paying national processing fees.

Although filing a single regional application is obviously simpler than filing separate applications with each individual country's patent office, this approach can also be more risky, since only one examiner will rule on the patentability for all member countries. This risk can be minimized, at a price, by filing national patent applications at the same time the regional application is filed.

Patent Cooperation Treaty (PCT) Filings

Since many inventions require substantial research and development prior to commercialization, a popular option is to file an application under the Patent Cooperation Treaty (PCT) rather than a direct national or regional patent application.

The PCT route is a convenient way to obtain a patentability search (in Europe or in the U.S.) and an initial examination on a single, international patent application. By filing a PCT application, examination costs for each country or region (including potentially high costs for obtaining and filing appropriate translations) can be delayed for eight months (if Chapter I is selected) or 18 months (if Chapter II is selected). In addition to the advantage of deferred expenses, the results of the examination and the passage of time can enable a better assessment of the patentability – or marketability – of the invention.

Although it delays the payment of major expenses and provides for a single search, foreign filing via the PCT can increase the overall cost of patenting since the costs of initial examination are in addition to – not in lieu of – the patent costs in each designated country or region.

Filing internationally via the PCT also ultimately delays the granting of a foreign patent and, therefore, the rights to exclude others. Therefore, if a competing product or process is already being made, used, or sold in a foreign country, direct national filings should be pursued.

Patentability Requirements of Foreign Countries

Although patentability requirements in most foreign countries are similar to those in the U.S., some differences should be considered when filing a patent application outside of the U.S. For example, some countries will not allow patents for software or for certain biotechnology-related inventions such as transgenic animals. In addition, methods for the treatment of a human or animal body by surgery, therapy, or diagnostic methods cannot be patented in Europe.

However, patent protection for therapeutic or diagnostic methods may often still be obtained in Europe simply by drafting claims in different formats known as the first or second medical use (if a first medical use is already known). First or second medical use claims will not be enforced against the medical practitioner, but rather against the company supplying the practitioner with the therapeutic or diagnostic product.

Chapter 8

Who Is an Inventor on a Patent?

Inventorship is a legal question that can be complex and is therefore best determined by a patent attorney. Unlike authorship, not all members of a research team are necessarily inventors. The only members qualifying as inventors are those who made a material contribution to the conception of the complete and operative invention as defined in the patent claims. As long as the conception is of a workable invention, the ultimate reduction to practice is irrelevant to an inventorship determination.

If the reduction to practice requires extraordinary skill, however, or if no way of making or using a conceived composition of matter is known, contributions to the reduction to practice may be inventive contributions. In certain unpredictable sciences, U.S. courts have held that a complete conception can only occur when the invention has been successfully reduced to practice.

A good faith determination of inventorship must be made by a patent attorney before an application is filed. Although inventorship can be corrected on a pending application or patent, procedures for correcting inventorship can be time consuming and costly. In addition, if material misrepresentations or omissions were made to the Patent Office regarding inventorship, the patent could be held invalid. A patent may also be held unenforceable if the inventorship determination is erroneous and was made with “deceptive intent.”

Inventorship must be determined for each claim of the patent application. For there to be joint or co-inventors of a claim, each inventor must have made some contribution to the same subject matter. However, each joint inventor need not physically work together or at the same time [or] …make the same type or amount of contribution (35 U.S.C. 116).

Chapter 9

Who Owns the Patent?

In the U.S., inventorship provides the starting point for determining who owns a patent. The general rule is that the inventors own the rights in the invention, including the rights to apply for and obtain a patent. When there is more than one inventor, U.S. patent law provides that:

> *In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners (35 U.S.C. 262).*

The rule that an inventor owns the patent rights in his or her invention is, however, subject to two general exceptions. An inventor may not own the patent rights if the rights have been expressly or impliedly obligated to another.

"The only members [of a research team] qualifying as inventors are those who made a material contribution to the conception of the complete and operative invention…"

A signed employment agreement can expressly obligate an inventor to assign the rights in the invention to an employer. Most courts will enforce an employment agreement that requires assignment to the employer of all rights to inventions conceived and reduced to practice by the employee during and in connection with his or her employment. Courts in the majority – but not all – states will also enforce employment agreements that obligate assignment to the employer of inventions conceived by the employee during the course of employment, even if reduced to practice some time later – for example while the employee is working for another employer.

Holdover Agreement

A "holdover agreement," which requires an employee to assign to the employer rights to inventions that were conceived only after the employee left the company, is generally only enforced by a court if it is reasonable, based on the totality of the circumstances. Factors weighed in determining reasonableness include whether the restriction is:

- necessary to protect a legitimate interest of the employer (for example, the employer's trade secrets or confidential information, or if the invention is an improvement to an invention originally conceived during employment);
- not unduly restrictive on the employee's employment opportunities; and
- not injurious to the public's interest in promoting competition, creativity, and invention.

Implied Contract

Even when a written employment agreement has not been signed, a court may nevertheless recognize an implied contract, or obligation on the employee to assign patent rights to his or her employer. For example, when the employee was specifically hired to invent or solve a particular problem, an implied contract to assign between the employee and employer may be held to exist. In addition, where the employee holds a position of trust with the company (such as a corporate officer), a court may read an implied contract to assign patent rights to that company. According to the shop right doctrine, if an employee uses a nontrivial amount of the employer's time and/or resources to create an invention, the employee must grant to the employer a nonexclusive, nontransferable, royalty-free license to use the invention for the term of the patent.

Bayh-Dole and *Stanford v. Roche*

The Bayh-Dole Act of 1980 allows universities and research institutions to obtain exclusive rights in technology developed from government-funded research. Although most universities have patent policies requiring that inventors assign their rights in an invention to

"An inventor owns the rights to his or her invention, unless those rights have been expressly or implied obligated to another."

the university or research institute, the Supreme Court has held that these policies do not prevent an inventor from actually assigning his or her rights to a company. "In most circumstances, an inventor must expressly grant his rights in an invention to his employer if the employer is to obtain those rights." (*Stanford v. Roche,* S.Ct. 2011)

Assignment Agreement

To ensure ownership, companies, universities and research institutes should have inventors execute an appropriate assignment agreement and file the signed agreement with the United States Patent and Trademark Office (USPTO) in conjunction with the filing of a patent application. Although not a requirement, proper recordation of a patent in the USPTO effectively:

- lists the patent assignee on the cover page of the issued patent; and
- protects the owner against challenges by successive purported assignees should the inventor later attempt to reassign the same patent to a new entity – for example, a new employer.

An assignment typically transfers all personal property rights provided by a patent, or an undivided fraction of all of the rights (for example, a 50% interest). Transfer of lesser rights in a patent may be accomplished through a license agreement.

Chapter 10

How Long Is a Patent in Effect?

Historically, U.S. utility and plant patents were granted for a period of 17 years, measured from the patent issue date (indicated on the cover page of the patent). Design patents, on the other hand, were granted for a period of 14 years from the date of issuance.

Pursuant to the General Agreement on Tariffs and Trade (GATT), however, which became effective in the U.S. on June 8, 1995, the term of a U.S. patent issued on an application filed after June 7, 1995, is 20 years from the earliest effective U.S. filing date.*

Transitional status was granted to patents in force on June 8, 1995 and to patents that issue from applications filed prior to June 8, 1995, by providing a term of either 17 years from the issue date or 20 years from the earliest effective U.S. filing date (the longer of the two).The term of a design patent was unaffected by GATT and continues to be 14 years from the date of issuance.

What is the Patent Term?

Patent Right	Patent Term
Patent issued before June 8, 1995 or patent issued from a patent application filed before June 8, 1995	17 years from issue date or 20 years from the earliest effective filing date, whichever is longer (transitional status)
Patent issued from a patent application filed on or after June 8, 1995	20 years from the earliest effective filing date

The patent term may be further extended based on certain regulatory exclusivities.

Patent Term Extensions (PTEs) and Patent Term Adjustments (PTAs)

For patent applications filed on or after May 29, 2000, the patent term extends 20 years from the first effective filing date together with any patent term adjustment (PTA). For example, the patent term may be adjusted (days added to the 20 year term) for the PTO's failure to take action within prescribed limits or otherwise issue the patent within three years. While the patent term itself cannot be reduced, any extension which may be warranted in view of PTO failures may be lost if the PTO determines that the applicant failed to engage in reasonable efforts to conclude processing or examination of an application, for example, by failing to reply within three months after receiving an office action or submitting an incomplete reply.

In addition to any adjustments under 35 USC Section 154, Section 156 provides for extension of the patent term for products that have been subject to a regulatory review period (e.g. drugs or medical devices) before its commercial marketing or use. This section, which implements provisions of the 1984 Hatch-Waxman legislation restores a portion of the patent term during which a patentee is unable to sell or market a product while awaiting government approval. Only one restoration may be sought. A restoration period can not be obtained for agency review of a subsequently approved drug covered by the same patent whose marketing also is delayed for reasons of FDA procedures. Applications must be filed with the USPTO within 60 days after a product has been approved by the agency.

* i.e., The filing date of the patent application or the earliest filing date of a prior U.S. application to which a continuation (e.g., file wrapper continuation, continuation, continuation-in-part, or divisional) patent application claims priority.

Maintenance Fees

Issued patents will expire unless maintenance fees are paid at designated time periods (3.5, 7.5 and 11.5 years post issuance). If the patent owner can prove within two years of the expiration that the nonpayment was “unavoidable” or “unintentional,” however, a patent may be reinstated.

About Foley Hoag LLP

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About the Author

Beth E. Arnold is a partner in Foley Hoag's patent group. For over 25 years she has focused on obtaining worldwide patent protection on biomedical products and technologies for some of the most innovative companies and research institutions in the world. She also routinely performs patent due diligence in connection with public or private financings; renders clearance, non-infringement, and invalidity opinions; and negotiates and drafts a variety of research, development and commercialization agreements. Ms. Arnold was formerly an in-house patent counsel at Genzyme Corporation, as well as a pharmaceutical researcher. She received a B.S. in biology from the University of Rhode island, a M.S. in molecular biology from Boston University, and a J.D. from Northeastern University.

Click the image below for a full biography.

Beth E. Arnold

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